

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Diaz, Chair
Senator Brodeur, Vice Chair

MEETING DATE: Wednesday, March 24, 2021

TIME: 11:30 a.m.—2:00 p.m.

PLACE: Pat Thomas Committee Room, 412 Knott Building

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

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION

PUBLIC TESTIMONY WILL BE RECEIVED FROM ROOM A3 AT THE DONALD L. TUCKER CIVIC CENTER, 505 W. PENSACOLA STREET, TALLAHASSEE, FL. 32301

TAB	OFFICE and APPOINTMENT (HOME CITY)	FOR TERM ENDING	COMMITTEE ACTION

Senate Confirmation Hearing: A public hearing will be held for consideration of the below-named executive appointment to the office indicated.

Secretary of Health Care Administration

1	Marsteller, Simone ()	Pleasure of Governor	Recommend Confirm Yeas 8 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION

2	CS/SB 1080 Regulated Industries / Hutson (Compare H 987)	Tobacco and Nicotine Products; Revising age limitations relating to mail order, Internet, and remote sales of tobacco products; providing that it is unlawful for persons under 21 years of age to smoke tobacco or vape in, on, or within 1,000 feet of the real property comprising a public or private elementary, middle, or secondary school during specified hours; requiring retail nicotine product dealers to acquire a permit; providing civil and criminal penalties relating to selling, delivering, bartering, furnishing, or giving nicotine products to certain persons and possessing and acquiring nicotine products, respectively, etc.	Fav/CS Yeas 8 Nays 0

RI 03/09/2021 Fav/CS
HP 03/24/2021 Fav/CS
AP

3	SB 1786 Burgess (Similar CS/H 1165)	Payments for Birth-related Neurological Injuries; Increasing the amount that may be awarded to the parents or legal guardians of an infant found to have sustained a birth-related neurological injury; requiring that such amount be revised annually; providing for retroactive application, etc.	Fav/CS Yeas 8 Nays 0

BI 03/16/2021 Favorable
HP 03/24/2021 Fav/CS
AP

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

Wednesday, March 24, 2021, 11:30 a.m.—2:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	SB 1770 Jones (Similar H 1233, Compare H 1235, Linked S 1772)	Genetic Counseling; Creating the "Genetic Counseling Workforce Act"; providing licensure, licensure renewal, and continuing education requirements; requiring the Department of Health to adopt by rule continuing education requirements; revising the definition of the term "health care practitioner" to include licensed genetic counselors, etc. HP 03/24/2021 Fav/CS AP RC	Fav/CS Yeas 9 Nays 0
5	SB 1772 Jones (Identical H 1235, Compare H 1233, Linked S 1770)	Fees/Genetic Counselor Licenses; Requiring the Department of Health to adopt by rule procedures for the issuance and annual renewal of genetic counselor licenses, including a specified application fee; authorizing the department to waive payment of the fee by rule; providing for the deposit and use of fee proceeds, etc. HP 03/24/2021 Fav/CS AP RC	Fav/CS Yeas 9 Nays 0
6	SB 1242 Book (Similar CS/H 905)	Program of All-Inclusive Care for the Elderly; Authorizing the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs, to approve entities applying to deliver PACE services in the state; requiring notice of applications to be published in the Florida Administrative Register; requiring existing PACE organizations to meet specified requirements under certain circumstances; requiring the agency to oversee and monitor the PACE program and organizations, etc. HP 03/24/2021 Fav/CS AHS AP	Fav/CS Yeas 8 Nays 0
7	SB 1268 Baxley (Similar H 373)	Coverage for Hearing Aids for Children; Requiring certain individual health insurance policies to provide coverage for hearing aids for children 18 years of age or younger, under certain circumstances; requiring certain individual health maintenance organization contracts to provide coverage for hearing aids for children 18 years of age or younger, under certain circumstances; requiring the hearing aids to be prescribed, fitted, and dispensed by specified health care providers; specifying certain coverage requirements, etc. BI 03/03/2021 Favorable HP 03/24/2021 Favorable AP	Favorable Yeas 8 Nays 0

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

Wednesday, March 24, 2021, 11:30 a.m.—2:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	SB 1292 Bean (Similar CS/H 1057)	Medicaid; Deleting a requirement for the Agency for Health Care Administration to submit an annual report to the Legislature on the operation of the pharmaceutical expense assistance program; deleting a requirement for the agency to submit an annual report to the Legislature on certain direct and indirect care costs; requiring the agency to establish certain procedures related to prior authorization requests rather than prior consultation requests; revising the definitions of the terms “medical necessity” and “medically necessary” to delete a requirement that determinations of medical necessity be made by certain licensed physicians, etc. HP 03/24/2021 Fav/CS AHS AP	Fav/CS Yeas 8 Nays 0
9	SB 1976 Brodeur (Identical H 1157)	Freestanding Emergency Departments; Deleting an obsolete provision relating to a prohibition on new emergency departments located off the premises of licensed hospitals; prohibiting a freestanding emergency department from holding itself out to the public as an urgent care center; requiring a freestanding emergency department to clearly identify itself as a hospital emergency department using certain signage; requiring a freestanding emergency department to post signs in certain locations which contain specified statements; requiring health insurers to post certain information regarding appropriate use of emergency care services on their websites and update such information at least annually, etc. HP 03/24/2021 Favorable AHS AP	Favorable Yeas 8 Nays 0
10	SB 1366 Brodeur (Compare H 497)	Licensure Examinations for Dental Practitioners; Authorizing passage of a dental examination produced by the Western Regional Examining Board (WREB) to satisfy licensure examination requirements for applicants to practice dentistry in this state; requiring the Board of Dentistry to have representation on WREB's board of directors and certain committees for a specified purpose; authorizing passage of a dental hygiene examination produced by WREB to satisfy licensure examination requirements for applicants to practice as dental hygienists in this state, etc. HP 03/24/2021 Favorable JU RC	Favorable Yeas 6 Nays 2

Other Related Meeting Documents

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

Wednesday, March 24, 2021, 11:30 a.m.—2:00 p.m.

35

STATE OF FLORIDA
DEPARTMENT OF STATE

Division of Elections

I, Laurel M. Lee, Secretary of State,
do hereby certify that

Simone Marstiller

is duly appointed

Secretary,

Agency for Health Care Administration

for a term beginning on the Fifth day of February, A.D., 2021, to
serve at the pleasure of the Governor and is subject to be
confirmed by the Senate during the next regular session of the
Legislature.

Given under my hand and the Great Seal of the
State of Florida, at Tallahassee, the Capital, this
the Nineteenth day of February, A.D., 2021.

Laurel M. Lee

Secretary of State



RON DESANTIS
GOVERNOR

RECEIVED
DEPARTMENT OF STATE

2021 FEB -9 AM 11:01

DIVISION OF ELECTIONS
TALLAHASSEE, FL

February 5, 2021

Secretary Laurel M. Lee
Department of State
R.A. Gray Building, Room 316
500 South Bronough Street
Tallahassee, Florida 32399-0250

Dear Secretary Lee:

Please be advised I have made the following appointment under the provisions of Section 20.42, Florida Statutes:

Dr. Simone Marstiller

as Secretary of the Agency for Health Care Administration, subject to confirmation by the Senate. This appointment is effective February 5, 2021 for a term ending at the pleasure of the Governor.

Sincerely,

Ron DeSantis
Governor

RD/jf

HAND DELIVERED

OATH OF OFFICE

(Art. II, § 5(b), Fla. Const.)

RECEIVED

STATE OF FLORIDA

2021 FEB 17 PM 3:41

County of Leon

DIVISION OF ELECTIONS
TALLAHASSEE, FL

I do solemnly swear (or affirm) that I will support, protect, and defend the Constitution and Government of the United States and of the State of Florida; that I am duly qualified to hold office under the Constitution of the State, and that I will well and faithfully perform the duties of

Secretary, Agency of Healthcare Administration

(Title of Office)

on which I am now about to enter, so help me God.

[NOTE: If you affirm, you may omit the words "so help me God." See § 92.52, Fla. Stat.]

Simone Marsteller

Signature

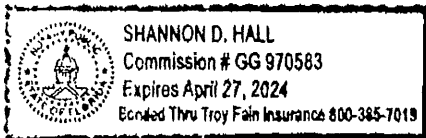
Sworn to and subscribed before me by means of ☒ physical presence or
online notarization, this 17th day of January, 2021

Shannon D. Hall

Signature of Officer Administering Oath or of Notary Public

Shannon D. Hall

Print, Type, or Stamp Commissioned Name of Notary Public



Personally Known ☒ OR

Produced Identification ☐

Type of Identification Produced _____

ACCEPTANCE

I accept the office listed in the above Oath of Office.

Mailing Address: ☒ Home ☐ Office

Street or Post Office Box

City, State, Zip Code

Simone Marsteller

Print Name

Simone Marsteller

Signature

The Florida Senate
Committee Notice Of Hearing

IN THE FLORIDA SENATE
TALLAHASSEE, FLORIDA

IN RE: Executive Appointment of
Simone Marstiller
Secretary of Health Care Administration

NOTICE OF HEARING

TO: Secretary Simone Marstiller

YOU ARE HEREBY NOTIFIED that the Committee on Health Policy of the Florida Senate will conduct a hearing on your executive appointment on Wednesday, March 24, 2021, in the Pat Thomas Committee Room, 412 Knott Building, commencing at 11:30 a.m., pursuant to Rule 12.7(1) of the Rules of the Florida Senate.

Please be present at the time of the hearing.
DATED this the 16th day of March, 2021

Committee on Health Policy



Senator Manny Diaz, Jr.
As Chair and by authority of the committee

cc: Members, Committee on Health Policy
Office of the Sergeant at Arms

THE FLORIDA SENATE

COMMITTEE WITNESS OATH

CHAIR:

Please raise your right hand and be sworn in as a witness.

Do you swear or affirm that the evidence you are about to give will be the truth, the whole truth, and nothing but the truth?

WITNESS'S NAME: Simone Marstiller

ANSWER: I do.

Pursuant to §90.605(1), *Florida Statutes*: "The witness's answer shall be noted in the record."

COMMITTEE NAME: Health Policy Committee

DATE: March 24, 2021

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

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

03/24/21

Meeting Date

Bill Number (if applicable)

Topic Senate Confirmation Hearing

Amendment Barcode (if applicable)

Name Simone Marstiller

Job Title Secretary of Health Care Administration

Address 2727 Mahan Drive

Phone 850.412.3606

Street

Tallahassee

FL

32308

Email simone.marstiller@ahca.myflorida.com

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Agency for Health Care Administration

Appearing at request of Chair: ☒ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

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

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

3/24/2021

Meeting Date

Bill Number (if applicable)

Topic Confirmation of Secretary Simone Marstiller

Amendment Barcode (if applicable)

Name Audrey Brown

Job Title President/CEO

Address 200 W. College Ave.

Phone 850-386-2904

Street

Tallahassee

FL

32301

Email audrey@fahp.net

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Association of Health Plans

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/CS/SB 1080

INTRODUCER: Health Policy Committee; Regulated Industries Committee and Senator Hutson

SUBJECT: Tobacco and Nicotine Products

DATE: March 24, 2021

REVISED: _____

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. <u>Oxamendi</u>	<u>Imhof</u>	<u>RI</u>	Fav/CS
2. <u>Looke</u>	<u>Brown</u>	<u>HP</u>	Fav/CS
3. _____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1080 relates to the regulation of the retail sale of tobacco products and nicotine products. The bill:

- Increases the minimum age to lawfully purchase and possess tobacco products and nicotine products from 18 years of age to 21 years of age.
- Creates a new part of ch. 569, F.S., to regulate the sale of, and create a separate licensing structure for, the sale of “nicotine dispensing devices” and nicotine products.
- Regulates tobacco products under part I of ch. 569, F.S., which consists of the current-law provisions.
- Regulates nicotine products under part II of ch. 569, F.S., which includes the requirements in current law for the sale of nicotine products, and additional provisions for the regulation of nicotine product sales the same as currently apply to the regulation of tobacco product sales.
- Excludes tobacco products from the definition of nicotine products.
- Requires retail dealers of nicotine products to have a permit issued by the Division of Alcoholic Beverages and Tobacco, but does not require a fee for the permit. However, the holder of a retail tobacco products dealer permit may sell nicotine products without an additional permit.
- Preempts to the state the establishment of a minimum age for purchasing or possessing tobacco or nicotine products as well as regulation of the marketing, sale, or delivery of tobacco or nicotine products.
- Prohibits smoking and vaping by any person under 21 years of age on or near school property. (Current law applies the prohibition to persons under 18 years of age).

- Keeps the exemption in current law for underage persons in the military and persons acting in the scope of lawful employment.
- Requires age verification before a sale or delivery of tobacco products to person who appear to be under 30 years of age. (This complies with federal law.)

The effective date of the bill is October 1, 2021.

II. Present Situation:

Regulation of Tobacco Products

The Division of Alcoholic Beverages and Tobacco (division) within the Department of Business and Professional Regulation (DBPR) is the state agency responsible for the regulation and enforcement of tobacco products under ch. 569, F.S.

Tobacco Products Definitions

Section 569.002(6), F.S., defines the term “tobacco products” to include loose tobacco leaves and products made from tobacco leaves, in whole or in part, and cigarette wrappers, which can be used for smoking, sniffing, or chewing.

Section 210.25(12), F.S., provides a separate definition for the term “tobacco products” in the context of the taxation of these products and the licensing of tobacco product manufacturers, importers, exporters, distributing agents, or wholesale dealers under part II of ch. 210, F.S. In this context the term “tobacco products” means:

loose tobacco suitable for smoking; snuff; snuff flour; cavendish; plug and twist tobacco; fine cuts and other chewing tobaccos; shorts; refuse scraps; clippings, cuttings, and sweepings of tobacco, and other kinds and forms of tobacco prepared in such manner as to be suitable for chewing; but “tobacco products” does not include cigarettes, as defined by s. 210.01(1), or cigars.

The definition of “tobacco products” in s. 569.002(6), F.S., is limited to the regulation of tobacco products by the division under ch. 569, F.S., and does not affect the taxation of such products under ch. 210, F.S.

Retail Tobacco Products Dealer Permits

A person must obtain a retail tobacco products dealer permit from the division for each place of business where tobacco products are sold, including sales made through a vending machine.¹ Section 569.003, F.S., relates to retail tobacco products dealer permits, the permit application, qualifications, fees, renewals, and duplicates. Section 569.003(2), F.S., stipulates that permits may only be issued to persons who are 18 years of age or older or to corporations the officers of which are 18 years of age or older. The division is authorized to refuse to issue a permit to any person, firm, association, or corporation whose permit has been revoked; to any corporation with

¹ Section 569.003, F.S.

an officer who has had his or her permit revoked; or to any person who is or has been an officer of a corporation whose permit has been revoked.

The fee for an annual permit is established in rule by the division at an amount to cover the regulatory costs of the program, not to exceed \$50. The fees are deposited into the Alcoholic Beverage and Tobacco Trust Fund within the DBPR.²

Mail Order, Internet, Other Remote Sales of Tobacco Products, and Tobacco Products Permits

Section 210.095(5), F.S., provides requirements for the delivery of mail order, Internet, and other remote sales of tobacco products, including age verification requirements, all of which is generally referred to as “delivery sales.” It also defines 10 relevant terms.

Specific notice and shipping requirements are provided for all delivery sales, whether in-state or out-of-state. Each person who mails, ships, or otherwise delivers tobacco products in connection with an order for a delivery sale is required to:

- Include, as part of the shipping documents, in a clear and conspicuous manner, the following statement: “Tobacco Products: Florida law prohibits shipping to individuals under 18 years of age and requires the payment of all applicable taxes.”
- Use a method of mailing, shipping, or delivery which obligates the delivery service to:
 - Require the signature of an adult who resides at the delivery address and obtain proof of the legal minimum purchase age of the individual accepting delivery, if the individual appears to be under 27 years of age.
 - Require proof that the individual accepting delivery is either the addressee or the adult designated by the addressee, in the form of a valid, government-issued identification card bearing a photograph of the individual who signs to accept delivery of the shipping container.
- Provide to the delivery service, if such service is used, evidence of full compliance with requirements for the collection and remittance of all taxes imposed on tobacco products by this state with respect to the delivery sale.³

If a person accepts a purchase order for a delivery sale and delivers the tobacco products without using a delivery service, the person must comply with all of the requirements that apply to a delivery service.⁴ Before making sales or shipping orders, entities must provide specific notice to the division as to shipper and receiver, with monthly reporting.⁵ There are requirements specific to purchase orders.⁶

Section 210.095(8), F.S., provides that the penalty for the following violations of the delivery sale requirements is a misdemeanor of the third degree:

- A delivery sale delivers tobacco products, on behalf of a delivery service, to an individual who is under 18 years of age.

² Section 569.003(1)(c), F.S.

³ Section 210.095(5), F.S.

⁴ *Id.*

⁵ Section 210.095(6), F.S.

⁶ Section 210.095(7), F.S.

- A violation of any provision in s. 210.095, F.S., by an individual who is under 18 years of age.

Florida law does not provide a criminal penalty classification for a misdemeanor of the third degree. However, the prohibitions and second degree misdemeanor penalties⁷ in s. 569.101, F.S., (prohibiting the sale, delivery, bartering, furnishing, or giving, directly or indirectly, to any person who is under 18 years of age, any tobacco product, and s. 569.11, F.S., prohibiting persons under 18 years of age from possessing, directly or indirectly, any tobacco product) apply to s. 210.095, F.S., relating to the delivery of tobacco products to persons under the age of 18.

Section 210.15, F.S., relates to permits for the sale of specific tobacco products. A requirement for issuance of such a permit is for a person to be of good moral character and not less than 18 years of age. In addition, permits to corporations may be issued only to corporations whose officers are of good moral character and not less than 18 years of age.⁸

Signage Requirement

Retail tobacco products dealers must post a clear and conspicuous sign that the sale of tobacco products is prohibited to persons under the age of 18 and that proof of age is required for purchase. The division is required to make the signs available to retailer dealers and must also have instructional material in the form of a calendar or similar format to assist in determining the age of the person attempting to purchase a tobacco product.⁹

Annual Report

The DBPR is required to submit an annual report to the Governor and Legislature regarding the enforcement of tobacco products, including:

- The number and results of compliance visits by the division;
- The number of violations for failure of a retailer to hold a valid license;
- The number of violations for selling tobacco products to anyone under the age of 18 and the results of administrative hearings on such violations; and
- The number of people under the age of 18 cited for violations, including sanctions imposed as a result of such citation, related to misrepresenting their age, purchasing tobacco products underage, or misrepresenting military service for the purpose of obtaining tobacco products underage.¹⁰

Tobacco Products and Minors

Current law prohibits the sales of tobacco products to, and the possession of tobacco products by, person under the age of 18. Section 569.101, F.S., prohibits the sale, delivery, bartering, furnishing, or giving of tobacco products to persons under the age of 18. A violation of this

⁷ Section 775.082, F.S., provides that the penalty for a misdemeanor of the second degree is punishable by a term of imprisonment not to exceed 60 days. Section 775.083, F.S., provides that the penalty for a misdemeanor of the second degree is punishable by a fine not to exceed \$500.

⁸ Section 210.15(2)(b), F.S.

⁹ Section 569.14, F.S.

¹⁰ Section 569.19, F.S.

prohibition is a second degree misdemeanor.¹¹ A second or subsequent violation within one year of the first violation is a first degree misdemeanor.¹²

It is a complete defense to a person charged with a violation of s. 569.101, F.S., if the buyer or recipient falsely evidenced that he or she was 18 years of age or older, a prudent person would believe the buyer or recipient to be 18 years of age or older, and the buyer or recipient presented false identification¹³ upon which the person relied in good faith.¹⁴

Section 569.11, F.S., prohibits persons under the age of 18 years from possessing, directly or indirectly, any tobacco products:

- A first violation of this prohibition is a non-criminal violation with a penalty of 16 hours of community service or a \$25 fine, and attendance at a school-approved anti-tobacco program, if locally available.
- A second or subsequent violation within 12 weeks of the first violation is punishable with a \$25 fine.

Any second or subsequent violation within the 12-week time period after the first violation is punishable as a first violation.¹⁵

Eighty percent of all civil penalties received by a county court under s. 569.11, F.S., must be remitted to the Department of Revenue for transfer to the Department of Education for teacher training, and for research and evaluation to reduce and prevent the use of tobacco products, nicotine products, or nicotine dispensing devices by children. The remaining 20 percent of civil penalties received by a county court must remain with the clerk of the county court to cover administrative costs.¹⁶

Section 569.002(7), F.S., provides that the term “any person under the age of 18” does not include any person under age 18 who:

- Has had his or her disability of nonage removed under ch. 743, F.S.;
- Is in the military reserve or on active duty in the Armed Forces of the United States;
- Is otherwise emancipated by a court of competent jurisdiction and released from parental care and responsibility; or
- Is acting in his or her scope of lawful employment with an entity licensed under the provisions of ch. 210, F.S., relating to taxation of cigarettes and other tobacco products, or ch. 569, F.S., relating to tobacco products.

¹¹ *Supra* note 6.

¹² Section 775.082, F.S., provides that the penalty for a misdemeanor of the first degree is punishable by a term of imprisonment not exceeding one year. Section 775.083, F.S., provides that the penalty for a misdemeanor of the first degree is punishable by a fine not to exceed \$1,000.

¹³ Identification includes carefully checking “a driver license or an identification card issued by this state or another state of the United States, a passport, or a United States armed services identification card presented by the buyer or recipient and acted in good faith and in reliance upon the representation and appearance of the buyer or recipient in the belief that the buyer or recipient was 18 years of age or older.” See s. 569.101(3)(c), F.S.

¹⁴ Section 569.101(3)(c), F.S.

¹⁵ Section 569.11(1), F.S.

¹⁶ Section 569.11(6), F.S.

To prevent persons under 18 years of age from purchasing or receiving tobacco products, the sale or delivery of tobacco products is prohibited, except when those products are under the direct control or line of sight of the dealer or the dealer's agent or employee. If a tobacco product is sold from a vending machine, the vending machine must have:

- An operational lock-out device which is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lock-out device to allow the dispensing of one tobacco product;
- A mechanism on the lock-out device to prevent the machine from functioning if the power source for the lock-out device fails or if the lock-out device is disabled; and
- A mechanism to ensure that only one tobacco product is dispensed at a time.¹⁷

These requirements for the sale of tobacco products do not apply to an establishment that prohibits persons under 18 years of age on the premises and do not apply to the sale or delivery of cigars and pipe tobacco.¹⁸

Section 569.0075, F.S., prohibits the giving of sample tobacco products to persons under the age of 18.

Section 569.12, F.S., provides enforcement authority to full-time, part-time, and auxiliary law enforcement officers for the provisions of ch. 569, F.S. The section also authorizes a county or municipality to designate certain of its employees or agents as tobacco product enforcement officers within specified guidelines. Such enforcement officers are authorized to issue a citation to a person under 18 years of age based on a reasonable cause to believe that a civil infraction has been committed. Similar authority is provided for correctional probation officers. Details are provided as to the required elements of the citation.

Retail tobacco products dealers (retailers) must post a clear and conspicuous sign that the sale of tobacco products is prohibited to persons under the age of 18 and that proof of age is required for purchase. The division is required to make the signs available to retailers. Retailers must also have instructional material in the form of a calendar or similar format to assist in determining the age of the person attempting to purchase a tobacco product.¹⁹

Section 569.19, F.S., requires the division to annually provide to the Legislature and the Governor, by December 31, a progress report on its enforcement actions specific to the number and results of compliance visits, number of violations for failure of a retailer to hold a valid license, number of violations of selling tobacco products to persons under age 18, results of administrative hearings on these issues, and number of persons under age 18 cited for violations of underage purchases and sanctions imposed as a result of a citation.

Section 386.212, F.S., in the Florida Clean Indoor Air Act,²⁰ prohibits any person under the age of 18 from smoking tobacco within 1,000 feet of a public or private elementary, middle, or secondary school between the hours of 6:00 a.m. and midnight.²¹ A violation of this prohibition

¹⁷ Section 569.007(1), F.S.

¹⁸ Section 569.007(2) and (3), F.S.

¹⁹ Section 569.14, F.S.

²⁰ Part II of ch. 386, F.S.

²¹ Section 386.212(1), F.S.

is punishable by a maximum noncriminal civil penalty not to exceed \$25, or 50 hours of community service or, where available, successful completion of a school-approved anti-tobacco “alternative to suspension” program.²²

Administrative Penalties

A retail tobacco dealer permit-holder can be disciplined under the division’s penalty guidelines. For a violation of the prohibition in s. 569.06, F.S., against the sale of tobacco products to persons under 18 years of age, the guidelines provide:

- 1st occurrence -- \$500 fine.
- 2nd occurrence -- \$1,000 fine.
- 3rd occurrence -- \$2,000 fine and a 20-day suspension of the dealer permit.
- 4th occurrence -- revocation of the dealer permit.

These penalties are based on a single violation in which the permit-holder committed or knew about the violation; or a pattern of at least three violations on different dates within a 12-week period by employees, independent contractors, agents, or patrons on the licensed premises or in the scope of employment in which the permit-holder did not participate; or violations which were occurring in an open and notorious manner on the licensed premises.²³

Section 569.008, F.S., provides a process for a retail tobacco products dealer to mitigate penalties imposed against a dealer because of an employee’s illegal sale of a tobacco product to a person under 18 years of age.²⁴ The process encourages retail tobacco products dealers to comply with responsible practices. The division may mitigate penalties if:

- The dealer is qualified as a responsible dealer having established and implemented specified practices designed to ensure that the dealer’s employees comply with ch. 569, F.S., such as employee training;
- The dealer had no knowledge of that employee’s violation at the time of the violation and did not direct, approve, or participate in the violation; or
- The sale was made through a vending machine equipped with an operational lock-out device.²⁵

Nicotine Dispensing Devices

Section 877.112, F.S., provides requirements for the sale of nicotine dispensing devices and nicotine products to minors, such as electronic cigarettes (e-cigarettes). This statute extends the current prohibitions related to tobacco products to the sale, gifting, possession, or use of nicotine dispensing devices and nicotine products to and by persons under 18 years of age.

A license is not required to sell or offer for sale “nicotine dispensing devices” or “nicotine products.”

²² Section 386.212(3), F.S.

²³ Fla. Admin. Code R. 61A-2.022(1) (2019).

²⁴ The Florida Responsible Vendor Act in ss. 561.701 - 561.706, F.S., provides a comparable process for mitigation of penalties against vendors of alcoholic beverages.

²⁵ Section 569.008(3), F.S.

A “nicotine dispensing device” is:

any product that employs an electronic, chemical, or mechanical means to produce vapor from a nicotine product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product, any replacement cartridge for such device, and any other container of nicotine in a solution or other form intended to be used with or within an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product.²⁶

A “nicotine product” is:

any product that contains nicotine, including liquid nicotine intended for human consumption, whether inhaled, chewed, absorbed, dissolved or ingested by any means. The definition does not include a tobacco product under Florida law, a drug or device under federal law, or a product that contains incidental nicotine.²⁷

The sale or giving of nicotine products or nicotine dispensing devices to any person under 18 years of age is prohibited and punishable as a second degree misdemeanor.²⁸ It is a complete defense to a violation if an underage person falsely misrepresented his or her age, the underage person had the appearance to a prudent person to 18 years of age or older, and the person carefully checked, and relied on, the driver license or identification card of the recipient.²⁹

Persons under 18 years of age possessing, purchasing, or misrepresenting their age or military service to obtain nicotine products or nicotine dispensing devices commit a noncriminal violation. The penalty is 16 hours of community service or a \$25 fine for a first violation, and attendance at a school-approved anti-tobacco and nicotine program, if available. A second or subsequent violation within 12 weeks of the first violation requires a \$25 fine. Any second or subsequent violation not within the 12-week time period after the first violation is punishable as provided for a first violation.³⁰

If a person under 18 years of age is found by the court to have committed such a noncriminal violation and that person has failed to complete community service, pay the required fine, or attend a school-approved anti-tobacco and nicotine program, if locally available, the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for 30 or 45 consecutive days, depending on the infraction.³¹

Eighty percent of civil penalties specific to possession of nicotine products or nicotine dispensing devices by minors and misrepresenting age in making such purchases are remitted to the Department of Revenue for transfer to the Department of Education for teacher training and for research and evaluation to reduce and prevent the use of tobacco products, nicotine products,

²⁶ Section 877.112(1)(a), F.S.

²⁷ Section 877.112(1)(b), F.S.

²⁸ *Supra* note 5.

²⁹ Section 877.112(5), F.S.

³⁰ Sections 877.112(6) and (7), F.S.

³¹ Section 877.112(8), F.S.

or nicotine dispensing devices by children. The remaining 20 percent of civil penalties received by a county court are retained by the clerk of the county court to cover administrative costs.³²

Subsection 877.112(10), F.S., requires a retail dealer of nicotine products and nicotine dispensing devices to post signs that the sale of nicotine products and nicotine dispensing devices to persons under 18 years of age is prohibited. This signage requirement is similar to the signs required for retail tobacco products dealers under s. 569.14, F.S.

Nicotine products or nicotine dispensing devices may not be sold or delivered by self-service merchandising, except when such products are under the direct control of, or in the line of sight where effective control may be reasonably maintained by, the retailer or their agent or employee.³³

To prevent persons under 18 years of age from purchasing or receiving nicotine products or nicotine dispensing devices, s. 877.112(12), F.S., requires retailers to comply with restrictions identical to the restrictions on the sale of tobacco products in s. 569.007(1), F.S., such as requiring the products to be sold or delivered only when under the direct control or line of sight of the retailer and requiring a lock-out device if the products are sold or delivered from a vending machine.

Regulation of Vaping

During the 2019 legislative session, CS/SB 7012³⁴ was enacted to implement Amendment 9 to the Florida Constitution,³⁵ which was approved by the voters of Florida on November 6, 2018, to ban the use of vapor-generating electronic devices, such as electronic cigarettes (e-cigarettes), in enclosed indoor workplaces, as part of the Florida Clean Indoor Air Act. The use of e-cigarettes is commonly referred to as vaping.

The use of vapor-generating electronic devices is permitted in the enclosed indoor workplace of a “vapor-generating device retailer” or “retail vape shop,” which is defined as “any enclosed indoor workplace dedicated to or predominantly for the retail sale of vapor-generating electronic devices and components, parts, and accessories for such products, in which the sale of other products or services is merely incidental.” Vaping is permitted at the same locations authorized to permit tobacco smoking, i.e., private residences whenever not being used for certain commercial purposes, stand-alone bars, designated rooms in hotels and other public lodging establishments, retail tobacco shops, facilities owned or leased by a membership association, smoking cessation program locations, medical or scientific research locations, and customs smoking rooms in airport in-transit lounges.³⁶

Local governments may adopt more restrictive local ordinances on the use of vapor-generating electronic devices.³⁷

³² Section 877.112(9), F.S.

³³ Section 877.112(11), F.S.

³⁴ See ch. 2019-14, Laws of Fla.

³⁵ FLA. CONST. art. X, s. 20.

³⁶ See ch. 386, part II, F.S.

³⁷ *Id.*

The above provisions were approved by the Governor and took effect July 1, 2019.

Unlike the retail sale of tobacco products, which is subject to regulation under ch. 569, F.S., the sale of vape products is only regulated under the provisions of s. 877.112, F.S. While tobacco products in Florida are subject to specific taxation under ch. 210, F.S., nicotine products are only subject to sales taxes.

Rates of Youth Vaping

According to Centers for Disease Control (CDC) latest National Youth Tobacco Surveys, electronic cigarettes (e-cigarettes) were the most commonly used tobacco product among high school (19.6 percent; 3.02 million) and middle school (4.7 percent; 550,000) students.³⁸ The CDC found that:

From 2019 to 2020, decreases in current use of any tobacco product, any combustible tobacco product, multiple tobacco products, e-cigarettes, cigars, and smokeless tobacco occurred among high school and middle school students; these declines resulted in an estimated 1.73 million fewer current youth tobacco product users in 2020 than in 2019 (6.20 million) (3). From 2019 to 2020, no significant change occurred in the use of cigarettes, hookahs, pipe tobacco, or heated tobacco products. The comprehensive and sustained implementation of evidence-based tobacco control strategies at the national, state, and local levels, combined with tobacco product regulation by FDA, is warranted to help sustain this progress and to prevent and reduce all forms of tobacco product use among U.S. youths.³⁹

The study found that use of e-cigarettes declined from 2019 to 2020, reversing previous trends. The declines were likely attributable to multiple factors at the national, state, and local levels. The report noted that “in December 2019, the federal minimum age of sale of all tobacco product types increased from 18 to 21 years.⁴⁰ The report indicated that the FDA issued guidance in January 2020 to prioritize enforcement against certain flavored e-cigarette products that appeal to youths, including mint and fruit flavors.⁴¹ The FDA report further stated that “several states and communities also recently restricted the sale of flavored tobacco products, including e-cigarettes.⁴²

³⁸ Centers for Disease Control and Prevention, *Tobacco Product Use Among Middle and High School Students — United States, 2020, December 18, 2020*, available at [Tobacco Product Use Among Middle and High School Students — United States, 2020 | MMWR \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/tobacco-product-use-among-middle-and-high-school-students-united-states-2020-18-2020-000-02.htm) (last visited March 16, 2021).

³⁹ *Id.*

⁴⁰ Food and Drug Administration, *Newly signed legislation raises federal minimum age of sale of tobacco products to 21, 2019*, available at <https://www.fda.gov/tobacco-products/ctp-newsroom/newly-signed-legislation-raises-federal-minimum-age-sale-tobacco-products-21>[external icon](#) (last visited March 16, 2021).

⁴¹ FDA Center for Tobacco Products, *Enforcement priorities for Electronic Nicotine Delivery Systems (ENDS) and other deemed products on the market without premarket authorization (revised)*, available at <https://www.fda.gov/media/133880/download> (last visited March 16, 2021).

⁴² See Campaign for Tobacco Free Kids, *States & Localities that have Restricted the Sale of Flavored Tobacco Products*, available at [0398.pdf \(tobaccofreekids.org\)](https://www.tobaccofreekids.org/images/stories/pdfs/0398.pdf) (last visited March 16, 2021).

Nearly 70 percent of e-cigarette users reported using a flavored product, and the availability of flavors such as mint and chocolate was a reason that many students cited for trying e-cigarettes. The findings came a year after the U.S. Surgeon General declared the surge in youth vaping an epidemic.⁴³

Health Issues Relating to Vaping

The CDC is conducting an ongoing national investigation of vaping-related lung injuries. The CDC, the federal Food and Drug Administration (FDA), state and local health departments, and public health and clinical stakeholders have been investigating and monitoring the nationwide illness outbreak related to vaping. The condition has been labelled “E-cigarette, or Vaping, product use-Associated Lung Injury,” or EVALI. AS of February 18, 2020, the CDC reports that 2,807 people have been hospitalized and 68 people have died across 29 states and Washington, D.C.⁴⁴ Two of the deaths have occurred in Florida, and 103 cases of vaping-related illness hospitalizations have been documented in Florida as of December 3, 2019.⁴⁵

National Minimum Age of Sale of Tobacco Products

As part of the federal budget revisions adopted in December 2019 and signed into law on December 20, 2019, the federal minimum age for the sale of tobacco products was increased to 21 years of age.⁴⁶ The specific tobacco provisions in the budget amended section 906(d) of the Federal Food, Drug, and Cosmetic Act to increase the federal minimum age to purchase tobacco products from 18 to 21 years of age, and to prohibit retailers from selling tobacco products to any person younger than 21 years of age. The provisions also require the FDA to update its applicable tobacco regulations within specified timelines.

As part of the rule update process, the FDA must update the relevant age verification requirements to require age verification for individuals under age 30 (as opposed to the current age verification threshold for individuals under age 27).

U.S. Federal Food and Drug Administration Enforcement

The FDA has “deemed” ENDS products, i.e., vaping products, to be tobacco products.⁴⁷ A brief explanation of “deeming” is helpful in this context. The Family Smoking Prevention and

⁴³ See “Surgeon General Warns Youth Vaping Is Now An ‘Epidemic,’” December 18, 2018, *available at* <https://www.npr.org/sections/health-shots/2018/12/18/677755266/surgeon-general-warns-youth-vaping-is-now-an-epidemic> (last visited March 16, 2021).

⁴⁴ Centers for Disease Control and Prevention, *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, *available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html (last visited March 16, 2021).

⁴⁵ See Naseem S. Miller, *Florida reports second vaping death*, Orlando Sentinel, Dec. 11, 2019, *available at* <http://www.orlandosentinel.com/news/os-ne-florida-reports-second-vaping-death-20191211-dvz3tehxebvkvkavhe2jdiepe-story.html> (last visited March 16, 2021).

⁴⁶ See the “Further Consolidated Appropriations Act, 2020,” Rules Committee print 116-44, Text of the House Amendment to the Senate Amendment to H.R. 1865, December 16, 2019, beginning at page 1492 of 1773, *available at* <https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-116HR1865SA-RCP116-44.PDF> (last visited March 16, 2020).

⁴⁷ See 21 CFR 1100-1143. For all intents and purposes, “Electronic Nicotine Delivery Systems” or ENDS products is a reference to vaping products.

Tobacco Control Act (2009) (the act) authorized the FDA to regulate tobacco products. The act broadly defined “tobacco products” as any product that is “made or derived from tobacco” and that is “intended for human consumption.” However, the act, when passed, immediately applied to a few products, namely cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. To regulate any other tobacco products, the act requires the FDA to assert jurisdiction through regulation. In other words, for the FDA to start regulating cigars, e-cigarettes, hookah, and other products not regulated by the federal government, the FDA must create a rule through its formal notice-and-comment rulemaking process. A rule, or regulation, that extends the FDA’s jurisdiction to all tobacco products is often referred to as a Deeming Regulation because the language of the act states that the FDA can regulate additional tobacco products that it “deems to be subject” to the act.⁴⁸

New tobacco products may not be legally marketed in the United States without a tobacco product marketing order from the FDA, which evaluates based on the product’s risks to the population as a whole. A “new tobacco product” is:

- Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
- Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.⁴⁹

The affected products include:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors’ access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.⁵⁰

There are three pathways to market for a person intending to market new tobacco products:

- A premarketing order issued by the FDA after submission of a premarket application;
- A finding by the FDA that the product is “substantial equivalent” to a “predicate” product and does not raise different questions of public health than the predicate product; and
- Receiving an exemption from demonstrating substantial equivalence.⁵¹

⁴⁸ See *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, available at <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the> (Feb. 26, 2021.) See also Tobacco Control Legal Consortium, *A Deeming Regulation: What is Possible Under the Law*, available at <https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-deeming-reg-what-is-possible-2014.pdf> (last visited March 16, 2021).

⁴⁹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §910(a)(1).

⁵⁰ *Supra*, note 48.

⁵¹ FDA, *Market and Distribute a Tobacco Product*, available at <https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product> (last visited March 16, 2021).

New tobacco products commercially marketed after February 15, 2007, but before March 22, 2011, with a Substantial Equivalency Report submitted by March 22, 2011, are known as “provisional SE tobacco products” and may continue to be marketed unless FDA issues an order that the new product is not substantially equivalent.⁵²

III. Effect of Proposed Changes:

The bill creates a separate licensing structure for the sale of “nicotine dispensing devices” and “nicotine products,” by creating a new part of ch. 569, F.S., to regulate the sale of such products. Under the bill:

- Tobacco products would be regulated under part I of ch. 569, F.S., consisting of ss. 569.002 through 569.23, F.S., which comprise the current provisions in ch. 569, F.S.
- Nicotine products would be regulated under part II, consisting of ss. 569.31 through 569.45, F.S., which includes the requirements in current law for the sale of nicotine products, and additional provisions for regulating nicotine product sales the same as currently apply to the regulation of tobacco product sales.

The bill changes the title of ch. 569, F.S., from “Tobacco Products” to “Tobacco and Nicotine Products,” and directs the Division of Law Revision to create parts I and II of ch. 569, F.S., entitled “Tobacco Products” and “Nicotine Products,” respectively.

The bill preempts to the state the establishment of a minimum age for purchasing or possessing tobacco or nicotine products as well as regulation of the marketing, sale, or delivery of tobacco or nicotine products.

Tobacco Products

The bill increases the minimum age to lawfully purchase and possess tobacco products from 18 years of age to 21 years of age. It revises the minimum age requirements in the relevant provisions in ch. 210 and in ch. 569, F.S., including:

- Section 210.095(5), F.S., relating to mail order, Internet, and remote sales of tobacco products, and age verification related for such sales. The bill also requires the individual making a delivery of tobacco products to require the person accepting delivery to provide proof of their legal minimum purchase age if the individual appears to be under 30 years of age, rather than the current 27 years of age. (This latter provision is modified to ensure conformity with recent federal law provisions.)⁵³
- Section 210.15 (1)(b), F.S., relating to the qualification for a person applying for a permit for the sale of tobacco products.
- Sections 569.007(1) and (2), F.S., relating to the prohibition on the sale or delivery of tobacco products to an underage person.
- Section 569.101, F.S., relating to the prohibition and penalties against the sale, delivery, barter, furnishing, or giving of tobacco products to an underage person.
- Section 569.11, F.S., relating to the prohibition on the possession of tobacco products by underage persons.

⁵² *Id.*

⁵³ *Supra* note 47.

- Section 569.14, F.S., revising the signage requirements for dealers of tobacco products.

The bill revises the definition of the term “any person under the age of 18,” to “any person under the age of 21” and deletes the exemptions for persons who have had the disability of nonage removed under ch. 743, F.S., and emancipated minors. Under the bill, the prohibitions against the sale of tobacco products to, and possession of tobacco products by, persons under 21 years of age would apply to such persons. Persons in the military reserve or active duty in the Armed Forces of the United States and persons acting within the scope of lawful employment, if under the age of 21, would not be prohibited from possessing or purchasing tobacco products.

The bill also amends ss. 210.095(8)(e) and (g), F.S., to provide that the penalty for a violation of the delivery sale requirements in this section, including a delivery sale to a person under the legal age to possess tobacco products, is a misdemeanor of the second degree. The incorrect reference to a misdemeanor of the third degree is deleted.

Smoking and Vaping Near School Property

The bill amends s. 386.212, F.S., to increase the applicable age from 18 years of age to 21 years of age in the prohibition against smoking and vaping on or near school property during the hours of 6 a.m. to midnight and related penalties.

Nicotine Dispensing Devices and Nicotine Products

Definitions

The bill creates s. 569.31, F.S., to define the terms used in part II of ch. 569, F.S.

The bill defines the term “nicotine dispensing device” to mean “any product that employs an electronic, chemical, or mechanical means to produce vapor or aerosol from a nicotine product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product, any replacement cartridge for such device, and any other container of nicotine in a solution or other form intended to be used with or within an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product.”

The bill defines the term “nicotine product” to mean “any product that contains nicotine, including liquid nicotine, which is intended for human consumption, whether inhaled, chewed, absorbed, dissolved, or ingested by any means.” The term “nicotine product” also includes any nicotine dispensing device.

Under the bill, the following products are not considered to be nicotine products:

- Tobacco products;
- Products regulated as a drug or device by the FDA; or
- Products that contain incidental nicotine.

The definitions of “nicotine dispensing device” and “nicotine product” in the bill are the same as the terms are currently defined in s. 877.112, F.S.

Section 569.31, F.S., defines the term “any person under the age of 21” to not include any person under the age of 21 who is:

- In the military reserve or on active duty in the Armed Forces of the United States; or
- Acting in his or her scope of lawful employment.⁵⁴

Retail Nicotine Products Dealer Permits

The bill creates s. 569.32, F.S., to require persons who deal, at retail, in nicotine products or who allow a nicotine products vending machine to be located in their premises, to obtain a retail nicotine products dealer permit from the division. This permit does not allow for the sale of tobacco products. However, the holder of a retail tobacco products dealer permit may sell nicotine products without an additional permit.

The bill requires a person to obtain a retail nicotine products dealer permit for each place of business or the premises where nicotine products are to be sold face-to-face or through a vending machine, but no fee is provided for the permit. The division may only issue permits to persons who are 21 years or older or corporations with officers who are 21 years or older. The bill provides the place or premises covered by a permit is subject to inspection and search without a search warrant by the division, or its authorized assistants, and by sheriffs, deputy sheriffs, or police officers, to determine compliance with requirements for nicotine sales and dealing.

The provisions for the issuance and renewal of a retail nicotine products dealer permit are comparable to the requirements for a retail tobacco products dealer permit. However, the bill does not require a retail dealer to pay a fee for a retail nicotine products dealer permit.

Section 569.33, F.S., provides that a retail nicotine products dealer, by accepting a permit, consents to the inspection and search of the place or premises covered by the permit without a warrant by the division or its authorized assistants, and by sheriffs, deputy sheriffs, or police officers, to determine compliance with part II of ch. 569, F.S.⁵⁵

Section 569.34, F.S., prohibits the dealing, at retail, of nicotine products. A person who violates this prohibition commits a noncriminal violation, punishable by a fine of not more than \$500.⁵⁶ However, a retail tobacco products dealer is not required to have a separate or additional permit to deal, at retail, in nicotine products.

Section 569.35, F.S., provides administrative penalties for a violation of the requirements in part II of ch. 569, F.S. Under the bill, the division may assess a fine of up to \$1,000 for a violation. All fines collected must be deposited by the division into the General Revenue Fund. The division may also suspend the imposition of a penalty against a dealer, conditioned upon the dealer's compliance with terms the division considers appropriate.⁵⁷

⁵⁴ See s. 569.002(9), F.S., as amended by the bill, providing a comparable provision for the retail tobacco products dealer permit.

⁵⁵ See s. 569.004, F.S., providing a comparable provision for the retail tobacco products dealer permit.

⁵⁶ See s. 569.005, F.S., providing a comparable provision, including the same penalty, for the retail tobacco products dealer permit.

⁵⁷ See s. 569.006, F.S., providing a comparable provision for the retail tobacco products dealer permit.

Section 569.39, F.S., authorizes the division to adopt rules to administer part II of ch. 569, F.S.

Nicotine Products and Persons Under the Age of 21

The bill repeals s. 877.112, F.S., which currently regulates the retail sale nicotine products in this state, including the sale of such products to, and possession by, minors. The requirements of s. 877.112, F.S., are incorporated into part II of ch. 569, F.S., and revised to increase the minimum lawful age to 21 from 18 years of age as follows:

- Section 569.37, F.S., requires sales and deliveries of nicotine products to be under the direct control or line of sight of the dealer or the dealer's agent or employee. If the sale or delivery is made through a vending machine, the vending machine must be equipped with an operational lockout device that is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lockout device to allow the dispensing of one nicotine product. The bill also prohibits sales by means of self-merchandising, which is an open display of products providing the consumer with direct access to nicotine products. However, self-merchandising is permitted if the establishment prohibits persons under 21 years of age on the licensed premises.⁵⁸
- Section 569.41(1), F.S., prohibits the sale, delivery, barter, furnishing, or giving (sale or delivery) of nicotine products to underage persons;⁵⁹
- Section 569.41(2), F.S., provides criminal penalties for the sale or delivery of nicotine products to underage persons of a misdemeanor of the second degree for a first violation and a misdemeanor of the first degree for second of subsequent violation within one year of the first violation.⁶⁰
- Section 569.41(3), F.S., provides the following affirmative defenses for a person charged with such a violation:⁶¹
 - The buyer falsely represented that he or she was 21 years of age or older;
 - The appearance of the buyer would indicate, to a prudent person, that the buyer was 21 years of age or older; and
 - The person carefully checked a driver license or identification card and acted in good faith in reliance upon the representation and appearance of the buyer or recipient in the belief the buyer or recipient of 21 years of age or older.
- Section 569.38, F.S., prohibits the gifting of nicotine product samples to underage persons;⁶²
- Sections 569.42(1) through (5), F.S., prohibit the knowing possession of nicotine products by persons under the lawful minimum age, prohibiting the misrepresentation of age or military service for the purpose of inducing a dealer or an agent or servant of a dealer to sell or deliver any nicotine product, and providing that any person who violates such prohibitions commits a non-criminal violation, punishable as follows:
 - A first violation carries a penalty of 16 hours of community service or a \$25 fine, and attendance at a school-approved anti-tobacco and anti-nicotine program, if locally available.
 - A second violation within 12 weeks of the first violation is punishable with a \$25 fine.

⁵⁸ See ss. 877.112(11) and (12), F.S.

⁵⁹ See s. 877.112(2), F.S.

⁶⁰ See s. 877.112(4), F.S.

⁶¹ See s. 877.112(5), F.S.

⁶² See s. 877.112(3), F.S.

- A court may suspend or withhold issuance of a driver's license for persons under 21 years of age who fail to complete the noncriminal penalties for knowingly possessing or misrepresenting their age in order to purchase nicotine products.⁶³
- Section 569.42(6), F.S., requires 80 percent of all civil penalties received from violating prohibitions related to the possession or sale of nicotine products by a county court to be remitted to the Department of Revenue for transfer to the Department of Education for teacher training and for research and evaluation to reduce and prevent the use of nicotine products and nicotine products by children. The remaining 20 percent of civil penalties received by a county court must remain with the clerk of the county court to cover administrative costs.⁶⁴
- Section 569.43, F.S., requires nicotine product retailers to post a clear and conspicuous sign that the sale of nicotine products is prohibited to persons under the age of 21 and that proof of age is required for purchase.⁶⁵

The bill creates s. 569.381, to provide a process to encourage a retail nicotine products dealer to comply with responsible practices to prevent the sale of nicotine products to persons under 21 years of age. This process is the same as is currently provided in s. 569.008, F.S., for retail tobacco product dealers. Under the bill, if the division finds that a retail nicotine products retailer's employee has illegally sold nicotine products to a person under 21 years of age, the division may mitigate penalties if:

- The nicotine product retailer is qualified as a responsible retailer by establishing and implementing specified practices designed to ensure that the nicotine product retailer's employees comply with Florida laws regulating the sale of nicotine products, such as employee training;
- The nicotine product retailer had no knowledge of that employee's violation at the time of the violation and did not direct, approve, or participate in the violation; and
- If the sale was made through a vending machine, the machine was equipped with an operational lock-out device.

Annual Report

Section 569.44, F.S., requires the division to submit an annual report, by December 31, to the Governor and Legislature on the progress of implementing and enforcing the above requirements, including:

- The number and results of compliance visits by the division;
- The number of violations for failure of a retailer to hold a valid permit;
- The number of violations for selling nicotine products to anyone under the age of 21 and the results of administrative hearings on such violations; and
- The number of people under the age of 21 cited, including sanctions imposed as a result of such citation.⁶⁶

⁶³ See ss. 877.112(6), (7), and (8), F.S.

⁶⁴ See s. 877.112(9), F.S.

⁶⁵ See s. 877.112(10), F.S.

⁶⁶ See s. 569.19, F.S., providing a comparable provision for the retail tobacco products dealer permit.

Mail Order, Internet, and Other Remote Sales of Nicotine Products in Florida

Section 569.45, F.S., provides requirements for the delivery of mail order, Internet, and other remote sales of nicotine products, referred to as “delivery sales.”⁶⁷ Under the bill, each person who mails, ships, or otherwise delivers nicotine products in connection with an order for a delivery sale must:

- Include, as part of the shipping documents, in a clear and conspicuous manner, the following statement: “Nicotine Products: Florida law prohibits shipping to individuals under 21 years of age.”
- Use a method of mailing, shipping, or delivery which obligates the delivery service to:
 - Require the signature of an adult who resides at the delivery address and obtain proof of the legal minimum purchase age of the individual accepting delivery, if the individual appears to be under 30 years of age.
 - Require proof that the individual accepting delivery is either the addressee or the adult designated by the addressee, in the form of a valid, government-issued identification card bearing a photograph of the individual who signs to accept delivery of the shipping container.

Before the first delivery to a consumer, the bill requires the person mailing, shipping, or delivering the nicotine products to:

- Obtain a certification from the person accepting delivery that includes reliable confirmation that the person accepting the delivery is an adult, and a written statement under penalty of perjury providing the person’s date of birth, address, and confirmation that the person wants to accept the delivery;
- Make a good faith effort to verify the information in the certification by checking the information against a commercially available database or obtaining a photocopy of the person’s ID;
- Provide the person accepting the delivery a notice stating nicotine products are illegal for underage youths and sales of such products are restricted to individuals who provide verifiable proof of legal age to purchase;
- Receive payment by a credit card or debit card in the name of the person accepting the delivery or a personal or company check of the person accepting the delivery, if the order is made in accordance with an advertisement on the Internet;
- Submit to the credit card company necessary information so that the words “nicotine product” appear on the person’s credit card statement when a purchase is made using a credit card; and
- Make a phone call to the person accepting the delivery to confirm the order before shipping the order.

The bill requires a person who accepts a purchase order for a delivery sale and delivers the nicotine products without using a delivery service to comply with all of the delivery service requirements.

⁶⁷ See s. 210.095, F.S., providing comparable provisions for delivery sales of tobacco products.

The bill imposes a penalty for knowingly violating the delivery sale requirements as a misdemeanor of the second degree.⁶⁸

Effective Date

The effective date of the bill is October 1, 2021.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

Article VII, Section 19 of the State Constitution requires a “state tax or fee imposed, authorized, or raised under this section must be contained in a separate bill that contains no other subject.” A “fee” is defined by the State Constitution to mean “any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service.”

Article VII, Section 19 of the State Constitution also requires that a tax or fee raised by the Legislature must be approved by two-thirds of the membership of each house of the Legislature.

Under the bill, a fee for a retail nicotine products dealer permit is not imposed.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

⁶⁸ *Supra*, note 6.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Business and Professional Regulation (DBPR) may incur indeterminate expenses related to personnel costs or modification of operational priorities needed to accommodate the additional licensure of dealers of vapor-generating electronic devices, which will not be offset by a permit fee.

VI. Technical Deficiencies:

None.

VII. Related Issues:**Age of Tobacco Purchase in Other States**

As of January 1, 2021, 31 states have raised the tobacco purchase age to 21 years of age, along with Washington, DC, and over 500 localities.⁶⁹ In Florida, Alachua County and the City of Fort Lauderdale have raised their minimum age for purchase of tobacco products to 21 years of age.⁷⁰

Age Restrictions on Youth Access to Electronic Cigarettes in Other States

As of December 15, 2020, all states and the District of Columbia have laws that restrict youth access to electronic cigarettes, or e-cigarettes. In this context, *e-cigarette* broadly refers to any product, and its component parts and accessories, that contains nicotine and/or other substances intended for use in the form of an aerosol, often referred to as vapor. In 32 states, the restriction is set at age 21. Two states set the restriction at age 19. In 16 states, the restriction is set at age 18. There are certain exceptions and exemptions that are applicable within any given state.⁷¹

The bill amends s. 569.002(6), F.S., to modify the definition of “tobacco products” in the context of the regulation of the retail sale of tobacco products. Section 210.25(11), F.S., relating to the taxation of on tobacco products other than cigarettes or cigars, also defines the term “tobacco products.” Because the bill does not revise the definition of “tobacco products” in part II ch. 210, F.S., which governs the excise tax and surcharge imposed and collected on tobacco products other than cigars and cigarettes, the bill does not affect:

- The taxation of vapor-generating electronic devices;

⁶⁹ See Campaign for Tobacco-Free Kids, *States and Localities that have Raised the Minimum Legal Sale Age for Tobacco Products to 21*, available at https://www.tobaccofreekids.org/assets/content/what_we_do/state_local_issues/sales_21/states_localities_MLSA_21.pdf (last visited March 16, 2021).

⁷⁰ *Id.*

⁷¹ See Public Health Law Center at Mitchell Hamline School of Law, “Youth Access to E-Cigarettes, States with Laws Restricting Youth Access to E-Cigarettes, Enacted as of December 15, 2020,” available at <https://www.publichealthlawcenter.org/sites/default/files/States-with-Laws-Restricting-Youth-Access-to-ECigarettes-Dec2020.pdf> (last visited March 16, 2021).

- The collection of excise taxes and surcharge taxes on other tobacco products; or
- The licensure, reporting, and recordkeeping of manufacturers and distributors of vapor-generating electronic devices or other tobacco products.

Types of Nicotine Devices Subject to Federal Enforcement Priorities

The nicotine devices that are subject to enhanced enforcement by the FDA are cartridge-based nicotine devices. Tank-based vaping devices will not be subject to enhanced federal FDA enforcement.⁷²

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 210.095, 210.15, 386.212, 569.002, 569.003, 569.004, 569.006, 569.007, 569.0075, 569.008, 569.009, 569.101, 569.11, 569.12, 569.14, and 569.19.

This bill creates the following sections of the Florida Statutes: 569.0025, 569.31, 569.315, 569.32, 569.33, 569.34, 569.35, 569.37, 569.38, 569.381, 569.39, 567.41, 569.42, 569.43, 569.44, and 569.45.

This bill repeals section 877.112 of the Florida Statutes.

IX. Additional Information:

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

CS/CS by Health Policy on March 24, 2021:

The committee substitute creates ss. 569.0025 and 569.315, F.S., to preempt to the state the establishment of a minimum age for purchasing or possessing tobacco or nicotine products as well as regulation of the marketing, sale, or delivery of tobacco or nicotine products.

CS by Regulated Industries on March 9, 2021:

The committee substitute:

- Creates a separate licensing structure for the sale of “nicotine dispensing devices” and nicotine products, by creating a new part II in ch. 569, F.S., to regulate the sale of such products.
- Regulates tobacco products under part I consisting of ss. 569.002 through 569.23, F.S., which consists of the current law provisions.
- Regulates nicotine products under part II, consisting of ss. 569.31 through 569.45, F.S., which includes the requirements in current law for the sale of nicotine products and additional provisions for the regulation of nicotine product sales the same as currently apply to the regulation of tobacco product sales.
- Does not define the term tobacco products to include nicotine products.

⁷² *Supra* note 48.

- Defines the term “nicotine dispensing device” and the term “vapor-generating electronic device.”
- Requires nicotine products retail dealers to have a permit issued by the Division of Alcoholic Beverages and Tobacco, but does not require a fee.
- Retains the exemption in the definition for “any person under the age of 21” for underage persons in the military and persons acting in the scope of lawful employment.
- Revises the prohibition against smoking and vaping on or near school property to apply to persons under 21 years, and does not apply the prohibition to all hours of the day.
- Amends ss. 210.095(8)(e) and (g), F.S., to provide that the penalty for a violation of the delivery sale requirements in this section, including a delivery sale to a person under the legal age to possess tobacco products, is a misdemeanor of the second degree, and deleting the incorrect reference to a misdemeanor of the third degree.
- Does not amend s. 569.007(1), F.S., to provide that sales of tobacco products from a vending machine are only permissible from a machine that is located in an establishment that prohibits persons under age 21 on the licensed premises at all times.
- Removes the provision in the bill limiting the sale of tobacco products through vending machines to a location that prohibit persons under 21 years of age on the premises.
- Does not create s. 569.101(4), F.S., to require a person to verify that a person purchasing a tobacco product is not under 21 years of age, and specify the type of documentation that may be used to verify age.
- Makes several technical and conforming changes to the bill.

B. Amendments:

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
03/24/2021	.	
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The Committee on Health Policy (Hutson) recommended the following:

Senate Amendment (with title amendment)

Delete lines 265 - 653
and insert:

Section 7. Section 569.0025, Florida Statutes, is created
to read:

569.0025 Preemption.—The establishment of the minimum age
for purchasing or possessing, and the regulation for the
marketing, sale, or delivery of, tobacco products is preempted
to the state. However, this section does not preempt the ability



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11 of a political subdivision to require retail licensure for the
12 sale of tobacco products.

13 Section 8. Paragraph (c) of subsection (1) of section
14 569.003, Florida Statutes, is amended to read:

15 569.003 Retail tobacco products dealer permits;
16 application; qualifications; fees; renewal; duplicates.—

17 (1)

18 (c) Permits shall be issued annually, upon payment of the
19 annual permit fee prescribed by the division. The division shall
20 fix the fee in an amount sufficient to meet the costs incurred
21 by it in carrying out its permitting, enforcement, and
22 administrative responsibilities under this part ~~chapter~~, but the
23 fee may not exceed \$50. The proceeds of the fee shall be
24 deposited into the Alcoholic Beverage and Tobacco Trust Fund.

25 Section 9. Section 569.004, Florida Statutes, is amended to
26 read:

27 569.004 Consent to inspection and search without warrant.—
28 An applicant for a permit, by accepting the permit when issued,
29 agrees that the place or premises covered by the permit is
30 subject to inspection and search without a search warrant by the
31 division or its authorized assistants, and by sheriffs, deputy
32 sheriffs, or police officers, to determine compliance with this
33 chapter, including part II of this chapter if the applicant
34 deals, at retail, in nicotine products within the state or
35 allows a nicotine products vending machine to be located on its
36 premises within the state.

37 Section 10. Section 569.006, Florida Statutes, is amended
38 to read:

39 569.006 Retail tobacco products dealers; administrative



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penalties.—The division may suspend or revoke the permit of the dealer upon sufficient cause appearing of the violation of any of the provisions of this chapter, including part II of this chapter if the dealer deals, at retail, in nicotine products within the state or allows a nicotine products vending machine to be located on its premises within the state, by a dealer or by a dealer's agent or employee. The division may also assess and accept administrative fines of up to \$1,000 against a dealer for each violation. The division shall deposit all fines collected into the General Revenue Fund as collected. An order imposing an administrative fine becomes effective 15 days after the date of the order. The division may suspend the imposition of a penalty against a dealer, conditioned upon the dealer's compliance with terms the division considers appropriate.

Section 11. Subsections (1) and (2) of section 569.007, Florida Statutes, are amended to read:

569.007 Sale or delivery of tobacco products;
restrictions.—

(1) In order to prevent persons under 21 ~~18~~ years of age from purchasing or receiving tobacco products, the sale or delivery of tobacco products is prohibited, except:

(a) When under the direct control or line of sight of the dealer or the dealer's agent or employee; or

(b) Sales from a vending machine are prohibited under the provisions of paragraph (1)(a) and are only permissible from a machine that is equipped with an operational lockout device which is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lockout device to allow the dispensing



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of one tobacco product. The lockout device must include a mechanism to prevent the machine from functioning if the power source for the lockout device fails or if the lockout device is disabled, and a mechanism to ensure that only one tobacco product is dispensed at a time.

(2) The provisions of subsection (1) shall not apply to an establishment that prohibits persons under 21 ~~18~~ years of age on the licensed premises.

Section 12. Section 569.0075, Florida Statutes, is amended to read:

569.0075 Gift of sample tobacco products prohibited.—The gift of sample tobacco products to any person under the age of 21 ~~18~~ by an entity licensed or permitted under the provisions of chapter 210 or this part ~~chapter~~, or by an employee of such entity, is prohibited and is punishable as provided in s. 569.101.

Section 13. Subsection (1), paragraphs (b) and (c) of subsection (2), and subsection (3) of section 569.008, Florida Statutes, are amended to read:

569.008 Responsible retail tobacco products dealers; qualifications; mitigation of disciplinary penalties; diligent management and supervision; presumption.—

(1) The Legislature intends to prevent the sale of tobacco products to persons under 21 ~~18~~ years of age and to encourage retail tobacco products dealers to comply with responsible practices in accordance with this section.

(2) To qualify as a responsible retail tobacco products dealer, the dealer must establish and implement procedures designed to ensure that the dealer's employees comply with the



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provisions of this part ~~chapter~~. The dealer must provide a training program for the dealer's employees which addresses the use and sale of tobacco products and which includes at least the following topics:

(b) Methods of recognizing and handling customers under 21 ~~18~~ years of age.

(c) Procedures for proper examination of identification cards in order to verify that customers are not under 21 ~~18~~ years of age.

(3) In determining penalties under s. 569.006, the division may mitigate penalties imposed against a dealer because of an employee's illegal sale of a tobacco product to a person under 21 ~~18~~ years of age if the following conditions are met:

(a) The dealer is qualified as a responsible dealer under this section.

(b) The dealer provided the training program required under subsection (2) to that employee before the illegal sale occurred.

(c) The dealer had no knowledge of that employee's violation at the time of the violation and did not direct, approve, or participate in the violation.

(d) If the sale was made through a vending machine, the machine was equipped with an operational lock-out device.

Section 14. Section 569.009, Florida Statutes, is amended to read:

569.009 Rulemaking authority.—The division shall adopt any rules necessary to administer and enforce the provisions of this part ~~chapter~~.

Section 15. Section 569.101, Florida Statutes, is amended



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to read:

569.101 Selling, delivering, bartering, furnishing, or giving tobacco products to persons under 21 ~~18~~ years of age; criminal penalties; defense.—

(1) It is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, to any person who is under 21 ~~18~~ years of age, any tobacco product.

(2) Any person who violates subsection (1) commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. However, any person who violates subsection (1) for a second or subsequent time within 1 year of the first violation, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(3) A person charged with a violation of subsection (1) has a complete defense if, at the time the tobacco product was sold, delivered, bartered, furnished, or given:

(a) The buyer or recipient falsely evidenced that she or he was 21 ~~18~~ years of age or older;

(b) The appearance of the buyer or recipient was such that a prudent person would believe the buyer or recipient to be 21 ~~18~~ years of age or older; and

(c) Such person carefully checked a driver license or an identification card issued by this state or another state of the United States, a passport, or a United States armed services identification card presented by the buyer or recipient and acted in good faith and in reliance upon the representation and appearance of the buyer or recipient in the belief that the buyer or recipient was 21 ~~18~~ years of age or older.

Section 16. Section 569.11, Florida Statutes, is amended to



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read:

569.11 Possession, misrepresenting age or military service to purchase, and purchase of tobacco products by persons under 21 ~~18~~ years of age prohibited; penalties; jurisdiction; disposition of fines.—

(1) It is unlawful for any person under 21 ~~18~~ years of age to knowingly possess any tobacco product. Any person under 21 ~~18~~ years of age who violates this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:

(a) For a first violation, 16 hours of community service or, instead of community service, a \$25 fine. In addition, the person must attend a school-approved anti-tobacco program, if locally available; or

(b) For a second or subsequent violation within 12 weeks after the first violation, a \$25 fine.

Any second or subsequent violation not within the 12-week period after the first violation is punishable as provided for a first violation.

(2) It is unlawful for any person under 21 ~~18~~ years of age to misrepresent his or her age or military service for the purpose of inducing a dealer or an agent or employee of the dealer to sell, give, barter, furnish, or deliver any tobacco product, or to purchase, or attempt to purchase, any tobacco product from a person or a vending machine. Any person under 21 ~~18~~ years of age who violates this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:

(a) For a first violation, 16 hours of community service



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or, instead of community service, a \$25 fine and, in addition, the person must attend a school-approved anti-tobacco program, if available; or

(b) For a second or subsequent violation within 12 weeks after the first violation, a \$25 fine.

Any second or subsequent violation not within the 12-week period after the first violation is punishable as provided for a first violation.

(3) Any person under 21 ~~18~~ years of age cited for committing a noncriminal violation under this section must sign and accept a civil citation indicating a promise to appear before the county court or comply with the requirement for paying the fine and must attend a school-approved anti-tobacco program, if locally available. If a fine is assessed for a violation of this section, the fine must be paid within 30 days after the date of the citation or, if a court appearance is mandatory, within 30 days after the date of the hearing.

(4) A person charged with a noncriminal violation under this section must appear before the county court or comply with the requirement for paying the fine. The court, after a hearing, shall make a determination as to whether the noncriminal violation was committed. If the court finds the violation was committed, it shall impose an appropriate penalty as specified in subsection (1) or subsection (2). A person who participates in community service shall be considered an employee of the state for the purpose of chapter 440, for the duration of such service.

(5) (a) If a person under 21 ~~18~~ years of age is found by the



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court to have committed a noncriminal violation under this section and that person has failed to complete community service, pay the fine as required by paragraph (1)(a) or paragraph (2)(a), or attend a school-approved anti-tobacco program, if locally available, the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 30 consecutive days.

(b) If a person under 21 ~~18~~ years of age is found by the court to have committed a noncriminal violation under this section and that person has failed to pay the applicable fine as required by paragraph (1)(b) or paragraph (2)(b), the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 45 consecutive days.

(6) Eighty percent of all civil penalties received by a county court pursuant to this section shall be remitted by the clerk of the court to the Department of Revenue for transfer to the Department of Education to provide for teacher training and for research and evaluation to reduce and prevent the use of tobacco products by children. The remaining 20 percent of civil penalties received by a county court pursuant to this section shall remain with the clerk of the county court to cover administrative costs.

Section 17. Section 569.12, Florida Statutes, is amended to read:

569.12 Jurisdiction; tobacco product and nicotine product enforcement officers or agents; enforcement.—

(1) In addition to the Division of Alcoholic Beverages and



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Tobacco of the Department of Business and Professional Regulation, any law enforcement officer certified under s. 943.10(1), (6), or (8) shall enforce the provisions of this chapter.

(2)(a) A county or municipality may designate certain of its employees or agents as tobacco product and nicotine product enforcement officers. The training and qualifications of the employees or agents for such designation shall be determined by the county or the municipality. Nothing in this section shall be construed to permit the carrying of firearms or other weapons by a tobacco product and nicotine product enforcement agent, nor does designation as a tobacco product and nicotine product enforcement officer provide the employee or agent with the power of arrest or subject the employee or agent to the provisions of ss. 943.085-943.255. Nothing in this section amends, alters, or contravenes the provisions of any state-administered retirement system or any state-supported retirement system established by general law.

(b) A tobacco and nicotine product enforcement officer is authorized to issue a citation to a person under the age of 21 ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has committed a civil infraction in violation of s. 386.212, ~~or~~ s. 569.11, or s. 569.42.

(3) A correctional probation officer as defined in s. 943.10(3) is authorized to issue a citation to a person under the age of 21 ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has committed a civil infraction in violation of s. 569.11 or s.



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569.42.

(4) A citation issued to any person violating the provisions of s. 569.11 or s. 569.42 shall be in a form prescribed by the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional Regulation and shall contain:

(a) The date and time of issuance.

(b) The name and address of the person to whom the citation is issued.

(c) The date and time the civil infraction was committed.

(d) The facts constituting reasonable cause.

(e) The number of the Florida statute violated.

(f) The name and authority of the citing officer.

(g) The procedure for the person to follow in order to contest the citation, perform the required community service, attend the required anti-tobacco or anti-tobacco and anti-nicotine program, or to pay the civil penalty.

Section 18. Section 569.14, Florida Statutes, is amended to read:

569.14 Posting of a sign stating that the sale of tobacco products or nicotine products to persons under 21 ~~18~~ years of age is unlawful; enforcement; penalty.—

(1) A dealer that sells tobacco products shall post a clear and conspicuous sign in each place of business where such products are sold which substantially states the following:

THE SALE OF TOBACCO PRODUCTS TO PERSONS UNDER THE AGE OF 21 ~~18~~ IS AGAINST FLORIDA LAW. PROOF OF AGE IS REQUIRED FOR PURCHASE.



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(2) A dealer that sells tobacco products and nicotine products or nicotine dispensing devices, ~~as defined in s. 877.112,~~ may use a sign that substantially states the following:

THE SALE OF TOBACCO PRODUCTS, NICOTINE PRODUCTS, OR
NICOTINE DISPENSING DEVICES TO PERSONS UNDER THE AGE
OF 21 ~~18~~ IS AGAINST FLORIDA LAW. PROOF OF AGE IS
REQUIRED FOR PURCHASE.

A dealer that uses a sign as described in this subsection meets the signage requirements of subsection (1) and s. 569.43(1) ~~s. 877.112.~~

(3) The division shall make available to dealers of tobacco products signs that meet the requirements of subsection (1) or subsection (2).

(4) Any dealer that sells tobacco products shall provide at the checkout counter in a location clearly visible to the dealer or the dealer's agent or employee instructional material in a calendar format or similar format to assist in determining whether a person is of legal age to purchase tobacco products. This point of sale material must contain substantially the following language:

IF YOU WERE NOT BORN BEFORE THIS DATE
(insert date and applicable year)
YOU CANNOT BUY TOBACCO PRODUCTS, NICOTINE PRODUCTS,
OR NICOTINE DISPENSING DEVICES.



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Upon approval by the division, in lieu of a calendar a dealer may use card readers, scanners, or other electronic or automated systems that can verify whether a person is of legal age to purchase tobacco products. Failure to comply with the provisions contained in this subsection shall result in imposition of administrative penalties as provided in s. 569.006.

(5) The division, through its agents and inspectors, shall enforce this section.

(6) Any person who fails to comply with subsection (1) is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 19. Section 569.19, Florida Statutes, is amended to read:

569.19 Annual report.—The division shall report annually with written findings to the Legislature and the Governor by December 31, on the progress of implementing the enforcement provisions of this part ~~chapter~~. This must include, but is not limited to:

(1) The number and results of compliance visits.

(2) The number of violations for failure of a retailer to hold a valid license.

(3) The number of violations for selling tobacco products to persons under age 21 ~~18~~, and the results of administrative hearings on the above and related issues.

(4) The number of persons under age 21 ~~18~~ cited for violations of s. 569.11 and sanctions imposed as a result of citation.

Section 20. Section 569.31, Florida Statutes, is created to read:



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

(1) “Dealer” is synonymous with the term “retail nicotine products dealer.”

(2) “Division” means the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional Regulation.

(3) “Nicotine dispensing device” means any product that employs an electronic, chemical, or mechanical means to produce vapor or aerosol from a nicotine product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product, any replacement cartridge for such device, and any other container of nicotine in a solution or other form intended to be used with or within an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product.

(4) “Nicotine product” means any product that contains nicotine, including liquid nicotine, which is intended for human consumption, whether inhaled, chewed, absorbed, dissolved, or ingested by any means. The term also includes any nicotine dispensing device. The term does not include a:

(a) Tobacco product, as defined in s. 569.002;

(b) Product regulated as a drug or device by the United States Food and Drug Administration under Chapter V of the Federal Food, Drug, and Cosmetic Act; or

(c) Product that contains incidental nicotine.

(5) “Permit” is synonymous with the term “retail nicotine products dealer permit.”

(6) “Retail nicotine products dealer” means the holder of a



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retail nicotine products dealer permit.

(7) "Retail nicotine products dealer permit" means a permit issued by the division under s. 569.32.

(8) "Self-service merchandising" means the open display of nicotine products, whether packaged or otherwise, for direct retail customer access and handling before purchase without the intervention or assistance of the dealer or the dealer's owner, employee, or agent. An open display of such products and devices includes the use of an open display unit.

(9) "Any person under the age of 21" does not include any person under the age of 21 who:

(a) Is in the military reserve or on active duty in the Armed Forces of the United States; or

(b) Is acting in his or her scope of lawful employment.

Section 21. Section 569.315, Florida Statutes, is created to read:

569.315 Preemption.—The establishment of the minimum age for purchasing or possessing, and the regulation for the marketing, sale, or delivery of, nicotine products is preempted to the state. However, this section does not preempt the ability of a political subdivision to require retail licensure for the sale of nicotine products.

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

And the title is amended as follows:

Delete lines 18 - 42

and insert:

creating s. 569.0025, F.S.; preempting the establishment of the minimum age for purchasing and



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possessing, and the regulation for the marketing,
sale, or delivery of, tobacco products to the state;
providing an exception; amending ss. 569.003, 569.004,
and 569.006, F.S.; conforming provisions to changes
made by the act; amending s. 569.007, F.S.; revising
age limitations relating to the sale and delivery of
tobacco products; revising applicability; amending s.
569.0075, F.S.; revising age limitations relating to
gifting sample tobacco products; amending s. 569.008,
F.S.; revising legislative intent; revising
qualification requirements for responsible retail
tobacco products dealers; conforming provisions to
changes made by the act; amending s. 569.009, F.S.;
conforming a provision to changes made by the act;
amending s. 569.101, F.S.; revising age limitations
relating to selling, delivering, bartering,
furnishing, or giving tobacco products to certain
persons; amending s. 569.11, F.S.; revising age
limitations relating to possessing and obtaining
tobacco products; amending s. 569.12, F.S.; expanding
the authority of tobacco product enforcement officers
to include nicotine products; amending s. 569.14,
F.S.; revising requirements for signage relating to
tobacco products, nicotine products, and nicotine
dispensing devices; conforming provisions to changes
made by the act; amending s. 569.19, F.S.; conforming
provisions to changes made by the act; creating s.
569.31, F.S.; defining terms; creating s. 569.315,
F.S.; preempting the establishment of the minimum age



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446 for purchasing and possessing, and the regulation for
447 the marketing, sale, or delivery of, nicotine products
448 to the state; providing an exception; creating s.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/24/2021	.	
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The Committee on Health Policy (Hutson) recommended the following:

Senate Substitute for Amendment (363164) (with title amendment)

Delete lines 265 - 653
and insert:

Section 7. Section 569.0025, Florida Statutes, is created to read:

569.0025 Preemption.—The establishment of the minimum age for purchasing or possessing, and the regulation for the marketing, sale, or delivery of, tobacco products is preempted



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to the state.

Section 8. Paragraph (c) of subsection (1) of section 569.003, Florida Statutes, is amended to read:

569.003 Retail tobacco products dealer permits; application; qualifications; fees; renewal; duplicates.—

(1)

(c) Permits shall be issued annually, upon payment of the annual permit fee prescribed by the division. The division shall fix the fee in an amount sufficient to meet the costs incurred by it in carrying out its permitting, enforcement, and administrative responsibilities under this part ~~chapter~~, but the fee may not exceed \$50. The proceeds of the fee shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund.

Section 9. Section 569.004, Florida Statutes, is amended to read:

569.004 Consent to inspection and search without warrant.—An applicant for a permit, by accepting the permit when issued, agrees that the place or premises covered by the permit is subject to inspection and search without a search warrant by the division or its authorized assistants, and by sheriffs, deputy sheriffs, or police officers, to determine compliance with this chapter, including part II of this chapter if the applicant deals, at retail, in nicotine products within the state or allows a nicotine products vending machine to be located on its premises within the state.

Section 10. Section 569.006, Florida Statutes, is amended to read:

569.006 Retail tobacco products dealers; administrative penalties.—The division may suspend or revoke the permit of the



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dealer upon sufficient cause appearing of the violation of any of the provisions of this chapter, including part II of this chapter if the dealer deals, at retail, in nicotine products within the state or allows a nicotine products vending machine to be located on its premises within the state, by a dealer or by a dealer's agent or employee. The division may also assess and accept administrative fines of up to \$1,000 against a dealer for each violation. The division shall deposit all fines collected into the General Revenue Fund as collected. An order imposing an administrative fine becomes effective 15 days after the date of the order. The division may suspend the imposition of a penalty against a dealer, conditioned upon the dealer's compliance with terms the division considers appropriate.

Section 11. Subsections (1) and (2) of section 569.007, Florida Statutes, are amended to read:

569.007 Sale or delivery of tobacco products;
restrictions.—

(1) In order to prevent persons under 21 ~~18~~ years of age from purchasing or receiving tobacco products, the sale or delivery of tobacco products is prohibited, except:

(a) When under the direct control or line of sight of the dealer or the dealer's agent or employee; or

(b) Sales from a vending machine are prohibited under the provisions of paragraph (1)(a) and are only permissible from a machine that is equipped with an operational lockout device which is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lockout device to allow the dispensing of one tobacco product. The lockout device must include a



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mechanism to prevent the machine from functioning if the power source for the lockout device fails or if the lockout device is disabled, and a mechanism to ensure that only one tobacco product is dispensed at a time.

(2) The provisions of subsection (1) shall not apply to an establishment that prohibits persons under 21 ~~18~~ years of age on the licensed premises.

Section 12. Section 569.0075, Florida Statutes, is amended to read:

569.0075 Gift of sample tobacco products prohibited.—The gift of sample tobacco products to any person under the age of 21 ~~18~~ by an entity licensed or permitted under the provisions of chapter 210 or this part ~~chapter~~, or by an employee of such entity, is prohibited and is punishable as provided in s. 569.101.

Section 13. Subsection (1), paragraphs (b) and (c) of subsection (2), and subsection (3) of section 569.008, Florida Statutes, are amended to read:

569.008 Responsible retail tobacco products dealers; qualifications; mitigation of disciplinary penalties; diligent management and supervision; presumption.—

(1) The Legislature intends to prevent the sale of tobacco products to persons under 21 ~~18~~ years of age and to encourage retail tobacco products dealers to comply with responsible practices in accordance with this section.

(2) To qualify as a responsible retail tobacco products dealer, the dealer must establish and implement procedures designed to ensure that the dealer's employees comply with the provisions of this part ~~chapter~~. The dealer must provide a



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training program for the dealer's employees which addresses the use and sale of tobacco products and which includes at least the following topics:

(b) Methods of recognizing and handling customers under 21 ~~18~~ years of age.

(c) Procedures for proper examination of identification cards in order to verify that customers are not under 21 ~~18~~ years of age.

(3) In determining penalties under s. 569.006, the division may mitigate penalties imposed against a dealer because of an employee's illegal sale of a tobacco product to a person under 21 ~~18~~ years of age if the following conditions are met:

(a) The dealer is qualified as a responsible dealer under this section.

(b) The dealer provided the training program required under subsection (2) to that employee before the illegal sale occurred.

(c) The dealer had no knowledge of that employee's violation at the time of the violation and did not direct, approve, or participate in the violation.

(d) If the sale was made through a vending machine, the machine was equipped with an operational lock-out device.

Section 14. Section 569.009, Florida Statutes, is amended to read:

569.009 Rulemaking authority.—The division shall adopt any rules necessary to administer and enforce the provisions of this part ~~chapter~~.

Section 15. Section 569.101, Florida Statutes, is amended to read:



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569.101 Selling, delivering, bartering, furnishing, or giving tobacco products to persons under 21 ~~18~~ years of age; criminal penalties; defense.—

(1) It is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, to any person who is under 21 ~~18~~ years of age, any tobacco product.

(2) Any person who violates subsection (1) commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. However, any person who violates subsection (1) for a second or subsequent time within 1 year of the first violation, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(3) A person charged with a violation of subsection (1) has a complete defense if, at the time the tobacco product was sold, delivered, bartered, furnished, or given:

(a) The buyer or recipient falsely evidenced that she or he was 21 ~~18~~ years of age or older;

(b) The appearance of the buyer or recipient was such that a prudent person would believe the buyer or recipient to be 21 ~~18~~ years of age or older; and

(c) Such person carefully checked a driver license or an identification card issued by this state or another state of the United States, a passport, or a United States armed services identification card presented by the buyer or recipient and acted in good faith and in reliance upon the representation and appearance of the buyer or recipient in the belief that the buyer or recipient was 21 ~~18~~ years of age or older.

Section 16. Section 569.11, Florida Statutes, is amended to read:



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569.11 Possession, misrepresenting age or military service to purchase, and purchase of tobacco products by persons under 21 ~~18~~ years of age prohibited; penalties; jurisdiction; disposition of fines.—

(1) It is unlawful for any person under 21 ~~18~~ years of age to knowingly possess any tobacco product. Any person under 21 ~~18~~ years of age who violates this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:

(a) For a first violation, 16 hours of community service or, instead of community service, a \$25 fine. In addition, the person must attend a school-approved anti-tobacco program, if locally available; or

(b) For a second or subsequent violation within 12 weeks after the first violation, a \$25 fine.

Any second or subsequent violation not within the 12-week period after the first violation is punishable as provided for a first violation.

(2) It is unlawful for any person under 21 ~~18~~ years of age to misrepresent his or her age or military service for the purpose of inducing a dealer or an agent or employee of the dealer to sell, give, barter, furnish, or deliver any tobacco product, or to purchase, or attempt to purchase, any tobacco product from a person or a vending machine. Any person under 21 ~~18~~ years of age who violates this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:

(a) For a first violation, 16 hours of community service or, instead of community service, a \$25 fine and, in addition,



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the person must attend a school-approved anti-tobacco program,
if available; or

(b) For a second or subsequent violation within 12 weeks
after the first violation, a \$25 fine.

Any second or subsequent violation not within the 12-week period
after the first violation is punishable as provided for a first
violation.

(3) Any person under 21 ~~18~~ years of age cited for
committing a noncriminal violation under this section must sign
and accept a civil citation indicating a promise to appear
before the county court or comply with the requirement for
paying the fine and must attend a school-approved anti-tobacco
program, if locally available. If a fine is assessed for a
violation of this section, the fine must be paid within 30 days
after the date of the citation or, if a court appearance is
mandatory, within 30 days after the date of the hearing.

(4) A person charged with a noncriminal violation under
this section must appear before the county court or comply with
the requirement for paying the fine. The court, after a hearing,
shall make a determination as to whether the noncriminal
violation was committed. If the court finds the violation was
committed, it shall impose an appropriate penalty as specified
in subsection (1) or subsection (2). A person who participates
in community service shall be considered an employee of the
state for the purpose of chapter 440, for the duration of such
service.

(5) (a) If a person under 21 ~~18~~ years of age is found by the
court to have committed a noncriminal violation under this



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section and that person has failed to complete community service, pay the fine as required by paragraph (1)(a) or paragraph (2)(a), or attend a school-approved anti-tobacco program, if locally available, the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 30 consecutive days.

(b) If a person under 21 ~~18~~ years of age is found by the court to have committed a noncriminal violation under this section and that person has failed to pay the applicable fine as required by paragraph (1)(b) or paragraph (2)(b), the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 45 consecutive days.

(6) Eighty percent of all civil penalties received by a county court pursuant to this section shall be remitted by the clerk of the court to the Department of Revenue for transfer to the Department of Education to provide for teacher training and for research and evaluation to reduce and prevent the use of tobacco products by children. The remaining 20 percent of civil penalties received by a county court pursuant to this section shall remain with the clerk of the county court to cover administrative costs.

Section 17. Section 569.12, Florida Statutes, is amended to read:

569.12 Jurisdiction; tobacco product and nicotine product enforcement officers or agents; enforcement.—

(1) In addition to the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional



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Regulation, any law enforcement officer certified under s. 943.10(1), (6), or (8) shall enforce the provisions of this chapter.

(2)(a) A county or municipality may designate certain of its employees or agents as tobacco product and nicotine product enforcement officers. The training and qualifications of the employees or agents for such designation shall be determined by the county or the municipality. Nothing in this section shall be construed to permit the carrying of firearms or other weapons by a tobacco product and nicotine product enforcement agent, nor does designation as a tobacco product and nicotine product enforcement officer provide the employee or agent with the power of arrest or subject the employee or agent to the provisions of ss. 943.085-943.255. Nothing in this section amends, alters, or contravenes the provisions of any state-administered retirement system or any state-supported retirement system established by general law.

(b) A tobacco and nicotine product enforcement officer is authorized to issue a citation to a person under the age of 21 ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has committed a civil infraction in violation of s. 386.212, ~~or~~ s. 569.11, or s. 569.42.

(3) A correctional probation officer as defined in s. 943.10(3) is authorized to issue a citation to a person under the age of 21 ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has committed a civil infraction in violation of s. 569.11 or s. 569.42.



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(4) A citation issued to any person violating the provisions of s. 569.11 or s. 569.42 shall be in a form prescribed by the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional Regulation and shall contain:

(a) The date and time of issuance.

(b) The name and address of the person to whom the citation is issued.

(c) The date and time the civil infraction was committed.

(d) The facts constituting reasonable cause.

(e) The number of the Florida statute violated.

(f) The name and authority of the citing officer.

(g) The procedure for the person to follow in order to contest the citation, perform the required community service, attend the required anti-tobacco or anti-tobacco and anti-nicotine program, or to pay the civil penalty.

Section 18. Section 569.14, Florida Statutes, is amended to read:

569.14 Posting of a sign stating that the sale of tobacco products or nicotine products to persons under 21 ~~18~~ years of age is unlawful; enforcement; penalty.—

(1) A dealer that sells tobacco products shall post a clear and conspicuous sign in each place of business where such products are sold which substantially states the following:

THE SALE OF TOBACCO PRODUCTS TO PERSONS UNDER THE AGE OF 21 ~~18~~ IS AGAINST FLORIDA LAW. PROOF OF AGE IS REQUIRED FOR PURCHASE.



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(2) A dealer that sells tobacco products and nicotine products or nicotine dispensing devices, ~~as defined in s. 877.112,~~ may use a sign that substantially states the following:

THE SALE OF TOBACCO PRODUCTS, NICOTINE PRODUCTS, OR
NICOTINE DISPENSING DEVICES TO PERSONS UNDER THE AGE
OF 21 ~~18~~ IS AGAINST FLORIDA LAW. PROOF OF AGE IS
REQUIRED FOR PURCHASE.

A dealer that uses a sign as described in this subsection meets the signage requirements of subsection (1) and s. 569.43(1) ~~s. 877.112.~~

(3) The division shall make available to dealers of tobacco products signs that meet the requirements of subsection (1) or subsection (2).

(4) Any dealer that sells tobacco products shall provide at the checkout counter in a location clearly visible to the dealer or the dealer's agent or employee instructional material in a calendar format or similar format to assist in determining whether a person is of legal age to purchase tobacco products. This point of sale material must contain substantially the following language:

IF YOU WERE NOT BORN BEFORE THIS DATE
(insert date and applicable year)
YOU CANNOT BUY TOBACCO PRODUCTS, NICOTINE PRODUCTS,
OR NICOTINE DISPENSING DEVICES.

Upon approval by the division, in lieu of a calendar a dealer



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may use card readers, scanners, or other electronic or automated systems that can verify whether a person is of legal age to purchase tobacco products. Failure to comply with the provisions contained in this subsection shall result in imposition of administrative penalties as provided in s. 569.006.

(5) The division, through its agents and inspectors, shall enforce this section.

(6) Any person who fails to comply with subsection (1) is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 19. Section 569.19, Florida Statutes, is amended to read:

569.19 Annual report.—The division shall report annually with written findings to the Legislature and the Governor by December 31, on the progress of implementing the enforcement provisions of this part ~~chapter~~. This must include, but is not limited to:

(1) The number and results of compliance visits.

(2) The number of violations for failure of a retailer to hold a valid license.

(3) The number of violations for selling tobacco products to persons under age 21 ~~18~~, and the results of administrative hearings on the above and related issues.

(4) The number of persons under age 21 ~~18~~ cited for violations of s. 569.11 and sanctions imposed as a result of citation.

Section 20. Section 569.31, Florida Statutes, is created to read:

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



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(1) "Dealer" is synonymous with the term "retail nicotine products dealer."

(2) "Division" means the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional Regulation.

(3) "Nicotine dispensing device" means any product that employs an electronic, chemical, or mechanical means to produce vapor or aerosol from a nicotine product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product, any replacement cartridge for such device, and any other container of nicotine in a solution or other form intended to be used with or within an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product.

(4) "Nicotine product" means any product that contains nicotine, including liquid nicotine, which is intended for human consumption, whether inhaled, chewed, absorbed, dissolved, or ingested by any means. The term also includes any nicotine dispensing device. The term does not include a:

(a) Tobacco product, as defined in s. 569.002;

(b) Product regulated as a drug or device by the United States Food and Drug Administration under Chapter V of the Federal Food, Drug, and Cosmetic Act; or

(c) Product that contains incidental nicotine.

(5) "Permit" is synonymous with the term "retail nicotine products dealer permit."

(6) "Retail nicotine products dealer" means the holder of a retail nicotine products dealer permit.



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(7) "Retail nicotine products dealer permit" means a permit issued by the division under s. 569.32.

(8) "Self-service merchandising" means the open display of nicotine products, whether packaged or otherwise, for direct retail customer access and handling before purchase without the intervention or assistance of the dealer or the dealer's owner, employee, or agent. An open display of such products and devices includes the use of an open display unit.

(9) "Any person under the age of 21" does not include any person under the age of 21 who:

(a) Is in the military reserve or on active duty in the Armed Forces of the United States; or

(b) Is acting in his or her scope of lawful employment.

Section 21. Section 569.315, Florida Statutes, is created to read:

569.315 Preemption.—The establishment of the minimum age for purchasing or possessing, and the regulation for the marketing, sale, or delivery of, nicotine products is preempted to the state.

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

And the title is amended as follows:

Delete lines 18 - 42

and insert:

creating s. 569.0025, F.S.; preempting the establishment of the minimum age for purchasing and possessing, and the regulation for the marketing, sale, or delivery of, tobacco products to the state; amending ss. 569.003, 569.004, and 569.006, F.S.;



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conforming provisions to changes made by the act;
amending s. 569.007, F.S.; revising age limitations
relating to the sale and delivery of tobacco products;
revising applicability; amending s. 569.0075, F.S.;
revising age limitations relating to gifting sample
tobacco products; amending s. 569.008, F.S.; revising
legislative intent; revising qualification
requirements for responsible retail tobacco products
dealers; conforming provisions to changes made by the
act; amending s. 569.009, F.S.; conforming a provision
to changes made by the act; amending s. 569.101, F.S.;
revising age limitations relating to selling,
delivering, bartering, furnishing, or giving tobacco
products to certain persons; amending s. 569.11, F.S.;
revising age limitations relating to possessing and
obtaining tobacco products; amending s. 569.12, F.S.;
expanding the authority of tobacco product enforcement
officers to include nicotine products; amending s.
569.14, F.S.; revising requirements for signage
relating to tobacco products, nicotine products, and
nicotine dispensing devices; conforming provisions to
changes made by the act; amending s. 569.19, F.S.;
conforming provisions to changes made by the act;
creating s. 569.31, F.S.; defining terms; creating s.
569.315, F.S.; preempting the establishment of the
minimum age for purchasing and possessing, and the
regulation for the marketing, sale, or delivery of,
nicotine products to the state; creating s.

By the Committee on Regulated Industries; and Senator Hutson

580-02578-21

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1 A bill to be entitled
 2 An act relating to tobacco and nicotine products;
 3 amending s. 210.095, F.S.; deleting the definition of
 4 the term "adult"; revising age limitations relating to
 5 mail order, Internet, and remote sales of tobacco
 6 products; amending s. 210.15, F.S.; requiring permits
 7 to be issued to persons or corporations whose officers
 8 are not under 21 years of age; amending s. 386.212,
 9 F.S.; providing that it is unlawful for persons under
 10 21 years of age to smoke tobacco or vape in, on, or
 11 within 1,000 feet of the real property comprising a
 12 public or private elementary, middle, or secondary
 13 school during specified hours; renaming ch. 569, F.S.;
 14 providing directives to the Division of Law Revision;
 15 amending s. 569.002, F.S.; defining the terms
 16 "nicotine product" and "nicotine dispensing device";
 17 conforming provisions to changes made by the act;
 18 amending ss. 569.003, 569.004, and 569.006, F.S.;
 19 conforming provisions to changes made by the act;
 20 amending s. 569.007, F.S.; revising age limitations
 21 relating to the sale and delivery of tobacco products;
 22 revising applicability; amending s. 569.0075, F.S.;
 23 revising age limitations relating to gifting sample
 24 tobacco products; amending s. 569.008, F.S.; revising
 25 legislative intent; revising qualification
 26 requirements for responsible retail tobacco products
 27 dealers; conforming provisions to changes made by the
 28 act; amending s. 569.009, F.S.; conforming a provision
 29 to changes made by the act; amending s. 569.101, F.S.;

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

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30 revising age limitations relating to selling,
 31 delivering, bartering, furnishing, or giving tobacco
 32 products to certain persons; amending s. 569.11, F.S.;
 33 revising age limitations relating to possessing and
 34 obtaining tobacco products; amending s. 569.12, F.S.;
 35 expanding the authority of tobacco product enforcement
 36 officers to include nicotine products; amending s.
 37 569.14, F.S.; revising requirements for signage
 38 relating to tobacco products, nicotine products, and
 39 nicotine dispensing devices; conforming provisions to
 40 changes made by the act; amending s. 569.19, F.S.;
 41 conforming provisions to changes made by the act;
 42 creating s. 569.31, F.S.; defining terms; creating s.
 43 569.32, F.S.; requiring retail nicotine product
 44 dealers to acquire a permit; providing requirements
 45 and authorizations for such permit; creating s.
 46 569.33, F.S.; specifying that an applicant for a
 47 retail nicotine products dealer permit consents to
 48 certain inspections and searches upon accepting such
 49 permit; creating s. 569.34, F.S.; prohibiting certain
 50 persons, firms, associations, or corporations from
 51 operating without a permit; providing civil penalties;
 52 creating s. 569.35, F.S.; providing administrative
 53 penalties for retail nicotine product dealers under
 54 certain circumstances; requiring the Division of
 55 Alcoholic Beverages and Tobacco to deposit funds
 56 collected from administrative fines into the General
 57 Revenue Fund; creating s. 569.37, F.S.; providing
 58 restrictions on the sale or delivery of nicotine

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59 products; creating s. 569.38, F.S.; prohibiting
 60 certain persons from gifting sample nicotine products
 61 to persons under a specified age; creating s. 569.381,
 62 F.S.; providing legislative intent; providing
 63 requirements for a dealer to qualify as a responsible
 64 retail nicotine products dealer; authorizing the
 65 division to mitigate certain penalties; requiring the
 66 division to develop and make available a nicotine
 67 products training program; requiring dealers to
 68 exercise diligence in the management and supervision
 69 of their premises and the supervision and training of
 70 certain persons; creating s. 569.39, F.S.; requiring
 71 the division to adopt rules; creating ss. 569.41 and
 72 569.42, F.S.; providing civil and criminal penalties
 73 relating to selling, delivering, bartering,
 74 furnishing, or giving nicotine products to certain
 75 persons and possessing and acquiring nicotine
 76 products, respectively; creating s. 569.43, F.S.;
 77 providing signage requirements relating to the sale of
 78 nicotine products or nicotine dispensing devices;
 79 providing criminal penalties; creating s. 569.44,
 80 F.S.; requiring the division to provide an annual
 81 report containing specified information to the
 82 Governor and the Legislature; creating s. 569.45,
 83 F.S.; defining terms; providing requirements for mail
 84 order, Internet, and remote sales of nicotine
 85 products; providing applicability; providing criminal
 86 penalties; repealing s. 877.112, F.S., relating to
 87 nicotine products and nicotine dispensing devices;

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88 providing an effective date.

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

92 Section 1. Paragraph (a) of subsection (1), paragraphs (a)
 93 and (c) of subsection (2), paragraph (a) of subsection (3),
 94 paragraph (a) of subsection (4), paragraphs (a) and (b) of
 95 subsection (5), and paragraphs (a), (b), (e), and (g) of
 96 subsection (8) of section 210.095, Florida Statutes, are amended
 97 to read:

98 210.095 Mail order, Internet, and remote sales of tobacco
 99 products; age verification.—

100 (1) For purposes of this section, the term:

101 ~~(a) "Adult" means an individual who is at least of the~~
 102 ~~legal minimum purchase age for tobacco products.~~

103 (2)

104 (a) A sale of tobacco products constituting a delivery sale
 105 pursuant to paragraph (1) (b) (1) (e) is a delivery sale
 106 regardless of whether the person accepting the order for the
 107 delivery sale is located inside or outside this state.

108 (c) A person may not make a delivery sale of tobacco
 109 products to any individual who is not 21 years of age or older
 110 ~~an adult.~~

111 (3) A person may not mail, ship, or otherwise deliver
 112 tobacco products in connection with an order for a delivery sale
 113 unless, before the first delivery to the consumer, the person
 114 accepting the order for the delivery sale:

115 (a) Obtains from the individual submitting the order a
 116 certification that includes:

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1. Reliable confirmation that the individual is 21 years of age or older ~~an adult~~; and

2. A statement signed by the individual in writing and under penalty of perjury which:

a. Certifies the address and date of birth of the individual; and

b. Confirms that the individual wants to receive delivery sales from a tobacco company and understands that, under the laws of this state, the following actions are illegal:

(I) Signing another individual's name to the certification;

(II) Selling tobacco products to individuals under the legal minimum purchase age; and

(III) Purchasing tobacco products, if the person making the purchase is under the legal minimum purchase age.

In addition to the requirements of this subsection, a person accepting an order for a delivery sale may request that a consumer provide an electronic mail address.

(4) The notice described in paragraph (3)(c) must include prominent and clearly legible statements that sales of tobacco products are:

(a) Illegal if made to individuals who are not 21 years of age or older ~~adults~~.

The notice must include an explanation of how each tax has been, or is to be, paid with respect to the delivery sale.

(5) Each person who mails, ships, or otherwise delivers tobacco products in connection with an order for a delivery sale must:

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(a) Include as part of the shipping documents, in a clear and conspicuous manner, the following statement: "Tobacco Products: Florida law prohibits shipping to individuals under 21 ~~18~~ years of age and requires the payment of all applicable taxes."

(b) Use a method of mailing, shipping, or delivery which obligates the delivery service to require:

1. The individual submitting the order for the delivery sale or another individual who is 21 years of age or older ~~adult~~ who resides at the individual's address to sign his or her name to accept delivery of the shipping container. Proof of the legal minimum purchase age of the individual accepting delivery is required only if the individual appears to be under 30 ~~27~~ years of age.

2. Proof that the individual is either the addressee or the individual who is 21 years of age or older ~~adult~~ designated by the addressee, in the form of a valid, government-issued identification card bearing a photograph of the individual who signs to accept delivery of the shipping container.

If the person accepting a purchase order for a delivery sale delivers the tobacco products without using a delivery service, the person must comply with all of the requirements of this section which apply to a delivery service. Any failure to comply with a requirement of this section constitutes a violation thereof.

(8)(a) Except as otherwise provided in this section, a violation of this section by a person other than an individual who is not 21 years of age or older ~~an adult~~ is a misdemeanor of

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the first degree, punishable as provided in s. 775.082 or s. 775.083, and:

1. For a first violation of this section, the person shall be fined \$1,000 or five times the retail value of the tobacco products involved in the violation, whichever is greater.

2. For a second or subsequent violation of this section, the person shall be fined \$5,000 or five times the retail value of the tobacco products involved in the violation, whichever is greater.

(b) A person who is 21 years of age or older ~~an adult~~ and knowingly submits a false certification under subsection (3) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For each offense, the person shall be fined \$10,000 or five times the retail value of the tobacco products involved in the violation, whichever is greater.

(e) A person who, in connection with a delivery sale, delivers tobacco products on behalf of a delivery service to an individual who is not 21 years of age or older ~~an adult~~ commits a misdemeanor of the ~~second~~ third degree, punishable as provided in s. 775.082 or s. 775.083.

(g) An individual who is not 21 years of age or older ~~an adult~~ and who knowingly violates any provision of this section commits a misdemeanor of the ~~second~~ third degree, punishable as provided in s. 775.082 or s. 775.083.

Section 2. Paragraph (b) of subsection (1) of section 210.15, Florida Statutes, is amended to read:

210.15 Permits.—

(1)

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(b) Permits shall be issued only to persons of good moral character who are not less than 21 ~~18~~ years of age. Permits to corporations shall be issued only to corporations whose officers are of good moral character and not less than 21 ~~18~~ years of age. There shall be no exemptions from the permit fees herein provided to any persons, association of persons, or corporation, any law to the contrary notwithstanding.

Section 3. Subsection (1) of section 386.212, Florida Statutes, is amended to read:

386.212 Smoking and vaping prohibited near school property; penalty.—

(1) It is unlawful for any person under 21 ~~18~~ years of age to smoke tobacco or vape in, on, or within 1,000 feet of the real property comprising a public or private elementary, middle, or secondary school between the hours of 6 a.m. and midnight. This section does not apply to any person occupying a moving vehicle or within a private residence.

Section 4. Chapter 569, Florida Statutes, entitled "Tobacco Products," is renamed "Tobacco and Nicotine Products."

Section 5. The Division of Law Revision is directed to:

(1) Create part I of chapter 569, Florida Statutes, consisting of ss. 569.002-569.23, Florida Statutes, to be entitled "Tobacco Products."

(2) Create part II of chapter 569, Florida Statutes, consisting of ss. 569.31-569.45, Florida Statutes, to be entitled "Nicotine Products."

Section 6. Section 569.002, Florida Statutes, is amended to read:

569.002 Definitions.—As used in this part ~~chapter~~, the

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term:

(1) "Dealer" is synonymous with the term "retail tobacco products dealer."

(2) "Division" means the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional Regulation.

(3) "Nicotine product" has the same meaning as provided in s. 569.31(4).

(4) "Nicotine dispensing device" has the same meaning as provided in s. 569.31(3).

(5) "Permit" is synonymous with the term "retail tobacco products dealer permit."

(6) ~~(4)~~ "Retail tobacco products dealer" means the holder of a retail tobacco products dealer permit.

(7) ~~(5)~~ "Retail tobacco products dealer permit" means a permit issued by the division pursuant to s. 569.003.

(8) ~~(6)~~ "Tobacco products" includes loose tobacco leaves, and products made from tobacco leaves, in whole or in part, and cigarette wrappers, which can be used for smoking, sniffing, or chewing.

(9) ~~(7)~~ "Any person under the age of 21 ~~18~~" does not include any person under the age of 21 ~~18~~ who:

(a) ~~Has had his or her disability of nonage removed under chapter 743;~~

~~(b)~~ Is in the military reserve or on active duty in the Armed Forces of the United States;

~~(c) Is otherwise emancipated by a court of competent jurisdiction and released from parental care and responsibility;~~
or

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(b) ~~(d)~~ Is acting in his or her scope of lawful employment with an entity licensed under the provisions of chapter 210 or this part ~~chapter~~.

Section 7. Paragraph (c) of subsection (1) of section 569.003, Florida Statutes, is amended to read:

569.003 Retail tobacco products dealer permits; application; qualifications; fees; renewal; duplicates.—

(1)

(c) Permits shall be issued annually, upon payment of the annual permit fee prescribed by the division. The division shall fix the fee in an amount sufficient to meet the costs incurred by it in carrying out its permitting, enforcement, and administrative responsibilities under this part ~~chapter~~, but the fee may not exceed \$50. The proceeds of the fee shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund.

Section 8. Section 569.004, Florida Statutes, is amended to read:

569.004 Consent to inspection and search without warrant.—
An applicant for a permit, by accepting the permit when issued, agrees that the place or premises covered by the permit is subject to inspection and search without a search warrant by the division or its authorized assistants, and by sheriffs, deputy sheriffs, or police officers, to determine compliance with this chapter, including part II of this chapter if the applicant deals, at retail, in nicotine products within the state or allows a nicotine products vending machine to be located on its premises within the state.

Section 9. Section 569.006, Florida Statutes, is amended to read:

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569.006 Retail tobacco products dealers; administrative penalties.—The division may suspend or revoke the permit of the dealer upon sufficient cause appearing of the violation of any of the provisions of this chapter, including part II of this chapter if the dealer deals, at retail, in nicotine products within the state or allows a nicotine products vending machine to be located on its premises within the state, by a dealer or by a dealer's agent or employee. The division may also assess and accept administrative fines of up to \$1,000 against a dealer for each violation. The division shall deposit all fines collected into the General Revenue Fund as collected. An order imposing an administrative fine becomes effective 15 days after the date of the order. The division may suspend the imposition of a penalty against a dealer, conditioned upon the dealer's compliance with terms the division considers appropriate.

Section 10. Subsections (1) and (2) of section 569.007, Florida Statutes, are amended to read:

569.007 Sale or delivery of tobacco products; restrictions.—

(1) In order to prevent persons under 21 ~~18~~ years of age from purchasing or receiving tobacco products, the sale or delivery of tobacco products is prohibited, except:

(a) When under the direct control or line of sight of the dealer or the dealer's agent or employee; or

(b) Sales from a vending machine are prohibited under the provisions of paragraph (1)(a) and are only permissible from a machine that is equipped with an operational lockout device which is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the

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machine by triggering the lockout device to allow the dispensing of one tobacco product. The lockout device must include a mechanism to prevent the machine from functioning if the power source for the lockout device fails or if the lockout device is disabled, and a mechanism to ensure that only one tobacco product is dispensed at a time.

(2) The provisions of subsection (1) shall not apply to an establishment that prohibits persons under 21 ~~18~~ years of age on the licensed premises.

Section 11. Section 569.0075, Florida Statutes, is amended to read:

569.0075 Gift of sample tobacco products prohibited.—The gift of sample tobacco products to any person under the age of 21 ~~18~~ by an entity licensed or permitted under the provisions of chapter 210 or this part ~~chapter~~, or by an employee of such entity, is prohibited and is punishable as provided in s. 569.101.

Section 12. Subsection (1), paragraphs (b) and (c) of subsection (2), and subsection (3) of section 569.008, Florida Statutes, are amended to read:

569.008 Responsible retail tobacco products dealers; qualifications; mitigation of disciplinary penalties; diligent management and supervision; presumption.—

(1) The Legislature intends to prevent the sale of tobacco products to persons under 21 ~~18~~ years of age and to encourage retail tobacco products dealers to comply with responsible practices in accordance with this section.

(2) To qualify as a responsible retail tobacco products dealer, the dealer must establish and implement procedures

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designed to ensure that the dealer's employees comply with the provisions of this ~~part chapter~~. The dealer must provide a training program for the dealer's employees which addresses the use and sale of tobacco products and which includes at least the following topics:

(b) Methods of recognizing and handling customers under 21 ~~18~~ years of age.

(c) Procedures for proper examination of identification cards in order to verify that customers are not under 21 ~~18~~ years of age.

(3) In determining penalties under s. 569.006, the division may mitigate penalties imposed against a dealer because of an employee's illegal sale of a tobacco product to a person under 21 ~~18~~ years of age if the following conditions are met:

(a) The dealer is qualified as a responsible dealer under this section.

(b) The dealer provided the training program required under subsection (2) to that employee before the illegal sale occurred.

(c) The dealer had no knowledge of that employee's violation at the time of the violation and did not direct, approve, or participate in the violation.

(d) If the sale was made through a vending machine, the machine was equipped with an operational lock-out device.

Section 13. Section 569.009, Florida Statutes, is amended to read:

569.009 Rulemaking authority.—The division shall adopt any rules necessary to administer and enforce the provisions of this ~~part chapter~~.

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Section 14. Section 569.101, Florida Statutes, is amended to read:

569.101 Selling, delivering, bartering, furnishing, or giving tobacco products to persons under 21 ~~18~~ years of age; criminal penalties; defense.—

(1) It is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, to any person who is under 21 ~~18~~ years of age, any tobacco product.

(2) Any person who violates subsection (1) commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. However, any person who violates subsection (1) for a second or subsequent time within 1 year of the first violation, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(3) A person charged with a violation of subsection (1) has a complete defense if, at the time the tobacco product was sold, delivered, bartered, furnished, or given:

(a) The buyer or recipient falsely evidenced that she or he was 21 ~~18~~ years of age or older;

(b) The appearance of the buyer or recipient was such that a prudent person would believe the buyer or recipient to be 21 ~~18~~ years of age or older; and

(c) Such person carefully checked a driver license or an identification card issued by this state or another state of the United States, a passport, or a United States armed services identification card presented by the buyer or recipient and acted in good faith and in reliance upon the representation and appearance of the buyer or recipient in the belief that the buyer or recipient was 21 ~~18~~ years of age or older.

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Section 15. Section 569.11, Florida Statutes, is amended to read:

569.11 Possession, misrepresenting age or military service to purchase, and purchase of tobacco products by persons under 21 ~~18~~ years of age prohibited; penalties; jurisdiction; disposition of fines.—

(1) It is unlawful for any person under 21 ~~18~~ years of age to knowingly possess any tobacco product. Any person under 21 ~~18~~ years of age who violates this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:

(a) For a first violation, 16 hours of community service or, instead of community service, a \$25 fine. In addition, the person must attend a school-approved anti-tobacco program, if locally available; or

(b) For a second or subsequent violation within 12 weeks after the first violation, a \$25 fine.

Any second or subsequent violation not within the 12-week period after the first violation is punishable as provided for a first violation.

(2) It is unlawful for any person under 21 ~~18~~ years of age to misrepresent his or her age or military service for the purpose of inducing a dealer or an agent or employee of the dealer to sell, give, barter, furnish, or deliver any tobacco product, or to purchase, or attempt to purchase, any tobacco product from a person or a vending machine. Any person under 21 ~~18~~ years of age who violates this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:

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(a) For a first violation, 16 hours of community service or, instead of community service, a \$25 fine and, in addition, the person must attend a school-approved anti-tobacco program, if available; or

(b) For a second or subsequent violation within 12 weeks after the first violation, a \$25 fine.

Any second or subsequent violation not within the 12-week period after the first violation is punishable as provided for a first violation.

(3) Any person under 21 ~~18~~ years of age cited for committing a noncriminal violation under this section must sign and accept a civil citation indicating a promise to appear before the county court or comply with the requirement for paying the fine and must attend a school-approved anti-tobacco program, if locally available. If a fine is assessed for a violation of this section, the fine must be paid within 30 days after the date of the citation or, if a court appearance is mandatory, within 30 days after the date of the hearing.

(4) A person charged with a noncriminal violation under this section must appear before the county court or comply with the requirement for paying the fine. The court, after a hearing, shall make a determination as to whether the noncriminal violation was committed. If the court finds the violation was committed, it shall impose an appropriate penalty as specified in subsection (1) or subsection (2). A person who participates in community service shall be considered an employee of the state for the purpose of chapter 440, for the duration of such service.

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(5) (a) If a person under 21 ~~18~~ years of age is found by the court to have committed a noncriminal violation under this section and that person has failed to complete community service, pay the fine as required by paragraph (1) (a) or paragraph (2) (a), or attend a school-approved anti-tobacco program, if locally available, the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 30 consecutive days.

(b) If a person under 21 ~~18~~ years of age is found by the court to have committed a noncriminal violation under this section and that person has failed to pay the applicable fine as required by paragraph (1) (b) or paragraph (2) (b), the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 45 consecutive days.

(6) Eighty percent of all civil penalties received by a county court pursuant to this section shall be remitted by the clerk of the court to the Department of Revenue for transfer to the Department of Education to provide for teacher training and for research and evaluation to reduce and prevent the use of tobacco products by children. The remaining 20 percent of civil penalties received by a county court pursuant to this section shall remain with the clerk of the county court to cover administrative costs.

Section 16. Section 569.12, Florida Statutes, is amended to read:

569.12 Jurisdiction; tobacco product and nicotine product enforcement officers or agents; enforcement.—

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(1) In addition to the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional Regulation, any law enforcement officer certified under s. 943.10(1), (6), or (8) shall enforce the provisions of this chapter.

(2) (a) A county or municipality may designate certain of its employees or agents as tobacco product and nicotine product enforcement officers. The training and qualifications of the employees or agents for such designation shall be determined by the county or the municipality. Nothing in this section shall be construed to permit the carrying of firearms or other weapons by a tobacco product and nicotine product enforcement agent, nor does designation as a tobacco product and nicotine product enforcement officer provide the employee or agent with the power of arrest or subject the employee or agent to the provisions of ss. 943.085-943.255. Nothing in this section amends, alters, or contravenes the provisions of any state-administered retirement system or any state-supported retirement system established by general law.

(b) A tobacco and nicotine product enforcement officer is authorized to issue a citation to a person under the age of 21 ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has committed a civil infraction in violation of s. 386.212, ~~or~~ s. 569.11, or s. 569.42.

(3) A correctional probation officer as defined in s. 943.10(3) is authorized to issue a citation to a person under the age of 21 ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has

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523 committed a civil infraction in violation of s. 569.11 or s.
 524 569.42.
 525 (4) A citation issued to any person violating the
 526 provisions of s. 569.11 or s. 569.42 shall be in a form
 527 prescribed by the Division of Alcoholic Beverages and Tobacco of
 528 the Department of Business and Professional Regulation and shall
 529 contain:
 530 (a) The date and time of issuance.
 531 (b) The name and address of the person to whom the citation
 532 is issued.
 533 (c) The date and time the civil infraction was committed.
 534 (d) The facts constituting reasonable cause.
 535 (e) The number of the Florida statute violated.
 536 (f) The name and authority of the citing officer.
 537 (g) The procedure for the person to follow in order to
 538 contest the citation, perform the required community service,
 539 attend the required anti-tobacco or anti-tobacco and anti-
 540 nicotine program, or to pay the civil penalty.
 541 Section 17. Section 569.14, Florida Statutes, is amended to
 542 read:
 543 569.14 Posting of a sign stating that the sale of tobacco
 544 products or nicotine products to persons under 21 ~~18~~ years of
 545 age is unlawful; enforcement; penalty.—
 546 (1) A dealer that sells tobacco products shall post a clear
 547 and conspicuous sign in each place of business where such
 548 products are sold which substantially states the following:
 549
 550 THE SALE OF TOBACCO PRODUCTS TO PERSONS UNDER THE AGE
 551 OF 21 ~~18~~ IS AGAINST FLORIDA LAW. PROOF OF AGE IS

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552 REQUIRED FOR PURCHASE.
 553
 554 (2) A dealer that sells tobacco products and nicotine
 555 products or nicotine dispensing devices, ~~as defined in s.~~
 556 ~~877.112~~, may use a sign that substantially states the following:
 557
 558 THE SALE OF TOBACCO PRODUCTS, NICOTINE PRODUCTS, OR
 559 NICOTINE DISPENSING DEVICES TO PERSONS UNDER THE AGE
 560 OF 21 ~~18~~ IS AGAINST FLORIDA LAW. PROOF OF AGE IS
 561 REQUIRED FOR PURCHASE.
 562
 563 A dealer that uses a sign as described in this subsection meets
 564 the signage requirements of subsection (1) and s. 569.43(1) ~~s.~~
 565 ~~877.112~~.
 566 (3) The division shall make available to dealers of tobacco
 567 products signs that meet the requirements of subsection (1) or
 568 subsection (2).
 569 (4) Any dealer that sells tobacco products shall provide at
 570 the checkout counter in a location clearly visible to the dealer
 571 or the dealer's agent or employee instructional material in a
 572 calendar format or similar format to assist in determining
 573 whether a person is of legal age to purchase tobacco products.
 574 This point of sale material must contain substantially the
 575 following language:
 576
 577 IF YOU WERE NOT BORN BEFORE THIS DATE
 578 (insert date and applicable year)
 579 YOU CANNOT BUY TOBACCO PRODUCTS, NICOTINE PRODUCTS,
 580 OR NICOTINE DISPENSING DEVICES.

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582 Upon approval by the division, in lieu of a calendar a dealer
 583 may use card readers, scanners, or other electronic or automated
 584 systems that can verify whether a person is of legal age to
 585 purchase tobacco products. Failure to comply with the provisions
 586 contained in this subsection shall result in imposition of
 587 administrative penalties as provided in s. 569.006.

588 (5) The division, through its agents and inspectors, shall
 589 enforce this section.

590 (6) Any person who fails to comply with subsection (1) is
 591 guilty of a misdemeanor of the second degree, punishable as
 592 provided in s. 775.082 or s. 775.083.

593 Section 18. Section 569.19, Florida Statutes, is amended to
 594 read:

595 569.19 Annual report.—The division shall report annually
 596 with written findings to the Legislature and the Governor by
 597 December 31, on the progress of implementing the enforcement
 598 provisions of this part ~~chapter~~. This must include, but is not
 599 limited to:

600 (1) The number and results of compliance visits.

601 (2) The number of violations for failure of a retailer to
 602 hold a valid license.

603 (3) The number of violations for selling tobacco products
 604 to persons under age 21 ~~18~~, and the results of administrative
 605 hearings on the above and related issues.

606 (4) The number of persons under age 21 ~~18~~ cited for
 607 violations of s. 569.11 and sanctions imposed as a result of
 608 citation.

609 Section 19. Section 569.31, Florida Statutes, is created to

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610 read:

611 569.31 Definitions.—As used in this part, the term:

612 (1) "Dealer" is synonymous with the term "retail nicotine
 613 products dealer."

614 (2) "Division" means the Division of Alcoholic Beverages
 615 and Tobacco of the Department of Business and Professional
 616 Regulation.

617 (3) "Nicotine dispensing device" means any product that
 618 employs an electronic, chemical, or mechanical means to produce
 619 vapor or aerosol from a nicotine product, including, but not
 620 limited to, an electronic cigarette, electronic cigar,
 621 electronic cigarillo, electronic pipe, or other similar device
 622 or product, any replacement cartridge for such device, and any
 623 other container of nicotine in a solution or other form intended
 624 to be used with or within an electronic cigarette, electronic
 625 cigar, electronic cigarillo, electronic pipe, or other similar
 626 device or product.

627 (4) "Nicotine product" means any product that contains
 628 nicotine, including liquid nicotine, which is intended for human
 629 consumption, whether inhaled, chewed, absorbed, dissolved, or
 630 ingested by any means. The term also includes any nicotine
 631 dispensing device. The term does not include a:

632 (a) Tobacco product, as defined in s. 569.002;

633 (b) Product regulated as a drug or device by the United
 634 States Food and Drug Administration under Chapter V of the
 635 Federal Food, Drug, and Cosmetic Act; or

636 (c) Product that contains incidental nicotine.

637 (5) "Permit" is synonymous with the term "retail nicotine
 638 products dealer permit."

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(6) "Retail nicotine products dealer" means the holder of a retail nicotine products dealer permit.

(7) "Retail nicotine products dealer permit" means a permit issued by the division under s. 569.32.

(8) "Self-service merchandising" means the open display of nicotine products, whether packaged or otherwise, for direct retail customer access and handling before purchase without the intervention or assistance of the dealer or the dealer's owner, employee, or agent. An open display of such products and devices includes the use of an open display unit.

(9) "Any person under the age of 21" does not include any person under the age of 21 who:

(a) Is in the military reserve or on active duty in the Armed Forces of the United States; or

(b) Is acting in his or her scope of lawful employment.

Section 20. Section 569.32, Florida Statutes, is created to read:

569.32 Retail nicotine products dealer permits; application; qualifications; renewal; duplicates.—

(1) (a) Each person, firm, association, or corporation that seeks to deal, at retail, in nicotine products within the state, or to allow a nicotine products vending machine to be located on its premises in the state, must obtain a retail nicotine products dealer permit for each place of business or premises at which nicotine products are sold. Each dealer owning, leasing, furnishing, or operating vending machines through which nicotine products are sold must obtain a permit for each machine and shall post the permit in a conspicuous place on or near the machine; however, if the dealer has more than one vending

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machine at a single location or if nicotine products are sold both over the counter and through a vending machine at a single location, the dealer need obtain only one permit for that location.

(b) Application for a permit must be made on a form furnished by the division and must set forth the name under which the applicant transacts or intends to transact business, the address of the location of the applicant's place of business within the state, and any other information the division requires. If the applicant has or intends to have more than one place of business dealing in nicotine products within the state, a separate application must be made for each place of business. If the applicant is a firm or an association, the application must set forth the names and addresses of the persons constituting the firm or association; if the applicant is a corporation, the application must set forth the names and addresses of the principal officers of the corporation. The application must also set forth any other information prescribed by the division for the purpose of identifying the applicant firm, association, or corporation. The application must be signed and verified by oath or affirmation by the owner, if a sole proprietor, or, if the owner is a firm, association, or partnership, by the members or partners thereof, or, if the owner is a corporation, by an executive officer of the corporation or by a person authorized by the corporation to sign the application, together with the written evidence of this authority.

(2) (a) Permits may be issued only to persons who are 21 years of age or older or to corporations the officers of which

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are 21 years of age or older.

(b) The division may refuse to issue a permit to any person, firm, association, or corporation the permit of which has been revoked, to any corporation an officer of which has had his or her permit revoked, or to any person who is or has been an officer of a corporation the permit of which has been revoked. Any permit issued to a firm, association, or corporation prohibited from obtaining a permit under this chapter shall be revoked by the division.

(3) Upon approval of an application for a permit, the division shall issue to the applicant a permit for the place of business or premises specified in the application. A permit is not assignable and is valid only for the person in whose name the permit is issued and for the place designated in the permit. The permit shall be conspicuously displayed at all times at the place for which issued.

Section 21. Section 569.33 Florida Statutes, is created to read:

569.33 Consent to inspection and search without warrant.—An applicant for a retail nicotine products dealer permit, by accepting the permit when issued, agrees that the place or premises covered by the permit is subject to inspection and search without a search warrant by the division or its authorized assistants, and by sheriffs, deputy sheriffs, or police officers, to determine compliance with this part.

Section 22. Section 569.34, Florida Statutes, is created to read:

569.34 Operating without a retail nicotine products dealer permit; penalty.—

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(1) It is unlawful for a person, firm, association, or corporation to deal, at retail, in nicotine products, in any manner, or to allow a nicotine products vending machine to be located on its premises, without having a retail nicotine product dealer permit as required by s. 569.32. A person who violates this section commits a noncriminal violation, punishable by a fine of not more than \$500.

(2) A retail tobacco products dealer, as defined in s. 569.002(4), is not required to have a separate or additional retail nicotine products dealer permit to deal, at retail, in nicotine products within the state, or allow a nicotine products vending machine to be located on its premises in the state. Any retail tobacco products dealer that deals, at retail, in nicotine products or allows a tobacco products vending machine to be located on its premises in the state, is subject to, and must be in compliance with, this part.

(3) Any person who violates this section shall be cited for such infraction and shall be cited to appear before the county court. The citation may indicate the time, date, and location of the scheduled hearing and must indicate that the penalty for a noncriminal violation is a fine of not more than \$500.

(a) A person cited for an infraction under this section may:

1. Post a \$500 bond; or

2. Sign and accept the citation indicating a promise to appear.

(b) A person cited for violating this section may:

1. Pay the fine, either by mail or in person, within 10 days after receiving the citation; or

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2. If the person has posted bond, forfeit the bond by not appearing at the scheduled hearing.

(c) If the person pays the fine or forfeits bond, the person is deemed to have admitted violating this section and to have waived the right to a hearing on the issue of commission of the violation. Such admission may not be used as evidence in any other proceeding.

(d) The court, after a hearing, shall make a determination as to whether an infraction has been committed. If the commission of an infraction has been proven beyond a reasonable doubt, the court may impose a civil penalty in an amount that may not exceed \$500.

(e) If a person is found by the court to have committed the infraction, that person may appeal that finding to the circuit court.

Section 23. Section 569.35, Florida Statutes, is created to read:

569.35 Retail nicotine product dealers; administrative penalties.—The division may suspend or revoke the permit of a dealer, including the retail tobacco products dealer permit of a retail tobacco products dealer as defined in s. 569.002(4), upon sufficient cause appearing of the violation of any of the provisions of this part, by a dealer, or by a dealer's agent or employee. The division may also assess and accept an administrative fine of up to \$1,000 against a dealer for each violation. The division shall deposit all fines collected into the General Revenue Fund as collected. An order imposing an administrative fine becomes effective 15 days after the date of the order. The division may suspend the imposition of a penalty

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against a dealer, conditioned upon the dealer's compliance with terms the division considers appropriate.

Section 24. Section 569.37, Florida Statutes, is created to read:

569.37 Sale or delivery of nicotine products; restrictions.—

(1) In order to prevent persons under 21 years of age from purchasing or receiving nicotine products, the sale or delivery of nicotine products is prohibited, except:

(a) When under the direct control or line of sight of the dealer or the dealer's agent or employee; or

(b) Sales from a vending machine are prohibited under paragraph (a) and are only permissible from a machine that is equipped with an operational lockout device that is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lockout device to allow the dispensing of one nicotine product. The lockout device must include a mechanism to prevent the machine from functioning if the power source for the lockout device fails or if the lockout device is disabled, and a mechanism to ensure that only one nicotine product is dispensed at a time.

(2) (a) A dealer that sells nicotine products may not sell, permit to be sold, offer for sale, or display for sale such products or devices by means of self-service merchandising.

(b) A dealer that sells nicotine products may not place such products or devices in an open display unit unless the unit is located in an area that is inaccessible to customers.

(3) The provisions of subsections (1) and (2) shall not

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813 apply to an establishment that prohibits persons under 21 years
 814 of age on the licensed premises.
 815 (4) A dealer or a dealer's agent or employee may require
 816 proof of age of a purchaser of a nicotine product before selling
 817 the product to that person.
 818 Section 25. Section 569.38, Florida Statutes, is created to
 819 read:
 820 569.38 Gift of sample nicotine products and nicotine
 821 dispensing devices.—The gift of sample nicotine products to any
 822 person under the age of 21 by an entity permitted under this
 823 part, or by an employee of such entity, is prohibited and is
 824 punishable as provided in s. 569.41.
 825 Section 26. Section 569.381, Florida Statutes, is created
 826 to read:
 827 569.381 Responsible retail nicotine products dealers;
 828 qualifications; mitigation of disciplinary penalties; diligent
 829 management and supervision; presumption.—
 830 (1) It is the intent of the Legislature to prevent the sale
 831 of nicotine products to persons under 21 years of age and to
 832 encourage retail nicotine products dealers to comply with
 833 responsible practices in accordance with this section.
 834 (2) To qualify as a responsible retail nicotine products
 835 dealer, the dealer must establish and implement procedures
 836 designed to ensure that the dealer's employees comply with this
 837 part. The dealer must provide a training program for the
 838 dealer's employees which addresses the use and sale of nicotine
 839 products and which includes at least the following topics:
 840 (a) Laws covering the sale of nicotine products.
 841 (b) Methods of recognizing and handling customers under 21

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842 years of age.
 843 (c) Procedures for proper examination of identification
 844 cards in order to verify that customers are not under 21 years
 845 of age.
 846 (d) The use of the age audit identification function on
 847 electronic point-of-sale equipment, where available.
 848 (3) In determining penalties under s. 569.35, the division
 849 may mitigate penalties imposed against a dealer because of an
 850 employee's illegal sale of a nicotine product to a person under
 851 21 years of age if the following conditions are met:
 852 (a) The dealer is qualified as a responsible dealer under
 853 this section.
 854 (b) The dealer provided the training program required under
 855 subsection (2) to that employee before the illegal sale
 856 occurred.
 857 (c) The dealer had no knowledge of that employee's
 858 violation at the time of the violation and did not direct,
 859 approve, or participate in the violation.
 860 (d) If the sale was made through a vending machine, the
 861 machine was equipped with an operational lock-out device.
 862 (4) The division shall develop and make available a model
 863 nicotine products training program designed to ensure adherence
 864 to this part by dealers and their employees which, if followed,
 865 will qualify dealers as responsible dealers.
 866 (5) Dealers shall exercise diligence in the management and
 867 supervision of their premises and in the supervision and
 868 training of their employees, agents, or servants. In proceedings
 869 to impose penalties under s. 569.35, proof that employees,
 870 agents, or servants of the dealer, while in the scope of their

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871 employment, committed at least three violations of s. 569.41
 872 during a 180-day period shall be prima facie evidence of a lack
 873 of due diligence by the dealer in the management and supervision
 874 of his or her premises and in the supervision and training of
 875 employees, agents, officers, or servants.

876 (6) The division may consider qualification as a
 877 responsible retail nicotine products dealer under this section
 878 as evidence that the dealer properly exercised the diligence
 879 required under this section.

880 Section 27. Section 569.39, Florida Statutes, is created to
 881 read:

882 569.39 Rulemaking authority.—The division shall adopt rules
 883 to administer and enforce this part.

884 Section 28. Section 569.41, Florida Statutes, is created to
 885 read:

886 569.41 Selling, delivering, bartering, furnishing, or
 887 giving nicotine products to persons under 21 years of age;
 888 criminal penalties; defense.—

889 (1) It is unlawful to sell, deliver, barter, furnish, or
 890 give, directly or indirectly, to any person who is under 21
 891 years of age, any nicotine product.

892 (2) Any person who violates subsection (1) commits a
 893 misdemeanor of the second degree, punishable as provided in s.
 894 775.082 or s. 775.083. However, any person who violates
 895 subsection (1) for a second or subsequent time within 1 year
 896 after the first violation commits a misdemeanor of the first
 897 degree, punishable as provided in s. 775.082 or s. 775.083.

898 (3) A person charged with a violation of subsection (1) has
 899 a complete defense if, at the time the nicotine product was

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900 sold, delivered, bartered, furnished, or given:

901 (a) The buyer or recipient falsely evidenced that she or he
 902 was 21 years of age or older;

903 (b) The appearance of the buyer or recipient was such that
 904 a prudent person would believe the buyer or recipient to be 21
 905 years of age or older; and

906 (c) Such person carefully checked a driver license or an
 907 identification card issued by the state or another state of the
 908 United States, a passport, or a United States armed services
 909 identification card presented by the buyer or recipient and
 910 acted in good faith and in reliance upon the representation and
 911 appearance of the buyer or recipient in the belief that the
 912 buyer or recipient was 21 years of age or older.

913 Section 29. Section 569.42, Florida Statutes, is created to
 914 read:

915 569.42 Possession, misrepresenting age or military service
 916 to purchase, and purchase of nicotine products by persons under
 917 21 years of age prohibited; penalties; jurisdiction; disposition
 918 of fines.—

919 (1) It is unlawful for any person under 21 years of age to
 920 knowingly possess any nicotine product. Any person under 21
 921 years of age who violates this subsection commits a noncriminal
 922 violation as provided in s. 775.08(3), punishable by:

923 (a) For a first violation, 16 hours of community service
 924 or, instead of community service, a \$25 fine. In addition, the
 925 person must attend a school-approved anti-tobacco and anti-
 926 nicotine program, if locally available; or

927 (b) For a second or subsequent violation within 12 weeks
 928 after the first violation, a \$25 fine.

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Any second or subsequent violation not within the 12-week period after the first violation is punishable as provided for a first violation.

(2) It is unlawful for any person under 21 years of age to misrepresent his or her age or military service for the purpose of inducing a dealer or an agent or employee of the dealer to sell, give, barter, furnish, or deliver any nicotine product, or to purchase, or attempt to purchase, any nicotine product from a person or a vending machine. Any person under 21 years of age who violates this subsection commits a noncriminal violation as defined in s. 775.08(3), punishable by:

(a) For a first violation, 16 hours of community service or, instead of community service, a \$25 fine and, in addition, the person must attend a school-approved anti-tobacco and anti-nicotine program, if available; or

(b) For a second or subsequent violation within 12 weeks after the first violation, a \$25 fine.

Any second or subsequent violation not within the 12-week period after the first violation is punishable as provided for a first violation.

(3) Any person under 21 years of age cited for committing a noncriminal violation under this section must sign and accept a civil citation indicating a promise to appear before the county court or comply with the requirement for paying the fine and must attend a school-approved anti-tobacco and anti-nicotine program, if locally available. If a fine is assessed for a violation of this section, the fine must be paid within 30 days

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after the date of the citation or, if a court appearance is mandatory, within 30 days after the date of the hearing.

(4) A person charged with a noncriminal violation under this section must appear before the county court or comply with the requirement for paying the fine. The court, after a hearing, shall make a determination as to whether the noncriminal violation was committed. If the court finds the violation was committed, it shall impose an appropriate penalty as specified in subsection (1) or subsection (2). A person who participates in community service shall be considered an employee of the state for the purpose of chapter 440, for the duration of such service.

(5) (a) If a person under 21 years of age is found by the court to have committed a noncriminal violation under this section and the person has failed to complete community service, pay the fine as required by paragraph (1) (a) or paragraph (2) (a), or attend a school-approved anti-tobacco and anti-nicotine program, if locally available, the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 30 consecutive days.

(b) If a person under 21 years of age is found by the court to have committed a noncriminal violation under this section and that person has failed to pay the applicable fine as required by paragraph (1) (b) or paragraph (2) (b), the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 45 consecutive days.

(6) Eighty percent of all civil penalties received by a

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987 county court under this section shall be remitted by the clerk
 988 of the court to the Department of Revenue for transfer to the
 989 Department of Education to provide for teacher training and for
 990 research and evaluation to reduce and prevent the use of
 991 nicotine products by children. The remaining 20 percent of civil
 992 penalties received by a county court under this section shall
 993 remain with the clerk of the county court to cover
 994 administrative costs.

995 Section 30. Section 569.43, Florida Statutes, is created to
 996 read:

997 569.43 Posting of a sign stating that the sale of nicotine
 998 products or nicotine dispensing devices to persons under 21
 999 years of age is unlawful; enforcement; penalty.—

1000 (1) A dealer that sells nicotine products shall post a
 1001 clear and conspicuous sign in each place of business at which
 1002 such products are sold which substantially states the following:

1003 THE SALE OF NICOTINE PRODUCTS OR NICOTINE DISPENSING
 1004 DEVICES TO PERSONS UNDER THE AGE OF 21 IS AGAINST
 1005 FLORIDA LAW. PROOF OF AGE IS REQUIRED FOR PURCHASE.

1006
 1007
 1008 (2) The division shall make available to dealers of
 1009 nicotine products signs that meet the requirements of subsection
 1010 (1).

1011 (3) Any dealer that sells nicotine products shall provide
 1012 at the checkout counter in a location clearly visible to the
 1013 dealer or the dealer's agent or employee instructional material
 1014 in a calendar format or similar format to assist in determining
 1015 whether a person is of legal age to purchase nicotine products.

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1016 This point of sale material must contain substantially the
 1017 following language:

1018
 1019 IF YOU WERE NOT BORN BEFORE THIS DATE
 1020 (insert date and applicable year)
 1021 YOU CANNOT BUY TOBACCO PRODUCTS, NICOTINE PRODUCTS, OR NICOTINE
 1022 DISPENSING DEVICES.

1023
 1024 Upon approval by the division, in lieu of a calendar a dealer
 1025 may use card readers, scanners, or other electronic or automated
 1026 systems that can verify whether a person is of legal age to
 1027 purchase nicotine products. Failure to comply with the
 1028 provisions contained in this subsection shall result in
 1029 imposition of administrative penalties as provided in s. 569.35.

1030 (4) The division, through its agents and inspectors, shall
 1031 enforce this section.

1032 (5) Any person who fails to comply with subsection (1)
 1033 commits a misdemeanor of the second degree, punishable as
 1034 provided in s. 775.082 or s. 775.083.

1035 Section 31. Section 569.44, Florida Statutes, is created to
 1036 read:

1037 569.44 Annual report.—The division shall report annually
 1038 with written findings to the Legislature and the Governor by
 1039 December 31, on the progress of implementing the enforcement
 1040 provisions of this part. This must include, but is not limited
 1041 to:

1042 (1) The number and results of compliance visits.

1043 (2) The number of violations for failure of a retailer to
 1044 hold a valid permit.

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1045 (3) The number of violations for selling nicotine products
 1046 to persons under age 21, and the results of administrative
 1047 hearings on the above and related issues.
 1048 (4) The number of persons under age 21 cited for violations
 1049 of s. 569.42 and sanctions imposed as a result of citation.
 1050 Section 32. Section 569.45, Florida Statutes, is created to
 1051 read:
 1052 569.45 Mail order, Internet, and remote sales of nicotine
 1053 products; age verification.—
 1054 (1) For purposes of this section, the term:
 1055 (a) "Consumer" means a person in the state who comes into
 1056 possession of any nicotine product who, at the time of
 1057 possession, is not intending to sell or distribute the nicotine
 1058 product, or is not a retailer.
 1059 (b) "Delivery sale" means any sale of nicotine products to
 1060 a consumer in the state for which:
 1061 1. The consumer submits the order for the sale by
 1062 telephonic or other voice transmission, mail, delivery service,
 1063 or the Internet or other online service; or
 1064 2. The nicotine products are delivered by use of mail or a
 1065 delivery service.
 1066 (c) "Delivery service" means any person engaged in the
 1067 commercial delivery of letters, packages, or other containers.
 1068 (d) "Legal minimum purchase age" means the minimum age at
 1069 which an individual may legally purchase nicotine products in
 1070 the state.
 1071 (e) "Retailer" means any person who is required to obtain a
 1072 retail nicotine products dealer permit or a retail tobacco
 1073 products dealer permit, as defined in s. 569.002.

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1074 (f) "Shipping container" means a container in which
 1075 nicotine products are shipped in connection with a delivery
 1076 sale.
 1077 (g) "Shipping document" means a bill of lading, airbill,
 1078 United States Postal Service form, or any other document used to
 1079 verify the undertaking by a delivery service to deliver letters,
 1080 packages, or other containers.
 1081 (2) (a) A sale of nicotine products constituting a delivery
 1082 sale under paragraph (1) (c) is a delivery sale regardless of
 1083 whether the person accepting the order for the delivery sale is
 1084 located inside or outside the state.
 1085 (b) A retailer must obtain a retail nicotine products
 1086 dealer permit or a retail tobacco products dealer permit, as
 1087 defined in s. 569.002, from the division under the requirements
 1088 of this chapter before accepting an order for a delivery sale.
 1089 (c) A person may not make a delivery sale of nicotine
 1090 products to any individual who is not 21 years of age or older.
 1091 (d) Each person accepting an order for a delivery sale must
 1092 comply with each of the following:
 1093 1. The age verification requirements set forth in
 1094 subsection (3).
 1095 2. The disclosure requirements set forth in subsection (4).
 1096 3. The shipping requirements set forth in subsection (5).
 1097 (3) A person may not mail, ship, or otherwise deliver
 1098 nicotine products in connection with an order for a delivery
 1099 sale unless, before the first delivery to the consumer, the
 1100 person accepting the order for the delivery sale:
 1101 (a) Obtains from the person submitting the order a
 1102 certification that includes:

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1103 1. Reliable confirmation that the person is 21 years of age
 1104 or older; and
 1105 2. A statement signed by the person in writing and under
 1106 penalty of perjury which:
 1107 a. Certifies the address and date of birth of the person;
 1108 and
 1109 b. Confirms that the person wants to receive delivery sales
 1110 from a nicotine products company and understands that, under the
 1111 laws of the state, the following actions are illegal:
 1112 (I) Signing another person's name to the certification;
 1113 (II) Selling nicotine products to individuals who are not
 1114 21 years of age or older; and
 1115 (III) Purchasing nicotine products, if the person making
 1116 the purchase is not 21 years of age or older.
 1117 (b) Makes a good faith effort to verify the information
 1118 contained in the certification provided by the individual under
 1119 paragraph (a) against a commercially available database that may
 1120 be reasonably relied upon for accurate age information or
 1121 obtains a photocopy or other image of a valid government-issued
 1122 identification card stating the date of birth or age of the
 1123 individual.
 1124 (c) Provides to the individual, via electronic mail or
 1125 other means, a notice meeting the requirements of subsection
 1126 (4).
 1127 (d) If an order for nicotine products is made pursuant to
 1128 an advertisement on the Internet, receives payment for the
 1129 delivery sale from the consumer by a credit or debit card issued
 1130 in the name of the consumer, or by personal or company check of
 1131 the consumer.

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1132 (e) The person accepting the order for delivery sale shall
 1133 submit, to each credit card acquiring company with which the
 1134 person has credit card sales, identification information in an
 1135 appropriate form and format so that the words "nicotine product"
 1136 may be printed in the purchaser's credit card statement when a
 1137 purchase of a nicotine product is made by credit card payment.
 1138 (f) Makes a telephone call after 5 p.m. to the purchaser
 1139 confirming the order before shipping the nicotine products. The
 1140 telephone call may be a person-to-person call or a recorded
 1141 message. The person accepting the order for delivery sale is not
 1142 required to speak directly with a person and may leave a message
 1143 on an answering machine or through voice mail.
 1144
 1145 In addition to the requirements of this subsection, a person
 1146 accepting an order for a delivery sale may request that a
 1147 consumer provide an electronic mail address.
 1148 (4) The notice described in paragraph (3)(c) must include
 1149 prominent and clearly legible statements that sales of nicotine
 1150 products are:
 1151 (a) Illegal if made to individuals who are not 21 years of
 1152 age or older.
 1153 (b) Restricted to those individuals who provide verifiable
 1154 proof of age in accordance with subsection (3).
 1155 (5) Each person who mails, ships, or otherwise delivers
 1156 nicotine products in connection with an order for a delivery
 1157 sale must:
 1158 (a) Include as part of the shipping documents, in a clear
 1159 and conspicuous manner, the following statement: "Nicotine
 1160 Products: Florida law prohibits shipping to individuals under 21

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1161 years of age."

1162 (b) Use a method of mailing, shipping, or delivery which
 1163 obligates the delivery service to require:

1164 1. The individual submitting the order for the delivery
 1165 sale or another person 21 years of age or older who resides at
 1166 the individual's address to sign his or her name to accept
 1167 delivery of the shipping container. Proof of the legal minimum
 1168 purchase age of the individual accepting delivery is required
 1169 only if the individual appears to be under 30 years of age.

1170 2. Proof that the individual is either the addressee or the
 1171 individual who is 21 years of age or older designated by the
 1172 addressee, in the form of a valid, government-issued
 1173 identification card bearing a photograph of the individual who
 1174 signs to accept delivery of the shipping container.

1175
 1176 If the person accepting a purchase order for a delivery sale
 1177 delivers the nicotine products without using a delivery service,
 1178 the person must comply with all of the requirements of this
 1179 section which apply to a delivery service. Any failure to comply
 1180 with a requirement of this section constitutes a violation
 1181 thereof.

1182 (6) This section does not apply to delivery sales of
 1183 nicotine products to a retail nicotine products dealer or a
 1184 retail tobacco products dealer, as defined in s. 569.002.

1185 (7) An individual 21 years of age or older who knowingly
 1186 violates any provision of this section commits a misdemeanor of
 1187 the second degree, punishable as provided in s. 775.082 or s.
 1188 775.083.

1189 (8) The Attorney General, the Attorney General's designee,

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1190 or a state attorney may bring an action in the appropriate court
 1191 in the state to prevent or restrain violations of this section
 1192 by any person.

1193 Section 33. Section 877.112, Florida Statutes, is repealed.

1194 Section 34. This act shall take effect October 1, 2021.

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The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: March 11, 2021

I respectfully request that **Senate Bill #1080**, relating to Tobacco and Nicotine Products, be placed on the:

- ☐ committee agenda at your earliest possible convenience.
- ☒ next committee agenda.

A handwritten signature in black ink, appearing to read "Travis Hutson". The signature is fluid and cursive, with a large initial "T" and "H".

Senator Travis Hutson
Florida Senate, District 7

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

THE FLORIDA SENATE

APPEARANCE RECORD

3/24/2021

Meeting Date

1080

Bill Number (if applicable)

413936

Amendment Barcode (if applicable)

Topic Local Control of Tobacco Prevention and Regulation of Nicotine Products

Name Ashley Lyerly

Job Title Director of Advocacy

Address P.O Box 43263

Phone 205-968-2266

Street

Vestavia

AL

35243

Email ashley.lyerly@lung.org

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing American Lung Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/21
Meeting Date

1080
Bill Number (if applicable)
413936
Amendment Barcode (if applicable)

Topic Nicotine Products

Name Susan Harbin

Job Title _____

Address _____ Phone _____
Street

City _____ State _____ Zip _____ Email _____

Speaking: ☐ For ☐ Against ☐ Information

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

Representing American Cancer Society Cancer Action Network

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

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THE FLORIDA SENATE

APPEARANCE RECORD

3/24/2021

Meeting Date

1080

Bill Number (if applicable)

Topic Local Control of Tobacco Prevention and Regulation of Nicotine Products

Amendment Barcode (if applicable)

Name Ashley Lyerly

Job Title Director of Advocacy

Address P.O Box 43263

Phone 205-968-2266

Street

Vestavia

AL

35243

Email ashley.lyerly@lung.org

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing American Lung Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

10/24/21

Meeting Date

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

1080

Bill Number (if applicable)

Topic ~~Nicotine~~ Nicotine Product

Amendment Barcode (if applicable)

Name Susan Harbin

Job Title Senior Director, Gov't Relations

Address _____
Street

Phone 770-546-8845

City

State

Zip

Email susan.harbin@cancer.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing American Cancer Society Cancer Action Network

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/21
~~03/22/20~~
Meeting Date

SB 1080
Bill Number (if applicable)

Topic Tobacco & Nicotine Products

Amendment Barcode (if applicable)

Name Joe Anne Hart

Job Title Chief Legislative Officer

Address 118 E. Jefferson St.

Phone 850-224-1089

Street

Tall FL 32311

City

State

Zip

Email jahart@floridadental.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Dental Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 1786

INTRODUCER: Health Policy Committee and Senator Burgess and others

SUBJECT: Payments for Birth-related Neurological Injuries

DATE: March 25, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	Favorable
2.	Smith	Brown	HP	Fav/CS
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1786 increases the cap on the periodic or lump-sum payment amount¹ from \$100,000 to \$250,000 that the Florida Birth-Related Neurological Injury Compensation Association (NICA) may pay parents or legal guardians of an infant found to have suffered a compensable birth-related neurological injury, as determined by an administrative law judge (ALJ). Further, the bill establishes a three percent annual increase of this cap to counteract increasing costs. The bill also increases the death benefit from \$10,000 to \$50,000. The provisions of the bill apply retroactively to claims filed on or after January 1, 2021.

The Florida Birth-Related Neurological Injury Compensation Plan (Plan) pays for compensation and medically necessary medical care and other services to persons with birth-related neurological injuries when a physician participating in the Plan delivers obstetrical services in connection with the birth, and an (ALJ) determines the claim is compensable.

NICA engaged an actuary to determine the viability and likely impact of increasing the parental award from \$100,000 to \$250,000. It was determined that the bill will have a negative fiscal impact on the Plan, but the actuary's report recommended increasing the parental award. See section V of this analysis.

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

¹ Also known as the parental award.

II. Present Situation:

Florida Birth-Related Neurological Injury Compensation Association

In 1988, the Legislature enacted the Florida Birth-Related Neurological Injury Compensation Plan² (Plan) to provide compensation, long-term medical care, and other services to persons with birth-related neurological injuries.³ If an infant suffers such an injury, and the physician participates in NICA and delivers obstetrical services in connection with the birth, then an administrative award for a compensable injury is the infant's sole and exclusive remedy for the injury, with exceptions.⁴ Although the benefits paid under the Plan are limited, the Plan does not require the claimant to prove malpractice and provides a streamlined administrative hearing process to resolve the claim.⁵

A "birth-related neurological injury" is an injury to the brain or spinal cord of a live infant who weighs at least 2,500 grams for a single gestation or, in the case of a multiple gestation, a live infant who weighs at least 2,000 grams at birth caused by oxygen deprivation or by mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital.⁶ Such an injury addressed by this statute renders the infant permanently and substantially mentally and physically impaired.⁷

The five-member board of directors of the Florida Birth-Related Neurological Injury Compensation Association (NICA) administers the Plan.⁸ Duties of NICA include:

- Administering the Plan;
- Administering the funds collected;
- Reviewing and paying claims;
- Directing the investment and reinvestment of any surplus funds over losses and expenses;
- Reinsuring the risks of the Plan in whole or in part;
- Suing and being sued, appearing and defending, in all actions and proceedings in its name; and
- Taking such legal action as may be necessary to avoid payment of improper claims.⁹

² Section 766.303(1), F.S.

³ Chapter 88-1, ss. 60-75, Laws of Fla., was enacted by the Legislature to stabilize and reduce malpractice insurance premiums for physicians practicing obstetrics. The intent of the Legislature is to provide compensation, on a no-fault basis, for a limited class of high costs catastrophic injuries, specifically birth-related neurological injuries, that result in unusually high costs for custodial care and rehabilitation. Section 766.301 F.S.

⁴ Section 766.31(1), F.S.

⁵ See *Florida Birth-Related Neurological Injury Compensation Ass'n v. McKaughan*, 668 So.2d 974, 977 (Fla. 1996).

⁶ Section 766.302(2), F.S.

⁷ *Id.*

⁸ Section 766.315(1) and (2), F.S. The Chief Financial Officer appoints the members of the NICA board.

⁹ Section 766.315(4), F.S.

NICA Funding

The funding for the Plan is derived from an initial appropriation of \$20 million by the Legislature at the time the Plan was created¹⁰ and annual assessments paid by physicians and hospitals.¹¹ The Plan pays, on behalf of a qualifying infant, the following benefits:

- Medically necessary and reasonable care, services, drugs, equipment, facilities, and travel;¹²
- Periodic or lump-sum award, not to exceed \$100,000, to the infant's parents or guardians;¹³
- Death benefit of \$10,000 for the infant; and
- Reasonable expenses for filing the claim under the Plan, including attorney's fees.¹⁴

The ALJ must require the Plan to immediately pay expenses previously incurred and require that future expenses be paid as incurred.¹⁵

The \$100,000 cash award limit was established when the NICA statutory provisions were enacted in 1988. If the initial award of \$100,000 established for the first birth year of 1989 was adjusted for inflation and assuming an annual increase of three percent, this would result in an indicated award of approximately \$250,000.¹⁶

Filing a Claim for Benefits

A claim for compensation under the Plan must be filed within five years of the birth of the infant alleged to be injured.¹⁷ First, the parents or guardians of the infant must file a petition with the Division of Administrative Hearings (DOAH).¹⁸ Then, the DOAH serves a copy of the petition upon NICA, the physician(s) and hospital named in the petition, the Division of Medical Quality Assurance, and the Agency for Health Care Administration.¹⁹ Within 10 days of filing the petition, the parents or guardian must provide to NICA all medical records, assessments, evaluations and prognoses, documentation of expenses, and documentation of any private or governmental source of services or reimbursement relative to the impairments.²⁰

Within 45 days from the date of service of a complete claim, NICA must file a response to the petition and submit relevant written information relating to the issue of whether the injury

¹⁰ Section 766.314(5)(b), F.S.

¹¹ Section 766.314, F.S., requires non-participating physicians to pay \$250 per year, participating physicians to pay \$5,000 per year, and hospitals to pay \$50 per infant delivered during the prior year.

¹² The Plan excludes coverage for expenses that are compensable by state or federal governments, or by private insurers. Section 766.31(1)(a), F.S.

¹³ Often the award is paid out over time to assist the parents or guardians in making necessary modifications to living quarters to accommodate a disabled child.

¹⁴ Section 766.31, F.S.

¹⁵ Section 766.31(2), F.S.

¹⁶ Turner Consulting, Inc., Consultants and Actuaries, *Proposed Increase in Parental Award-Section 766.31(b)(1), Florida Statutes*, (Jan. 14, 2020) (on file with the Senate Committee on Health Policy).

¹⁷ Section 766.313, F.S.

¹⁸ Section 766.305, F.S.

¹⁹ Section 766.305(2), F.S.

²⁰ Section 766.305(3), F.S.

alleged is a birth-related neurological injury.²¹ An ALJ from the DOAH will set a hearing on the claim to be conducted 60-120 days from the petition filing date.²²

The issue of whether the claim for compensation is covered by the Plan is determined exclusively in an administrative proceeding.²³ The ALJ presiding over the hearing makes the following determinations:

- Whether the injury claimed is a birth-related neurological injury;
- Whether obstetrical services were delivered by a participating physician;
- How much compensation, if any, is awardable under s. 766.31, F.S.; and
- Whether, if raised by the claimant or other party, the factual determination regarding the notice requirement in s. 766.316, F.S.²⁴

If the ALJ determines that an injury meets the definition of a birth-related neurological injury, compensation from the Plan is the exclusive legal remedy.²⁵ If the ALJ determines that, the injury alleged is not a birth-related neurological injury or that a participating physician did not deliver the obstetrical services, the ALJ will enter an order to that effect.²⁶ The ALJ may also bifurcate the proceeding and address compensability and notice first, and address an award, if any, in a separate proceeding.²⁷ If any party chooses to appeal the ALJ's order under s. 766.309, F.S., the appeal must be filed in the District Court of Appeal.²⁸

Notice Requirement

Section 766.316, F.S., requires any hospital with a participating physician on its staff and each participating physician under the Plan, to provide notice to an obstetrical patient as to the limited no-fault alternative for birth-related neurological injuries. The notice must:

- Be provided on forms furnished by the association; and
- Include a clear and concise explanation of a patient's rights and limitations under the Plan.

This section of statute also provides that the notice does not need to be provided to a patient when the patient has an emergency medical condition or when notice is not practicable.

III. Effect of Proposed Changes:

Section 1 amends s. 766.31, F.S., to increase the limit for periodic payments or a lump-sum payment of an award from \$100,000 to \$250,000, beginning January 1, 2021. Each January 1 thereafter, the award limit is increased by three percent. **Section 1** also increases the death benefit from \$10,000 to \$50,000.

²¹ Section 766.305(4), F.S.

²² Section 766.307(1), F.S.

²³ Section 766.301(1)(d), F.S.

²⁴ Section 766.309(1), F.S.

²⁵ Section 766.303(2), F.S., only allows a civil action in place of a claim under the Plan where there is clear and convincing evidence of bad faith or malicious purpose or willful and wanton disregard of human rights, safety, or property.

²⁶ Section 766.309(2), F.S.

²⁷ Section 766.309(4), F.S.

²⁸ Section 766.311(1), F.S.

Section 2 provides that the amendments made to s. 766.31, F.S., by this act apply to claims filed under s. 766.305, F.S., on or after January 1, 2021.

Section 3 provides that the bill is effective July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Once a bill becomes law, it is presumed to apply only prospectively. The presumption against retroactive application may be rebutted by clear evidence of legislative intent.²⁹ To determine if the terms of a statute and the purpose of the enactment indicate retroactive application, a court may consider the language, structure, purpose, and legislative history of the enactment.³⁰

If the legislation clearly expresses an intent that the law should apply retroactively, then the second inquiry is whether retroactive application is constitutionally permissible.³¹ Even when the Legislature has clearly expressed its intention that the statute be given a retroactive application, courts must refuse to do so if it impairs vested rights, creates new obligations, imposes new penalties,³² or impairs an obligation of contract.³³ For example, ex post facto legislation, i.e., a law that expands criminal liability retroactively by either creating a new crime for past conduct or by increasing the penalty for past conduct, is forbidden by both the State Constitution and the United States Constitution. Statutes that do not alter vested rights, but relate only to remedies or procedure may be applied retroactively.³⁴

²⁹ *Florida Ins. Guar. Ass'n, Inc. v. Devon Neighborhood Ass'n, Inc.*, 67 So. 3d 187 (Fla. 2011).

³⁰ *Id.*

³¹ *Menendez v. Progressive Exp. Ins. Co., Inc.*, 35 So. 3d 873 (Fla. 2010); *State Farm Mut. Auto. Ins. Co. v. Laforet*, 658 So. 2d 55 (Fla. 1995).

³² *Id.*

³³ *Menendez v. Progressive Exp. Ins. Co., Inc.*, 35 So. 3d 873 (Fla. 2010).

³⁴ *Metropolitan Dade County v. Chase Federal Housing Corporation*, 737 So. 2d 494 (Fla. 1999).

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Increasing the cash payment limit from \$100,000 to \$250,000 would assist parents and legal guardians in meeting significant medical expenses and other necessary services and care of children with birth-related neurological injuries.

C. Government Sector Impact:**NICA Report³⁵**

NICA engaged actuaries to evaluate the viability and likely impact of the proposed increase in parental award, which is authorized pursuant to s. 766.31(1)(b), F.S. The actuaries concluded that, if the payment were increased from \$100,000 to \$250,000, this would result in additional expected costs to NICA of approximately \$2.70 million for the 2020 birth year. However, the actuaries noted:

[G]iven the current net assets of approximately \$393.2 million³⁶ plus the recent better than expected inflation levels, it is not likely this increase will significantly impact the overall financial position in the short-term. Given the erosion resulting from the impact of inflation on the parental award coupled with the current NICA financial position, we would recommend the proposed change from \$100,000 to \$250,000.

The actuaries also noted that NICA's financial position and the potential need for assessment level increases in the longer run would depend on actual investment results and inflation levels experienced over shorter term three to five year periods. The shortfall in assessments (i.e., without the additional investment income realized on the net assets and/or the better than expected inflation) and the indicated funding levels have in the past been offset by the better than expected realized NICA investment returns and inflation rates. To the extent this favorable relationship continues, the actuaries contend that it is likely additional increases in assessment levels will not be required. Alternatively, the actuaries note that volatility in the prospective results or increases in benefit inflation levels may require assessment level increases at some point in the longer term.

VI. Technical Deficiencies:

None.

³⁵ *Supra* note 15.

³⁶ Net assets were approximately \$426.5 million on June 30, 2020. Florida Birth-Related Neurological Injury Compensation Association, Financial Statements for years ended June 30, 2020 and 2019, pg. 5, available at <https://www.nica.com/downloads/2020%20NICA%20Audited%20Financial%20Statements.pdf> (last viewed Mar. 25, 2021).

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 766.31 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 24, 2021:

The CS increases the death benefit for an infant from \$10,000 to \$50,000. An ALJ must award this death benefit if he or she determines that the infant died due to a birth-related neurological injury and obstetrical services were delivered by a physician participating in the Plan at the time of birth. Like the changes made in the underlying bill, the increased death benefit under the CS would apply to claims filed on or after January 1, 2021.

- B. **Amendments:**

None.



719002

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/24/2021	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete line 30
and insert:
2. Death benefit for the infant in an amount of \$50,000
~~\$10,000.~~

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

And the title is amended as follows:

Between lines 7 and 8



719002

11 insert:
12 increasing the amount of the death benefit that may be
13 awarded;

By Senator Burgess

20-01693-21

20211786__

A bill to be entitled

An act relating to payments for birth-related neurological injuries; amending s. 766.31, F.S.; increasing the amount that may be awarded to the parents or legal guardians of an infant found to have sustained a birth-related neurological injury; requiring that such amount be revised annually; providing for retroactive application; providing an effective date.

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

Section 1. Paragraph (b) of subsection (1) of section 766.31, Florida Statutes, is amended to read:

766.31 Administrative law judge awards for birth-related neurological injuries; notice of award.—

(1) Upon determining that an infant has sustained a birth-related neurological injury and that obstetrical services were delivered by a participating physician at the birth, the administrative law judge shall make an award providing compensation for the following items relative to such injury:

(b)1. Periodic payments of an award to the parents or legal guardians of the infant found to have sustained a birth-related neurological injury, which award ~~may shall~~ not exceed \$100,000. However, at the discretion of the administrative law judge, such award may be made in a lump sum. Beginning on January 1, 2021, the award may not exceed \$250,000, and each January 1 thereafter the award authorized under this paragraph shall increase by 3 percent.

Page 1 of 2

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

20-01693-21

20211786__

2. Death benefit for the infant in an amount of \$10,000.

Section 2. The amendments made to s. 766.31, Florida Statutes, by this act apply to claims filed under s. 766.305, Florida Statutes, on or after January 1, 2021.

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

Page 2 of 2

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



The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 19, 2021

I respectfully request that **Senate Bill #1786**, relating to Payments for Birth-related Neurological Injuries, be placed on the:

- ☐ committee agenda at your earliest possible convenience.
- ☒ next committee agenda.

A handwritten signature in blue ink, appearing to read "Danny", is written over a horizontal line.

Senator Danny Burgess
Florida Senate, District 20

TURNER CONSULTING, INC.

CONSULTANTS AND ACTUARIES

125 Clairemont Avenue
Suite 540
Decatur, Georgia 30030
(404) 373-2326
Fax (404) 373-2311

January 14, 2020

Ms. Kenney Shipley
Executive Director
Florida Birth Related Neurological
Injury Compensation Association
2360 Christopher Place, Suite 1
Tallahassee, Florida 32308

Re: Proposed Increase in Parental Award – Section 766.31 (1) (b) (1), Florida Statutes

Dear Ms. Shipley:

This letter and the accompanying exhibits serve as a response to your request to consider the viability and likely impact on the Florida Birth Related Neurological Injury Association's (NICA) financial position of an increase in the parental award provision as stated in Section 766.31 (1) (b) (1) of the NICA Statutes. Specifically, we were requested to comment on the ability to increase the current parental award from the current amount of \$ 100,000 to \$ 250,000 per accepted claim in 2020 followed by an annual increase of three percent in each subsequent year without a change in the current assessment amounts in the short term (i.e. over the five-year period beginning in 2020).

It is my understanding the proposed increase in the parental award feature of the NICA statute is a response to the impact of inflation on this fixed award established in the original NICA statute. For example, the initial award of \$ 100,000 established for the first birth year of 1989 adjusted for inflation assuming an average annual increase of three percent results in an indicated award of approximately \$ 250,000 for birth year 2020 (i.e. $\$ 100,000 \times 1.03^{31} = 250,008$).

The actual funding level as well and the overall loss and loss adjustment expense reserve levels for NICA are directly impacted by the prospective average investment returns and average inflation applicable to the benefits covered by the NICA statutes. Based on the review of long term historical investment returns and inflation indices we have selected a long-term investment assumption of five percent per year and a long-term inflation rate of three and one-half percent for use in the estimation of funding levels and loss and LAE reserve levels. While actual investment and inflation results may vary from these selected estimates,

perhaps significantly, based on the experience to date as well as the review of longer term indices, we consider these assumptions to be reasonable estimates at this point in time. Since the actual experience will likely vary on an annual basis it is important to monitor the actual experience and refine these estimates as the experience emerges.

The average investment returns over the life of the NICA program through 2019 have exceeded the selected long-term return by approximately 50 basis points and the actual inflation rates have been a good bit lower than the longer-term indices would indicate. The combination of these two factors have resulted in the development of net assets of approximately \$ 393.2 million as of June 30, 2019. The experience to date coupled with the anticipated investment income on these net assets have resulted in NICA being able to forego any increase in the annual assessment levels per exposure unit over the thirty -one years of operations. That is, the additional investment income on these net assets (i.e. over and above the assets required to support the loss and LAE reserves on claims incurred to date) provides sufficient revenue in combination with the annual assessments to fund expected loss and LAE levels for the prospective 2020 birth year at the current \$ 100,000 parental award level. As shown on Exhibit I, Sheet 1, Item VII, Columns (1) and (2), the combination of hospital and physician assessments and the long term expected investment income on the current net assets will result in a surplus of approximately \$ 1.32 million at the current parental award of \$ 100,000 and a shortfall of approximately \$ 1.38 million at the proposed parental award of \$ 250,000.

The increase in the parental award from \$ 100,000 to \$ 250,000 results in additional expected costs of approximately \$ 2.70 million for the 2020 birth year. However, given the current net assets of approximately \$ 393.2 million plus the recent better than expected inflation levels, it is not likely this increase will significantly impact the overall financial position in the short-term. Given the erosion resulting from the impact of inflation on the parental award coupled with the current NICA financial position, we would recommend the proposed change from \$ 100,000 to \$ 250,000.

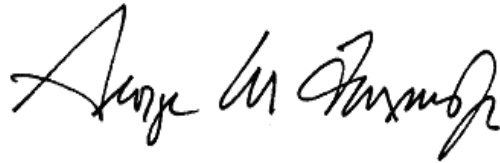
As mentioned previously, the NICA financial position and the potential need for assessment level increases in the longer run will depend on the actual investment results and inflation levels experienced over the shorter term three to five-year periods. The shortfall between hospital and physician assessments (i.e. without the additional investment income realized on the net assets and / or the better than expected inflation) and the indicated funding levels have in the past been offset by the better than expected differentials in actual NICA investment returns and inflation rates. To the extent this favorable relationship continues, it is likely additional increases in assessment levels will not be required. Alternatively,

Ms. Kenney Shipley
January 14, 2020
Page 3

volatility in the prospective investment results and / or increases in benefit inflation levels may require assessment level increases at some point in the longer term.

We have enjoyed working with you on this project and look forward to discussing any questions or comments you may have.

Sincerely,

A handwritten signature in black ink, appearing to read "George W. Turner Jr.", written in a cursive style.

George W. Turner Jr.
Fellow of the Casualty Actuarial Society,
Member of the American Academy of Actuaries

Cc: Tim Daughtry, Mark Crawshaw

Comparison of Indicated Funding Level to Current Assessment Levels

Before and After Proposed Change in Parental Award and
Before and After Impact of Additional Investment income on Surplus

	Hospital	Physicians	Combined (1) + (2)
	----- (1)	----- (2)	----- (3)
I. Recent Hospital and Physician Assessments (a)			
A. 2017	3,607,900	23,675,231	27,283,131
B. 2018	2,622,700	23,488,998	26,111,698
C. 2019	3,193,800	23,796,160	26,989,960
D. 2020	3,200,000	23,800,000	27,000,000
		Approximate Percent in Investments	Net Assets (Surplus)
	----- (1)	----- (2)	----- (3)
II. Investments and Net Assets - Per Financial Statements Ending (b)			
A. 6/30/13			2,637,474
B. 6/30/14			169,695,995
C. 6/30/15			160,803,995
D. 6/30/16			178,654,125
E. 6/30/17	1,158,494,820	34.75%	284,680,853
F. 6/30/18	1,210,964,330	36.35%	308,030,893
G. 6/30/19	1,315,790,163	33.60%	393,219,674
III. Estimated Long Term Investment Return			
A. Actual NICA Average Investment Return - 1991 to 2018			5.30%
B. Actual NICA Average Investment Return - 1990 to 1999			5.04%
C. Actual NICA Average Investment Return - 2000 to 2009			5.49%
D. Actual NICA Average Investment Return - 2010 to 2018			6.07%
E. Selected Investment Return Used in NICA Loss Reserve Reports			5.00%
IV. Indicated Long Term Average Investment Return on Current (2019) Net Assets = II.G. Col. (3) X III. E.			19,660,984
V. Combination of Current Hospital and Physician Assessments and Long Term Investment Return on Net Assets	I. D. Col. (3) + IV.		46,660,984
		Current Parental Award (i.e. \$ 100,000)	Proposed Parental Award (i.e. \$ 100,000)
		----- (1)	----- (2)
VI. Estimated 2020 Funding Level - Before and After Increase in Parental Award			
A. Investment Minus Inflation Differential of 1.50 % = See Exhibit I, Sheet 2, Item XII. A.		45,337,331	48,037,331
B. Investment Minus Inflation Differential of 3.25 % = See Exhibit I, Sheet 2, Item XII. B.		26,552,500	29,252,500
VII. Indicated 2020 Shortfall in Indicated Funding Level and Long Term Expected Revenue Based on Current NICA Reserve Report Prospective Assumptions =V - VI.A.		\$1,323,653	(\$1,376,347)

Notes: (a) Per information as provided by NICA management.
(b) Per prior NICA financial statements.

Comparison of Estimated Ultimate Loss & ALAE - After Inflation and Investment Income Offset

Before and After Proposed Change in Parental Award

	Based on NICA 9 30 19 Reserve Report Assumptions	
	Current Parental Award (\$ 100,000) (2)	Proposed Parental Award (\$ 250,000) (3)
I. Estimated 2020 Accepted Claims - All Types (Including Claimants Deceased Before Claim Reported) (a)	18.00	18.00
II. Estimated 2020 Accepted Claims - "DA" Claimants - Deceased Prior to Claim Report Date (a)	5.00	5.00
III. Estimated 2020 Accepted Claims - Excluding "DA" Claimants - (Includes "AAA" and "AAD" Claim Types) = I. - II.	13.00	13.00
IV. Estimated 2020 Cost Level Average Claim Size - Before Prospective Inflation and Investment Income Offset (b)		
A. "DA" Claims	125,860	125,860
B. Serious Claims - Excl. "DA"	5,150,000	5,150,000
C. Additional Expense Related to Increase in Parental Award from \$ 100,000 to \$ 250,000 - Applies to All Claim Types		150,000
V. Estimated Average Duration of Claim Payments - (2020 Cost Levels - After Mortality) (c)		
A. Approximate Duration - Differential of 1.50 % (Investment Minus Inflation) = Investment Return = 5 % - Inflation = 3.50 %	28.257	28.257
B. Approximate Duration - Differential of 3.25 % (Investment Minus Inflation) = Investment Return = 5.50 % Inflation = 2.25 %	24.940	24.940
VI. Indicated Inflation / Investment Income Adjustment (c)		
A. Investment Minus Inflation Differential of 1.50 % = Reserve Report Assumptions = Investment Return = 5.0 % Inflation = 3.50 %	0.65658	0.65658
B. Investment Minus Inflation Differential of 3.25 % = Recent NICA Investment and CPI Inflation Rates (5.50 % and 2.25 %)	0.37600	0.37600
VII. Indicated 2020 Present Value Average Claim Size - Excl. "DA" Claims (Applies to "AAA" and "AAD" Claim Types)		
A. Investment Minus Inflation Differential of 1.50 % - IV. B. X VI. A.	3,381,387	3,381,387
B. Investment Minus Inflation Differential of 3.25 % - IV. B. X VI. B.	1,936,400	1,936,400
VIII. Indicated 2020 Present Value Ultimate Loss & ALAE - Excl. "DA" Claims - ("AAA" and "AAD" Claim Types)		
A. Investment Minus Inflation Differential of 1.50 % - Col. (2) = III. X VII. A.; Col.(3) = III X {IV.C. + VII.A.}	43,958,031	45,908,031
B. Investment Minus Inflation Differential of 3.25 % - Col. (2) = III. X VII. B.; Col.(3) = III X {IV.C. + VII.B.}	25,173,200	27,123,200
IX. Indicated 2020 Level "DA" Claims Ultimate Loss & ALAE - Col. (2) = II. X IV.A. & Col. (3) = II. X {IV.A. +IV.C.}	629,300	1,379,300
X. Estimated ULAE Cost	500,000	500,000
XI. Estimated Cost of Denied Claims	250,000	250,000
XII. Indicated 2020 Birth Year Economic Cost - VIII + IX + X + XI		
A. Investment Minus Inflation Differential of 1.50 %	45,337,331	48,037,331
B. Investment Minus Inflation Differential of 3.25 %	26,552,500	29,252,500

Notes: (a) See Exhibit II , Item (17).

(b) See Exhibit III, Sheet 1, Item 1B.

(c) Indicated duration calculated based on discount factors shown in Exhibit I, Sheet 1a of NICA September 30, 2019 report.

Comparison of Indicated Funding Level to Current Assessment Levels

Before and After Proposed Change in Parental Award and Before and After Impact of Additional Investment income on Surplus	Current Parental Award ----- (1)	Proposed Parental Award ----- (2)
1. Current Net Assets (as of June 30, 2019)	393,219,674	393,219,674
2. Indicated 2020 Shorfall - See Exhibit I, Sheet 1, Item VII.	1,323,653	(1,376,347)
3. Impact on 2020 Ending Net Assets	394,543,327	391,843,327
4. Indicated Impact on Net Assets Assuming Short Term (Next Five Years) Inflation of 3.50 %		
A. 2021 - Ending	394,346,355	388,676,355
B. 2022 - Ending	392,497,191	383,569,641
C. 2023 - Ending	388,855,741	376,364,542
D. 2024 - Ending	383,272,898	366,892,349
E. Overall Change - Five Years = 4D - 1.	(9,946,776)	(26,327,325)
F. Diffence in the Change - Current Versus Proposed = 4E. Col. (2) - Col. (1)		(16,380,549)
5. Indicated Impact on Net Assets Assuming Short Term (Next Five Years) Inflation of 1.00 %		
A. 2021 - Ending	396,094,328	383,603,129
B. 2022 - Ending	395,479,789	389,809,789
C. 2023 - Ending	396,005,167	387,077,617
D. 2024 - Ending	396,094,328	383,603,129
E. Overall Change - Five Years = 5D - 1.	2,874,654	(9,616,545)
F. Diffence in the Change - Current Versus Proposed = 5E. Col. (2) - Col. (1)		(12,491,199)

Evaluated As of September 30, 2019

Actual Accepted as of 9/30/19												
Year of Birth	Deceased Prior to Claim Report Date	Deceased After Claim was Reported	Currently Accepted & Open	Total Accepted Claim Cts.	Estimated Ultimate Accepted			Insured Physicians	Claim Frequency per Insured Physician			
	"DA" @ 9 30 19	"AAD" @ 9 30 19	"AAA" @ 9 30 19	@ 9 30 19 (2)+(3)+(4)	Total Accepted Claim Counts (a)	"AAD" & "AAA" Claim Counts (b)	"DA" Claim Counts (6) - (7)		Total Accepted Claim (6) / (9)	"AAD" & "AAA" Claim (7) / (9)	"DA" Claim Counts (8) / (9)	% of Total Accepted "DA" (8) / (6)
	(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)	(10)	(11)
1989	4	7	4	15	15	11	4	570	0.0263	0.0193	0.0070	0.2667
1990	3	4	3	10	10	7	3	590	0.0169	0.0119	0.0051	0.3000
1991	4		4	8	8	4	4	653	0.0123	0.0061	0.0061	0.5000
1992	1	4	9	14	14	13	1	712	0.0197	0.0183	0.0014	0.0714
1993	2	5	8	15	15	13	2	731	0.0205	0.0178	0.0027	0.1333
1994	9	3	4	16	16	7	9	659	0.0243	0.0106	0.0137	0.5625
1995	5	1	5	11	11	6	5	682	0.0161	0.0088	0.0073	0.4545
1996	10	1	6	17	17	7	10	708	0.0240	0.0099	0.0141	0.5882
1997	6	3	8	17	17	11	6	737	0.0231	0.0149	0.0081	0.3529
1998	3	4	11	18	18	15	3	699	0.0258	0.0215	0.0043	0.1667
1999	9	6	3	18	18	9	9	665	0.0271	0.0135	0.0135	0.5000
2000	7	1	5	13	13	6	7	620	0.0210	0.0097	0.0113	0.5385
2001	9		4	13	13	4	9	676	0.0192	0.0059	0.0133	0.6923
2002	5	4	13	22	22	17	5	730	0.0301	0.0233	0.0068	0.2273
2003	6		3	9	9	3	6	785	0.0115	0.0038	0.0076	0.6667
2004	7	1	5	13	13	6	7	841	0.0155	0.0071	0.0083	0.5385
2005	2	4	7	13	13	11	2	891	0.0146	0.0123	0.0022	0.1538
2006	1	3	9	13	13	12	1	897	0.0145	0.0134	0.0011	0.0769
2007	5	3	7	15	15	10	5	963	0.0156	0.0104	0.0052	0.3333
2008	1	1	9	11	11	10	1	987	0.0111	0.0101	0.0010	0.0909
2009	6	1	10	17	17	11	6	1,044	0.0163	0.0105	0.0057	0.3529
2010	6	1	5	12	12	6	6	1,071	0.0112	0.0056	0.0056	0.5000
2011	2	2	10	14	14	12	2	1,091	0.0128	0.0110	0.0018	0.1429
2012	4		7	11	11	7	4	1,119	0.0098	0.0063	0.0036	0.3636
2013	3	1	7	11	11	8	3	1,143	0.0096	0.0070	0.0026	0.2727
2014	3	1	9	13	14	10	4	1,208	0.0116	0.0083	0.0033	0.2857
2015	5	1	12	18	20	15	5	1,273	0.0157	0.0118	0.0039	0.2500
2016	3		4	7	13	9	4	1,318	0.0099	0.0068	0.0030	0.3077
2017	2	1	9	12	19	15	4	1,356	0.0140	0.0111	0.0029	0.2105
2018	5		7	12	21	15	6	1,420	0.0148	0.0106	0.0042	0.2857
2019(9 Mo)			1	1	14	11	3	1,392	0.0101	0.0079	0.0022	0.2143
Subtotals												
89 to 18	138	63	207	408	433	290	143	26,839	0.0161	0.0108	0.0053	0.3303
89 to 99	56	38	65	159	159	103	56	7,406	0.0215	0.0139	0.0076	0.3522
00 to 09	49	18	72	139	139	90	49	8,434	0.0165	0.0107	0.0058	0.3525
10 to 15	23	6	50	79	82	58	24	6,905	0.0119	0.0084	0.0035	0.2927
00 to 15	72	24	122	218	221	148	73	15,339	0.0144	0.0096	0.0048	0.3303
04 to 14	40	18	85	143	144	103	41	11,255	0.0128	0.0092	0.0036	0.2847
02 to 13	48	21	92	161	161	113	48	11,715	0.0137	0.0096	0.0041	0.2981
(14) Selected									0.0125	0.0090	0.0035	0.2800
(15) Estimated 2020 Insured Physician									1,425			
									Total Accepted	"AAD" & "AAA"	"DA"	
(16) Indicated 2020 Accepted Claims - (14) X (15)									17.81	12.83	4.99	
(17) Selected 2020 Accepted Claims (16) Rounded									18.00	13.00	5.00	

Notes: (a) See Exhibit X, Sheet 1b, Column (8).

(b) See Exhibit X, Sheet 1a, Column (10) of the NICA September 30, 2019 loss and LAE reserve report.

"DA" Claimants ----- (2)	"AAA" & "AAD" Claimants ----- (3)

(1) Estimated 2020 Level Average Claim Size - Prior to Impact of Prospective Inflation & Investment Income Offset

(A) Based on Actual NICA Paid and Case Reserves - Excludes Loss Development - (Exhibit III, Sheet 2)	125,860	4,263,000
(B) Based on Estimated Ultimate Loss & ALAE - "AAA" & "AAD" - Estimate Underlying NICA Reserves (Exhibit III, Sheet 3)	125,860	5,150,000

(2) Estimated Inflation / Discount Factor (a)

(A) Based on NICA Selected Payment Pattern - 3.50 % Inflation / 5.00 % Discount	0.6566
(B) Based on NICA Selected Payment Pattern - 2.25 % Inflation / 5.50 % Discount	0.4376

----- BASED ON SELECTED NICA PAYMENT PATTERN

(3) Indicated 2020 Level Average Claim Size After Inflation and Discount - 3.50 % Inflation / 5.00 % Discount

(A) Based on Actual NICA Paid and Case Reserves - For Column (3) Only - Excludes Impact of Development (1A) X (2A)	125,860	2,799,001
(B) Based on Estimated Ultimate Loss & ALAE - "AAA" & "AAD" - For Column (3) Only - Includes Development (1B) X (2A)	125,860	3,381,387

(4) Indicated 2020 Level Average Claim Size After Inflation and Discount - 2.25 % Inflation / 5.50 % Discount

(A) Based on Actual NICA Paid and Case Reserves - For Column (3) Only - Excludes Impact of Development (1A) X (2B)	125,860	1,865,276
(B) Based on Estimated Ultimate Loss & ALAE - "AAA" & "AAD" - For Column (3) Only - Includes Development (1B) X (2B)	125,860	2,253,383

Notes: (a) Inflation / Investment Income adjustment factors are based on the payment pattern as shown in the September 30, 2019 NICA Loss and LAE Reserve Report.
 The combined inflation / investment income discount factors are based on the information shown in Exhibit I, Sheet 1c for the selected inflation / investment assumptions of 3.50 % and 5.00 %, respectively, as well as alternative assumptions of 2.25 % and 5.00 %. The alternative assumptions based on the more recent actual CPI inflation as opposed to the longer term inflation rates are for illustration only.

Evaluated As of September 30, 2019

BASED ON DA (Deceased Prior to Claim Report)						BASED ON AAA & AAD				
Year of Birth	Cumulative Loss & ALAE Payments @ 9 30 19	Incurred Loss & ALAE @ 9 30 19	# of Claims @ 9 30 19	Average Paid (2) / (4)	Average Incurred (3) / (4)	Cumulative Loss & ALAE Payments @ 9 30 19	Incurred Loss & ALAE @ 9 30 19	# of Claims @ 9 30 19	Average Paid (7) / (9)	Average Incurred (8) / (9)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
1989	486,837	486,837	4	121,709	121,709	14,162,088	25,744,292	11	1,287,463	2,340,390
1990	248,630	248,630	3	82,877	82,877	6,001,513	11,697,456	7	857,359	1,671,065
1991	399,310	399,310	4	99,827	99,827	9,075,507	27,201,317	4	2,268,877	6,800,329
1992	112,708	112,708	1	112,708	112,708	15,760,567	50,702,075	13	1,212,351	3,900,160
1993	172,674	172,674	2	86,337	86,337	20,687,857	46,713,170	13	1,591,374	3,593,321
1994	854,485	854,485	9	94,943	94,943	6,646,969	19,664,917	7	949,567	2,809,274
1995	571,862	571,862	5	114,372	114,372	10,272,799	32,307,588	6	1,712,133	5,384,598
1996	1,059,360	1,059,360	10	105,936	105,936	8,750,084	28,636,465	7	1,250,012	4,090,924
1997	685,563	685,563	6	114,261	114,261	11,749,950	39,182,989	11	1,068,177	3,562,090
1998	333,529	333,529	3	111,176	111,176	21,432,728	69,536,297	15	1,428,849	4,635,753
1999	943,610	943,610	9	104,846	104,846	11,299,348	25,842,414	9	1,255,483	2,871,379
2000	837,384	837,384	7	119,626	119,626	5,285,986	19,933,843	6	880,998	3,322,307
2001	1,042,908	1,042,908	9	115,879	115,879	6,246,396	27,747,018	4	1,561,599	6,936,755
2002	608,836	608,836	5	121,767	121,767	15,886,997	67,290,039	17	934,529	3,958,238
2003	724,755	724,755	6	120,793	120,793	4,059,382	15,531,486	3	1,353,127	5,177,162
2004	881,269	881,269	7	125,896	125,896	4,177,762	27,581,809	6	696,294	4,596,968
2005	245,168	245,168	2	122,584	122,584	7,506,359	32,482,058	11	682,396	2,952,914
2006	140,178	140,178	1	140,178	140,178	9,146,319	48,808,309	12	762,193	4,067,359
2007	468,956	468,956	5	93,791	93,791	9,705,285	38,309,754	10	970,529	3,830,975
2008	123,138	123,138	1	123,138	123,138	5,496,007	50,428,498	10	549,601	5,042,850
2009	910,857	910,857	6	151,809	151,809	6,308,135	57,741,223	11	573,467	5,249,202
2010	724,000	724,000	6	120,667	120,667	2,048,537	27,902,474	6	341,423	4,650,412
2011	248,839	248,839	2	124,419	124,419	4,323,116	47,260,345	12	360,260	3,938,362
2012	482,097	482,097	4	120,524	120,524	2,039,233	32,482,883	7	291,319	4,640,412
2013	394,926	394,926	3	131,642	131,642	3,834,475	28,888,144	8	479,309	3,611,018
2014	378,332	378,332	3	126,111	126,111	4,245,692	31,371,388	10	424,569	3,137,139
2015	503,904	646,663	5	100,781	129,333	2,516,847	43,848,985	13	193,604	3,372,999
2016	367,044	367,044	3	122,348	122,348	260,912	7,675,597	4	65,228	1,918,899
2017	238,587	238,587	2	119,294	119,294	463,283	19,355,128	10	46,328	1,935,513
2018	247,767	685,588	5	49,553	137,118	399,190	16,915,137	7	57,027	2,416,448
2019	0	0	0			0	1,130,000	1	0	1,130,000
89 to 18	15,437,513	16,018,094	138	111,866	116,073	228,665,938	974,837,236	249	918,337	3,915,009
89 to 99	5,868,567	5,868,567	56	104,796	104,796	135,839,411	377,228,979	103	1,318,829	3,662,417
00 to 09	5,983,450	5,983,450	49	122,111	122,111	75,867,164	413,756,511	96	790,283	4,309,964
10 to 15	2,732,098	2,874,858	23	118,787	124,994	16,959,363	183,851,745	50	339,187	3,677,035
00 to 15	8,715,548	8,858,307	72	121,049	123,032	43,162,882	190,566,253	47	918,359	4,054,601
04 to 14	4,997,761	4,997,761	40	124,944	124,944	48,711,519	330,514,470	78	624,507	4,237,365
02 to 13	5,953,020	5,953,020	48	124,021	124,021	47,146,799	363,193,018	86	548,219	4,223,175

(12) Selected Average Claim Based on 2019 Level Case Outstanding Loss & ALAE as of 9 30 19

(A) "DA" Claims - Deceased Prior to Report - See Column (5) Averages =====>	124,000
(B) "AAD" & "AAA" Claims - Claimant Alive at Date of Claim Report - See Column (11) Averages =====>	4,200,000

(13) Selected Adjusted to 2020 Cost Level (1.5 % Inflation)

(A) "DA" Claims - Deceased Prior to Report - See Column (5) Averages =====>	125,860
(B) "AAD" & "AAA" Claims - Claimant Alive at Date of Claim Report - See Column (11) Averages =====>	4,263,000

Birth Year Level Selected Ultimate Loss & ALAE										Birth Year Level
Year of Birth	All Claim Types (a)	DA Reported as of 9/30/19	Estimated Ultimate "AAA" & "AAD" (2) - (3)	Inflation Incurred Basis (b)	Adjustment Factor to 2020 Level	Estimated 2020 Level Ultimate Loss & ALAE (4) x (6)	Estimated Ultimate (c) "AAA" & "AAD" Claim Cts.	Indicated Average Claim Size		Average Claim Size Based on All Years Average (12) / (6)
								Birth Year Level (4) / (8)	2020 Level (7) / (8)	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
1989	22,744,366	486,837	22,257,529	0.90%	1.443	32,109,850	11.0	2,023,412	2,919,077	3,569,817
1990	10,127,471	248,630	9,878,841	0.70%	1.431	14,137,436	7.0	1,411,263	2,019,634	3,598,675
1991	21,555,127	399,310	21,155,817	0.59%	1.423	30,094,888	4.0	5,288,954	7,523,722	3,620,298
1992	40,554,986	112,708	40,442,278	0.54%	1.416	57,251,641	13.0	3,110,944	4,403,972	3,637,935
1993	39,661,412	172,674	39,488,738	0.50%	1.410	55,662,654	13.0	3,037,595	4,281,743	3,653,563
1994	17,705,455	854,485	16,850,970	0.43%	1.404	23,658,662	7.0	2,407,281	3,379,809	3,668,107
1995	26,859,165	571,862	26,287,303	0.43%	1.399	36,775,849	6.0	4,381,217	6,129,308	3,681,210
1996	25,032,766	1,059,360	23,973,406	0.34%	1.394	33,417,831	7.0	3,424,772	4,773,976	3,694,526
1997	33,278,721	685,563	32,593,158	0.32%	1.390	45,309,708	11.0	2,963,014	4,119,064	3,704,609
1998	57,952,515	333,529	57,618,986	0.39%	1.387	79,896,849	15.0	3,841,266	5,326,457	3,714,011
1999	23,909,383	943,610	22,965,773	0.46%	1.382	31,742,568	9.0	2,551,753	3,526,952	3,726,029
2000	18,189,514	837,384	17,352,130	0.40%	1.377	23,888,566	6.0	2,892,022	3,981,428	3,740,847
2001	25,250,521	1,042,908	24,207,613	0.44%	1.372	33,216,500	4.0	6,051,903	8,304,125	3,753,231
2002	59,029,612	608,836	58,420,777	0.38%	1.367	79,876,654	17.0	3,436,516	4,698,627	3,766,645
2003	14,276,590	724,755	13,551,834	0.39%	1.363	18,471,631	3.0	4,517,278	6,157,210	3,778,332
2004	25,036,644	881,269	24,155,375	4.59%	1.359	32,829,912	6.0	4,025,896	5,471,652	3,789,233
2005	31,622,874	245,168	31,377,707	0.89%	1.295	40,637,749	11.0	2,852,519	3,694,341	3,976,480
2006	47,208,814	140,178	47,068,636	4.50%	1.284	60,436,023	12.0	3,922,386	5,036,335	4,010,910
2007	39,790,584	468,956	39,321,628	4.46%	1.225	48,150,145	10.0	3,932,163	4,815,014	4,205,727
2008	53,730,897	123,138	53,607,759	1.39%	1.171	62,785,941	10.0	5,360,776	6,278,594	4,397,162
2009	63,518,830	910,857	62,607,973	0.36%	1.167	73,071,200	11.0	5,691,634	6,642,836	4,412,560
2010	31,761,482	724,000	31,037,482	0.44%	1.164	36,114,973	6.0	5,172,914	6,019,162	4,425,949
2011	54,666,871	248,839	54,418,032	0.46%	1.159	63,074,900	12.0	4,534,836	5,256,242	4,443,176
2012	39,780,063	482,097	39,297,965	8.91%	1.154	45,357,653	7.0	5,613,995	6,479,665	4,461,971
2013	40,883,699	394,926	40,488,773	0.71%	1.051	42,549,511	8.0	5,061,097	5,318,689	4,900,578
2014	48,078,170	378,332	47,699,838	0.20%	1.043	49,767,963	10.0	4,769,984	4,976,796	4,935,990
2015	71,038,029	646,663	70,391,366	1.86%	1.042	73,314,195	15.0	4,692,758	4,887,613	4,944,684
2016	29,860,051	367,044	29,493,007	0.27%	1.021	30,113,392	9.0	3,277,001	3,345,932	5,043,902
2017	63,341,203	238,587	63,102,616	0.25%	1.019	64,286,057	15.0	4,206,841	4,285,737	5,055,194
2018	71,809,267	685,588	71,123,679	0.17%	1.017	72,298,082	15.0	4,741,579	4,819,872	5,066,344
2019	53,480,950	-	53,480,950	1.50%	1.015	54,283,164	11.0	4,861,905	4,934,833	5,073,892
Totals:										
89 to 18	1,148,255,081	16,018,094	1,132,236,987			1,390,298,985	290	3,959,500	4,794,134	
89 to 99	319,381,367	5,868,567	313,512,800			440,057,937	103	3,100,790	4,272,407	
00 to 09	377,654,880	5,983,450	371,671,431			473,364,322	90	4,196,165	5,259,604	
10 to 17	379,409,567	3,480,489	375,929,078			404,578,644	82	4,626,946	4,933,886	
00 to 17	757,064,447	9,463,939	747,600,509			877,942,966	172	4,401,537	5,104,320	
05 to 16	551,940,363	5,130,199	546,810,164			625,373,644	121	4,561,491	5,168,377	
02 to 15	620,423,158	6,978,015	613,445,143			726,438,450	138	4,495,820	5,264,047	

(12) Selected 2020 Level Average Claim Size =====> 5,150,000

Notes: (a) See Exhibit IV, Sheet 2, Column (8) of the NICA 9/30/19 Loss and LAE Reserve report.
 (b) See Exhibit VI, Sheet 1 of the NICA 9/30/19 Loss and LAE Reserve report adjusted to estimated 2020 level - (i.e. X 1.015)
 (c) See Exhibit II, Column (7) attached.

11:30am

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

THE FLORIDA SENATE

APPEARANCE RECORD

3/24/21

Meeting Date

1786

Bill Number (if applicable)

Topic Payments for Birth-related Neurological Injuries

Amendment Barcode (if applicable)

Name Steve Winn

Job Title Executive Director

Address 2544 Blainstone Pines Dr

Phone 878-7364

Street

Tallahassee

FL

32301

Email

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/21
Meeting Date

SB 1786
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable) _____

Name Stephen Erenia

Job Title General Counsel

Address 119 S. Monroe St. Suite 202
Street

Phone 850-681-6788

City

State

Zip

Email _____

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Florida Birth-Related Neurological Injury Compensation ~~Trust~~

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 1770

INTRODUCER: Health Policy Committee and Senator Jones

SUBJECT: Genetic Counseling

DATE: March 25, 2021

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1770 creates a new licensed and regulated profession, genetic counseling, within the Department of Health (DOH), Division of Medical Quality Assurance (MQA), in part III of ch. 483, F.S., and authorizes the new practice act to be cited as the “Genetic Counseling Workforce Act.” The bill provides:

- Legislative intent and findings to establish a new profession;
- Definitions for:
 - Genetic counselor; and
 - Scope of practice of genetic counseling;
- Requirements for initial licensure, renewal, and continuing education (CE);
- Grounds for disciplinary action and penalties; and
- Exemptions from genetic counseling regulation for:
 - Commissioned medical officers of the United States Armed Forces or Public Health Service while on active duty; and
 - Health care practitioners as defined in s. 456.001, F.S., other than genetic counselors, who are practicing within the scope of their education, training, and licensure.

The bill amends s. 456.001, F.S., to include genetic counselors in the definition of a health care practitioner and makes a technical change to s. 20.43, F.S.

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

II. Present Situation:

Genetic Counselors

In 1971 the first class of master's degree genetic counselors graduated from Sarah Lawrence College in Bronxville, NY.¹

Since 2017, the University of South Florida (USF) has been the first and only accredited genetic counseling training program in Florida. The program includes a unique combination of training in medical genetics and genomics, public health, and communication and counseling skills. The genetic counseling degree is a comprehensive, 21-month, full-time program that consists of didactic and skill-based courses, multiple clinical rotations, and field experiences beginning in the first semester, independent learning opportunities, and a thesis research requirement. Upon successful completion of the program, students receive a master's of science in public health with a concentration in genetic counseling (MSPH-GC) and are eligible to sit for the national board certification exam that is administered by the American Board of Genetic Counseling (ABGC).

The program currently graduates five board-eligible genetic counselors each year. However, state licensure for the profession, if enacted, is expected to grow the program by attracting more genetic counselors to the state who can provide supervision for clinical training. USF reported receiving 18-to-20 times more applicants than the program can accommodate.²

Genetic counselors are not doctors but they may be part of the genetic health care team. They meet with individuals or families before or after genetic testing. They specialize in prenatal, pediatric, oncology, neurology, ophthalmology, psychiatry, and many other areas. They work in research, education, industry, marketing, and many other roles across the health care and genetics fields.³

Genetic counselors help patients understand:⁴

- The genetic risks based on family history;
- The genetic risks for certain diseases or cancer;
- Whether genetic testing might be right for the patient; and
- What the results of genetic tests may mean for the patient and his or her family.

With expertise in counseling, genetic counselors can also provide emotional support as patients and family make decisions and empower those individuals with information for their overall health care.⁵

¹ National Society of Genetic Counselors, *Our History*, available at <https://www.nsgc.org/About/About-NSGC> (last visited Mar. 22, 2021).

² University of South Florida, USF Health, College of Public Health, Graduate Admissions, *MSPH with a Concentration in Genetic Counseling* available at <https://health.usf.edu/publichealth/apply/graduate-admissions/genetic-counseling> (last visited Mar. 22, 2021).

³ National Society of Genetic Counselors, *Who Are Genetic Counselors?* available at <https://www.aboutgeneticcounselors.org/Who-Are-Genetic-Counselors/Who-Are-Genetic-Counselors> (last visited Mar. 22, 2021).

⁴ *Id.*

⁵ *Id.*

As of October 2020, according to the National Society of Genetic Counselors (NSGC), 26 states now license genetic counselors.⁶

Regulation of Health Care Professions

The DOH, Division of MQA, is responsible for licensing and regulating health care practitioners in order to preserve the health, safety, and welfare of the public.⁷ General licensing provisions applicable to all health care practitioners are contained in ch. 456, F.S., which also sets out in detail the regulatory policy framework. Specifically, regulation occurs when:⁸

- An unregulated practice can harm or endanger the health, safety, and welfare of the public;
- The potential for harm outweighs the potentially anticompetitive effect of the regulation;
- The public is not adequately protected by other means, of other statutes, federal law, or local ordinances; or
- Less restrictive means of regulation are not available.

The MQA has responsibility for:

- Licensing health care practitioners and certain facilities and businesses;
- Enforcing health care practitioner standards; and
- Providing licensure and disciplinary information to enable health care consumers to make more informed health care decisions.

Regulation of some professions occurs under the purview of a board or council of the DOH. A board is a statutorily-created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.⁹ In general, boards are responsible for approving or denying applications for licensure, establishing continuing education requirements, and disciplining practitioners for violations of their applicable practice act.¹⁰ Currently, the MQA licenses and regulates seven types of health care facilities and more than 200 license types in over 40 professions, while partnering with 22 boards and four councils.¹¹

Florida does not license or regulate genetic counselors.

Professional Regulation and The Florida Sunrise Act

Section 11.62, F.S., “The Sunrise Act,” sets forth legislative policy and minimum requirements for legislative review of bills proposing regulation of an unregulated occupation. In general, the Sunrise Act states that the regulation of an occupation or profession should not occur unless it is:

⁶ National Society of Genetic Counselors, *States Issuing Licenses for Genetic Counselors*, available at <https://www.nsgc.org/Policy-Research-and-Publications/State-Licensure-for-Genetic-Counselors/States-Issuing-Licenses> (last visited Mar. 22, 2021).

⁷ Section 20.43(1)(g), F.S.

⁸ Section 456.003(2), F.S.

⁹ Section 456.001(1), F.S.

¹⁰ *Id.*

¹¹ See Florida Department of Health, Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2019-2020*, available at <http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/documents/2019-2020-annual-report.pdf> (last visited Mar. 22, 2021).

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

The Sunrise Act directs the Legislature to consider the following factors when determining whether to regulate a profession:

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

The Sunrise Act also requires the proponents of the legislation to provide detailed information regarding the need and potential impact of the regulation. The Sunrise Questionnaire is used for that purpose.¹² The Sunrise Act requires the governmental agency that will be responsible for its implementation to also assess the cost of implementation, the technical sufficiency of the proposal, and whether alternatives to regulation exist.

In determining whether to recommend regulation, the legislative committee reviewing the proposal is directed to assess whether the proposed regulation is:

- Justified based on the statutory criteria and the information provided by both the proponents of regulation and the agency responsible for its implementation;
- The least restrictive and most cost-effective regulatory scheme necessary to protect the public; and
- Technically sufficient and consistent with the regulation of other professions under existing law.

Summary of the Florida Sunrise Act Questionnaire Responses

The Florida Association of Genetic Counselors (FLAGC) represents board-certified and board-eligible genetic counselors in the state of Florida. It is a state chapter of the national organization that represents genetic counselors, the National Society of Genetic Counselors or NSGC.

¹² A Sunrise Questionnaire has been provided by the proponent of the new regulation pursuant to s. 11.62(4), F.S. SB 1770 and has been submitted by The Florida Association of Genetic Counselors, *Sunrise Review for Proposed Licensing of Genetic Counselors* (on file with the Senate Committee on Health Policy).

According to FLAGC, there are currently 130 genetic counselors registered in the state of Florida certified by the American Board of Genetic Counseling. All 130 ABGC-certified genetic counselors would be subject to regulation under the bill.¹³

The FLAGC has provided to the Senate Health Policy Committee responses to the factors listed in s. 11.62(3)-(4), F.S., as evidence for the Legislature is to consider in determining whether licensure of genetic counselors is necessary to protect the health, safety, and welfare of the public. A summary of the responses follows.

Substantial Harm or Endangerment

The FLAGC's response to the substantial harm and endangerment factor is that patient harm from inadequate genetic counseling services is well-documented in published literature and patient testimonials but concedes that there is a lack of documented cases of harm to patients in the state of Florida. There is currently no state mechanism for individual patients or their providers to "look up a license" to see if the person offering or providing genetic counseling services is, in fact, appropriately trained and bound by professional standards.¹⁴

Measurability of Specialized Skill or Training

According to the FLAGC, genetic counseling is a profession that requires a large amount of measurable specialized skills and training. Genetic counseling requires extensive post-graduate training in the specialized fields of genetic medicine and psychosocial counseling, including:

- Interpretation of information about DNA variants and disorders.
- Discussing recurrence risks.
- Providing case-management and psychological support services.
- Interpreting complex genetic assays.
- Counseling clients regarding test results.

The FLAGC also points to the education genetic counselor requires to become eligible to take the ABGC certification examination, which is a minimum of 21 months or two academic years leading to a master's degree, followed by a requirement for the individual to take the ABGC Board Certification Examination, consisting of 200 multiple-choice questions based on the most recent ABGC Practice Analysis and which is conducted every three to five years.¹⁵

Unreasonable Effect on Job Creation or Retention

The FLAGC contends that allowing state licensure of genetic counselors would help lift current barriers to job creation, job retention, and the ability for individuals pursuing a career in genetic counseling to find employment while remaining in the state of Florida and that, by helping to attract and retain genetic counselors, state licensure will also help create more in-state training opportunities and increase competition in the field. Licensed health care practitioners also may

¹³ The Florida Association of Genetic Counselors (FLAGC), *Sunrise Review for Proposed Licensing of Genetic Counselors*, (on file with the Senate Committee on Health Policy).

¹⁴ *Id.*

¹⁵ *Id.*

be reimbursed for their services at higher rates than unlicensed practitioners, according to the FLAGC.¹⁶

Can the Public Be Effectively Protected by Other Means?

The FLAGC indicates that while registration or certification, rather than licensure, are lower cost options, neither would provide the legal framework for genetic counselors to specify a scope of practice, mandate CEs, regulate and impose discipline that will better protect the public, and allow them to be credentialed to practice independent of a physician and be fully integrated into health care systems.¹⁷

Favorable Cost-effectiveness and Economic Impact

The FLAGC asserts that the economic benefit and cost savings realized through state licensure of genetic counselors would far outweighs the administrative burden and fiscal impact to the state. Providing state licensure to genetic counselors would help to increase the number of genetic counselors employed within the state of Florida, according to the FLAGC, which will:¹⁸

- Expand patient access to services;
- Reduce out-of-pocket costs;
- Reduce costs to health care systems; and
- Provide a positive economic benefit to the state by increasing workforce opportunities.

III. Effect of Proposed Changes:

The bill creates the new licensed profession of genetic counseling within the DOH in part III of ch. 483, F.S., and the practice act authorizes it to be cited as the “Genetic Counseling Workforce Act;”

The bill creates:

- Section 483.912, F.S., to provide Legislative findings and intent.
- Section 483.913, F.S., to define:
 - The “department” to mean the DOH;
 - “Genetic counselor” as a person licensed to practice genetic counseling;
 - The “scope of practice of genetic counseling” as the process of advising individuals or families affected by, or at risk of, genetic disorders, including:
- Obtaining and evaluating individual, family, and medical histories to determine genetic risk for genetic or medical conditions and diseases in a patient, his or her offspring, and other family members;
- Discussing the features, natural history, means of diagnosis, genetic and environmental factors, and management of risk for genetic or medical conditions and diseases;
- Identifying, ordering, and coordinating genetic laboratory tests and other diagnostic studies as appropriate for a genetic assessment;

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

- Integrating genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic or medical conditions and diseases;
- Explaining the clinical implications of genetic laboratory tests and other diagnostic studies and their results;
- Evaluating the client's or family's responses to the condition or risk of recurrence and providing client-centered counseling and anticipatory guidance;
- Identifying and using community resources that provide medical, educational, financial, and psychosocial support and advocacy;
- Providing written documentation of medical, genetic, and counseling information for families and health care professionals; and
- Referring patients to a physician for diagnosis and treatment.
- Section 483.914, F.S., to set out the licensure requirements for any person desiring to be licensed as a genetic counselor. The bill requires the applicant to apply to DOH on a DOH-approved form. The DOH must issue a license under the bill to an applicant if he or she provides documentation of all following:
 - Good moral character;
 - Having earned:
 - A master's degree from a genetic counseling training program or an equivalent program as determined by the Accreditation Council of Genetic Counseling or its successor or an equivalent entity; or
 - A doctoral degree from a medical genetics training program accredited by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists;
 - Having taken and passed one of the following certification examinations as a genetic counselor:
 - The American Board of Genetic Counseling, Inc.;
 - The American Board of Medical Genetics and Genomics;
 - The Canadian Association of Genetic Counsellors; or
- A medical or clinical geneticist examination from:
 - The American Board of Medical Genetics and Genomics; or
 - The Canadian College of Medical Geneticists.

The DOH may also issue a temporary license for up to two years to an applicant who meets all requirements for licensure except for the examination requirement and is eligible to sit for the certification examination administered by the American Board of Genetic Counseling, Inc.

- Section 483.915, F.S., to require:
 - The DOH to renew a genetic counselor's license upon receipt of a renewal application, without any additional requirements such as those normally associated with license renewal such as continuing education (CE) credits and the reporting of arrests or convictions since the last licensure; and
 - The DOH to adopt by rule CE requirements consistent with nationally accepted standards of the American Board of Genetic Counseling, Inc.
- Section 483.916, F.S., to:
 - Prohibit any person from:

- Making a false or fraudulent statement in any application, affidavit, or statement presented to the DOH;
- Practicing genetic counseling or holding himself or herself out as a genetic counselor or as being able to practice genetic counseling or to render genetic counseling services without a license issued under the bill unless exempt from licensure;
- Using the title “genetic counselor” or any other title, designation, words, letters, abbreviations, or device tending to indicate that the person is authorized to practice genetic counseling unless that person holds a current license as a genetic counselor or is exempt from licensure.
- Provide that any person who violates the above commits a second degree misdemeanor, punishable as provided in ss. 775.082 or 775.083, F.S.
- Section 483.917, F.S., to provide:
 - That the following acts constitute grounds for denial of licensure or disciplinary action, as specified in s. 456.072(2), F.S.:
 - Attempting to obtain, obtaining, or renewing a license by fraudulent misrepresentation;
 - Having a license revoked, suspended, or otherwise acted against, including the denial of licensure in another jurisdiction;
 - Being convicted or found guilty of, or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the practice of genetic counseling, including a violation of federal laws or regulations regarding genetic counseling;
 - Making or filing a report or record that the licensee knows is false, intentionally or negligently failing to file a report or record required by state or federal law, willfully impeding or obstructing such filing, or inducing another person to impede or obstruct such filing. Such reports or records include only reports or records that are signed in a person’s capacity as a licensee;
 - Knowingly advertising services related to genetic counseling in a fraudulent, false, deceptive, or misleading manner;
 - Violating a previous order of the DOH entered in a disciplinary hearing or failing to comply with a subpoena issued by the DOH;
 - Practicing with a revoked, suspended, or inactive license;
 - Gross or repeated malpractice or the failure to deliver genetic counseling services with that level of care and skill which is recognized by a reasonably prudent licensed genetic counselor as being acceptable under similar conditions and circumstances;
 - Unprofessional conduct, including, but not limited to, any departure from or failure to conform to the minimal prevailing standards of acceptable practice, including, but not limited to, any of the following:
 - Practicing or offering to practice beyond the scope permitted by law or accepting and performing genetic counseling services the licensee knows, or has reason to know, he or she is not competent to perform;
 - Failing to refer a patient to a health care practitioner as defined in s. 456.001, F.S., if the licensee is unable or unwilling to provide genetic counseling services to the patient;
 - Failing to maintain the confidentiality of any information received under this part or failing to maintain the confidentiality of patient records pursuant to s. 456.057, unless such information or records are released by the patient or otherwise authorized or required by law to be released;

- Exercising influence on the patient or family in such a manner as to exploit the patient or family for financial gain;
- Violating this part or ch. 456, F.S., or any rules adopted pursuant thereto.
- That the DOH may enter an order denying licensure, or imposing penalties, against any applicant or licensee who is found guilty of violating any of the above or for s. 483.916, F.S.; and
- Section 483.918, F.S., to provide exemptions from the application of part III of ch. 893, F.S., for the following health care providers who also practice genetic counseling within the scope of practice of their professions:
 - Commissioned medical officers of the United States Armed Forces or the United States Public Health Service while on active duty or while acting within the scope of their military or public health responsibilities; and
 - Health care practitioners defined in s. 456.001, F.S., other than genetic counselors, who practice within the scope of their training, education, and licensure, and who are doing work consistent with that training, education, and licensure.

The bill makes two conforming and technical changes by:

- Amending s. 456.001, F.S., to include genetic counselors in the definition of health care practitioner; and
- Amending s. 20.43(8), F.S., to correct a technical error in the Florida Statutes relating to prior law under which health care professions were licensed and regulated by the Department of Business and Professional Regulation under ch. 455, F.S.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

CS/SB 1770 does not require applicants for genetic counseling licensure to pay a licensure or application fee. However, a separate bill, CS/SB 1772, provides that persons who apply to become licensed genetic counselors in Florida may be subject to an application fee of up to \$25, both for an initial application and for annual licensure renewal. *See* the staff analysis for CS/SB 1772 for further information on fees and the other provisions of that bill.

C. Government Sector Impact:

The DOH has not provided an estimated fiscal impact for the bill. The DOH will experience the costs of an increased workload to process applications for licensure and renewals and to regulate a new health care profession under the bill. The extent of these fiscal impacts is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.001 and 20.43.

This bill creates the following sections of the Florida Statutes: 483.911, 483.912, 483.913, 483.914, 483.915, 483.916, 483.917, and 483.918.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 24, 2021:

The CS:

- Defines the genetic counselor's scope of practice more specifically than the underlying bill and adds the ability to order genetic testing;
- Specifies the duration of initial licensure as two years;
- Corrects an error in the underlying bill related to the entity that actually accredits graduate programs; and

- Expands the time period in which those with temporary licenses must take the certification examination and removes the underlying bill's requirement for such an applicant to sit for the "next available" exam.

B. Amendments:

None.

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



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/24/2021	.	
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The Committee on Health Policy (Jones) recommended the following:

Senate Amendment

Delete lines 48 - 92
and insert:

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

(a) Obtaining and evaluating individual, family, and medical histories to determine genetic risk for genetic or medical conditions and diseases in a patient, his or her



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offspring, and other family members;

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

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

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

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

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

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

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

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

483.914 Licensure requirements.—

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

(2) The department shall issue a license, valid for 2



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years, to each applicant who:

(a) Has completed an application.

(b) Is of good moral character.

(c) Provides satisfactory documentation of having earned:

1. A master's degree from a genetic counseling training program or its equivalent as determined by the Accreditation Council of Genetic Counseling or its successor or an equivalent entity; or

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

(d) Has passed the examination for certification as:

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

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

(3) The department may issue a temporary license for up to 2 years to an applicant who meets all requirements for licensure except for the certification examination requirement imposed under paragraph (2) (d) and is eligible to sit for that certification examination.

By Senator Jones

35-01349-21

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A bill to be entitled

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

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

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

PART III
GENETIC COUNSELING

483.911 Short title.—This part may be cited as the "Genetic

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

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Counseling Workforce Act."

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

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

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

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

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

(a) Understand a diagnosis, the probable cause, and available options for treatment and management of a genetic disorder.

(b) Understand how heredity contributes to a genetic disorder and the risk of its occurrence.

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

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

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

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

483.914 Licensure requirements.-

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

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

(a) Has completed an application.

(b) Is of good moral character.

(c) Provides satisfactory documentation of having earned:

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

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

(d) Has passed the examination for certification as:

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

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

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

483.915 Licensure renewal and continuing education requirements.-

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

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

483.916 Prohibitions; penalties.-

(1) A person may not:

(a) Make a false or fraudulent statement in any application, affidavit, or statement presented to the department.

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

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

(2) A person who violates this section commits a

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117 misdemeanor of the second degree, punishable as provided in s.
118 775.082 or s. 775.083.

119 483.917 Grounds for disciplinary action; penalties.—

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

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

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

127 (c) Being convicted or found guilty of, or entering a plea
128 of nolo contendere to, regardless of adjudication, a crime in
129 any jurisdiction which directly relates to the practice of
130 genetic counseling, including a violation of federal laws or
131 regulations regarding genetic counseling.

132 (d) Making or filing a report or record that the licensee
133 knows is false, intentionally or negligently failing to file a
134 report or record required by state or federal law, willfully
135 impeding or obstructing such filing, or inducing another person
136 to impede or obstruct such filing. Such reports or records
137 include only reports or records that are signed in a person's
138 capacity as a licensee under this part.

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

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

145 (g) Practicing with a revoked, suspended, or inactive

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146 license.

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

152 (i) Unprofessional conduct, including, but not limited to,
153 any departure from or failure to conform to the minimal
154 prevailing standards of acceptable practice under this part and
155 department rule, including, but not limited to, any of the
156 following:

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

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

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

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

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

174 (2) The department may enter an order denying licensure to

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175 or imposing penalties against any applicant for licensure or any
 176 licensee who is found guilty of violating subsection (1) or s.
 177 483.916.

178 483.918 Exemptions.—This part does not apply to:
 179 (1) Commissioned medical officers of the United States
 180 Armed Forces or the United States Public Health Service while on
 181 active duty or while acting within the scope of their military
 182 or public health responsibilities.

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

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

190 456.001 Definitions.—As used in this chapter, the term:

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

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

200 20.43 Department of Health.—There is created a Department
 201 of Health.

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

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204 except such authority does not extend to any public records
 205 relating to the department's responsibilities for health care
 206 practitioners regulated under ~~part II~~ of chapter 456 ~~455~~.
 207 Section 4. This act shall take effect July 1, 2021.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: March 5th, 2021

I respectfully request that **Senate Bill #1770**, relating to Genetic Counselor Licenses, be placed on the:

- ☒ committee agenda at your earliest possible convenience.
- ☐ next committee agenda.

A handwritten signature in black ink, appearing to read "Shev", is written above a horizontal line.

Senator Shevrin D. "Shev" Jones
Florida Senate, District 35

Sunrise Review for Proposed Licensing of Genetic Counselors

Pursuant to Ch. 11.62 F.S., legislation proposing to establish a licensure framework for genetic counseling professionals is subject to the "Sunrise Act". The following provides evidence that licensure is necessary to protect the health, safety and welfare of the public. In addition, the proposed structure of licensure is minimally restrictive and ensures that genetic counseling services are widely available to the public.

The following factors are set forth in underscoring the importance of licensing genetic counselors:

a) *Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;*

The harm from inadequate genetic counseling services is well-documented in published literature as well as patient testimonials. While the potential for harm to Florida patients is recognizable and not remote, there is currently no state mechanism for individual patients or their providers to ensure a person offering genetic testing or providing "genetic counseling" services are in fact appropriately trained and bound by professional standards. Additionally, there is a lack of documented cases of harm to patients in the state of Florida, in no small part because there is no mechanism through which complaints about inappropriate genetic counseling may be lodged. However, there is a dearth of published literature on the harms of inadequate genetic counseling services as well as genetic counseling services being provided by non-genetic counselors.

The main responsibility of most genetic counselors is to provide direct patient care. As with any healthcare profession, inappropriate or inaccurate medical care could potentially harm clients with whom an inadequately trained genetic counselor has contact. Harm may also occur secondary to the client receiving the services from a non-genetics healthcare provider. Studies have shown that clinical errors are more likely in situations in which providers had less extensive knowledge, training, or certification in genetics. Genetic counselor licensure requiring that genetic counselors maintain their certification through continuing education would reduce these types of errors.

Additionally, licensure would allow action to be taken against a licensed genetic counselor who violates standard of practice. Harm to clients has been documented in cases where genetic counseling services are provided inappropriately, erroneously, or incompetently. Genetic counselors act as patient advocates for their clients, ensuring they are provided complete and accurate information as they navigate complex health care systems and often under stressful and emotional conditions.

Further, the lack of state licensure prevents genetic counselors from being credentialed to practice as independent practitioners and prevents health care systems from having a legal framework for scope-of-practice. Not only does the current system harm patient access and increase costs, it is depressing the number of genetic counselors practicing in the state of Florida despite rising demand for genetic services. This is evident through Florida having one of the lowest genetic counselor to patient ratios in the country, which further harms patient access and therefore the public's health and welfare.

Note: On pages 14-20 of this review, we provide specific documented examples of harm arising from inadequate genetic counseling services. This includes documented cases from across the country as well as cases from Florida.

b) *Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;*

By requiring board certification of the American Board of Genetic Counseling (ABGC) or Active Candidate Status as a condition of licensure to practice as a genetic counselor in Florida, we can provide a readily measurable or quantifiable standard that reasonably ensures examination or training requirements will assure initial and continuing professional or occupational ability. We would also be providing a quality standard that would be implemented to report and investigate suspected substandard practice and take disciplinary action, if necessary.

The practice of genetic counseling is distinguished from other healthcare practices by the extensive training required in the specialized fields of genetic medicine and psychosocial counseling. Genetic counselors identify families at risk for genetic disorders, investigate the nature of familial medical problems, and analyze inheritance patterns. They also interpret information about DNA variants and disorders, discuss recurrence risks, and provide case-management and psychological support services. Because of their intensive training, board certified genetic counselors are able to interpret complex genetic assays and can appropriately counsel clients regarding test results.

Genetic counselors also receive extensive clinical training in counseling techniques, equipping them with the ability to respond to the psychological dimensions of medical issues. Some of the functions that genetic counselors perform, such as obtaining a medical and family history, providing information regarding a particular diagnosis, and promoting client-centered decision-making are similar to the functions that physicians, physician assistants, nurse practitioners, dentists, chiropractors and nurses perform.

Because of their unique combination of specialized knowledge and skill sets, in the absence of a physician medical geneticist, genetic counselors function as the “genetics expert” on multidisciplinary healthcare teams.

Training of board certified genetic counselors is done within 2-year Master’s programs, of which there are currently 47 programs accredited across the U.S. - including one at the University of South Florida. The Standards for Graduate Programs in Genetic Counseling Seeking Accreditation by ACGC (the Standards) includes a separate section detailing the Practice-Based Competencies for entry-level genetic counselors. The Standards require genetic counseling master’s degree-granting programs to reside in a graduate degree-granting institution that is accredited by a regional accrediting association recognized by the U.S. Department of Education (or the equivalent provincial authority for Canadian educational institutions). Program duration must be a minimum of 21 months or two academic years. Instructional content must cover

established and evolving medical and clinical genetics principles and how genetic counselors apply this knowledge to patient care. This content must be sufficient in breadth and depth to prepare the student for the clinical practice of genetic counseling.

Substantial clinical training and fieldwork experience is also required to train genetic counseling graduate students. This training provides students with first-hand experience working in a variety of practice settings with individuals and families affected by a broad range of genetic conditions. A minimum of 50 “core cases” is required to develop fundamental genetic counselor skills that they can effectively apply in a wide variety of clinical settings and service-delivery models. An experienced, board-certified geneticist and/or board-certified genetic counselor must directly supervise these cases.

Cases must expose students to a variety of genetic issues throughout the life cycle, including preconception counseling, prenatal counseling, pediatric genetics, and adult and pre-symptomatic genetics. A subset of core cases must include direct work with individuals symptomatic for genetic conditions, as well as experience in conducting family sessions in which multiple family members are evaluated and/or counseled. To further enhance students’ clinical training, the core cases are augmented with additional fieldwork experiences in settings such as diagnostic laboratories, telemedicine clinics, research programs, public health clinics, and healthcare settings that include interacting with non-geneticists (non-geneticist physicians, nurses, nutritionists, etc.).

Because genetic counselors play a significant role in educating patients, other health professionals, students, and the public, graduate programs must include teaching opportunities with a variety of learners for their students. Programs are also required to provide students with instruction, observation, and participation in genetic laboratory activities so that they may become proficient in genetic-testing utilization, learn to choose appropriate clinical and research laboratories to send patient samples, and understand the analytic and clinical validity and clinical utility of various types of genetic testing. Students are also required to conduct research or other scholarly activities through a formal thesis, capstone project, or other independent-research project.

The Standards’ Practice-Based Competencies recognize that genetic counselors work in various settings and provide services to diverse clients, including patients and their families in healthcare settings, other healthcare professionals, research subjects, and the public. An entry-level genetic counselor must demonstrate the practice-based competencies to successfully practice as a genetic counselor. The didactic and experiential training components of a graduate genetic counseling curriculum must help develop these competencies. The Competencies are organized into the following domains, which can be applied in the varied practice settings in which genetic counselors serve their clients: (I) Genetics Expertise and Application; (II) Genetic Counseling Skills; (III) Education; and (IV) Professional Development & Professional Practice. Specific learning objectives accompany each competency and illustrate the skills that reflect achievement of the competency.

In 1996, the Accreditation Committee of the American Board of Genetic Counseling (ABGC) published minimum competencies necessary to enter the genetic counseling profession (Fine et al., *Journal of Genetic Counseling*, 1996, 5(3): 113-21. Established in 1993, ABGC defined and implemented the first comprehensive graduate program accreditation standards and minimum

competencies for entry-level genetic counselors in 1996. Although the American Board of Medical Genetics (ABMG) provided genetic counselor board certification prior to ABGC's creation, ABMG only accredited the clinical-training sites that genetic counselors and medical genetics fellows used—not the didactic/academic portion of genetic counseling graduate programs. Beginning in 2013, the accrediting function of the ABGC transitioned to a newly-incorporated organization, the Accreditation Council of Genetic Counseling. In the same year, a task force of this organization was convened to update the genetic counseling practice-based competencies. (Doyle et al., Journal of Genetic Counseling, 2016, 25(5):868-79.

Graduates of ACGC-accredited genetic counseling training programs are expected to have achieved these entry-level competencies and are thus eligible to apply for Active Candidate Status (ACS) to sit for the national certification examination that ABGC administers. Importantly, certification or ACS is not currently required for employment as a genetic counselor in Florida.

c) *Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;*

Allowing state licensure would help lift current barriers to job creation, job retention, and the ability for individuals pursuing a career in genetic counseling to find employment while remaining in the state of Florida. By helping to attract and retain genetic counselors, state licensure will also help create more in-state training opportunities and increase competition in the field.

1) Licensure would not impose significant burdens on individuals practicing or seeking to practice genetic counseling. The primary requirement for licensure is board-certification as a genetic counselor by the American Board of Genetic Counseling (ABGC) and/or American Board of Medical Genetics and Genomics (ABMGG), and for temporary licensure, active-candidate status (board eligible) for the ABGC-certification examination. Board certification is obtained by a national standardized examination that ABGC administers.

- According to our data, 98% of currently practicing genetic counselors in Florida are board-certified or eligible for active candidate status and would be eligible to apply for licensure. A grandfather clause could also potentially be inserted for those who have been practicing in the state since before certification became available, which would capture even more genetic counselors as eligible.

- Employers want to hire genetic counselors who are already board-certified as a minimum requirement as the field of genetics is increasingly complex.

- Those who are not board-certified currently work in roles where they do not call themselves genetic counselors but have other titles related to their occupation. For example – “medical science liaison” or “patient advocate”. Their ineligibility for licensure will allow them to continue in their roles since they do not use the title “genetic counselor” and most do not provide clinical genetic counseling services in these roles.

- Therefore requiring this standard is not imposing any extra burden on those within or seeking to enter the profession.

2) Conversely, the lack of state licensure for board certified genetic counselors creates a barrier to in-state employment opportunities that allow them to practice at the height of their competency. This results in genetic counselors seeking employment opportunities outside of the state in one of the 29 states which license them. This is demonstrated by the 2020 analysis by the U.S. Government Accountability Office which shows the state of Florida as having one of the lowest patient:genetic counselor ratios in the country despite growing demand.

- Demand for trained genetic counselors has rapidly increased as health care delivery moves towards a precision medicine model and the demand, availability, technology, usefulness, and complexity of genetic testing continues to rapidly expand. Not only is genetic counseling one of the fastest growing STEM professions in the country, but competitive salary rates for genetic counselors have also steadily grown. The Bureau of Labor Statistics projects the genetic counselor workforce to grow at more than twice the rate of other similar technical and medical professions. Data collected by the NSGC on newly certified genetic counselors prove an even higher rate of growth than what the BLS has estimated.

- With the extremely low genetic counselor-to-patient ratio, many Florida constituents are actually receiving genetic counseling services via telehealth from out-of-state genetic counselors due to the lack of genetic counseling services in Florida. In addition to ensuring these out-of-state practitioners are providing appropriate and quality genetic counseling services to people living in Florida, licensure will allow us to bring more genetic counselors to the state of Florida, creating new job opportunities, and increasing access to services. This has been the trend in other states who have already obtained licensure.

- The U.S. The Government Accountability Office analysis in 2020 shows a clear concentration of genetic counselor workforce in states who established licensure. The state of Utah became the first to implement licensure in 2002. Utah is now home to one of the largest genetic counselor workforces as well as the headquarters for a number of businesses focused on the growing field of genetics services. Before the State of Ohio passed licensure in 2012, Ohio State University Medical Center (OSU) had one cancer genetics clinic seeing an average of 6 patients per week. Immediately post licensure, genetic counselors were credentialed to practice independently. They went from seeing 6 patients per week to seeing 16 patients. They also opened two additional clinics, each seeing 16 patients per week. OSU alone now has more genetic counselors practicing clinically than the entire state of Florida. Licensure not only increased the state's Genetic Counselor workforce, it improved access dramatically.

3. Licensure would also not harm or impact other professions whose scope of service overlaps with genetic counselors.

- Other practitioners, such as physicians and nurses, who are appropriately credentialed under their own regulatory systems, will still be able to provide genetic assessment, advice, and referral as defined by their role, training, and scope of practice.

- The National Coalition for Health Professional Education in Genetics had developed baseline competencies in genetics for all health professionals. These guidelines stress the importance of collaboration between genetic counselors and other health professionals in providing quality, coordinated care for patients with genetic concerns.

- Genetic counselors work closely with other genetics specialists, and genetic counselor licensure would not preclude such specialists from practice. Physician and Ph.D. medical geneticists receive board certification from the American Board of Medical Genetics (ABMG). The Nurse Portfolio Credentialing Commission (NPCC) provides certification for nurses

practicing in medical genetics: The Advanced Clinical Genomics Nurse credential, abbreviated as ACGN, is offered to nurses with a minimum of a Master degree, and the Clinical Genomics Nurse credential, abbreviated as the CGN, is offered to nurses with a Baccalaureate degree.

d) *Whether the public is or can be effectively protected by other means;*

While certification of genetic counselors establishes initial competency and ongoing education, licensure will provide the legal framework for genetic counselor's specific scope of practice that will allow them to be credentialed to practice independent of a physician and be fully integrated into health care systems. Other methods that can be considered by the state to regulate the profession are described below. It should be stressed that while these regulatory models may address patient harm, none of the below regulations provide the workforce growth opportunities and economic benefit to the state that state licensure provides. The lack of licensure is depressing the workforce and blocking Floridians from opportunities available in other states. Available alternative regulatory schemes could result in additional administrative burden and additional regulations without resolving this key issue. State licensure will increase the likelihood that institutions will credential genetic counselors and, in turn, more hospitals, clinics, and private practices will hire genetic counselors. This could lead to more genetic counselors locating in Florida and thereby grow Florida's workforce, increasing access and affordability. Lack of access to a qualified genetic counselor can harm the public as individuals with genetic concerns cannot receive expert care from the healthcare practitioner who is most uniquely and specifically qualified to provide clinical genetic information, risk assessment, genetic testing and results discussion, psychosocial assessment, and support resources appropriate to their individual situation and needs.

Specific to protection of the public, licensure would provide Florida with the authority to take disciplinary action. Currently, there are no existing laws in Florida or at the federal level that provide the public with a mechanism to report a genetic counselor's incompetent, unethical, or unlawful behavior or to sanction a genetic counselor for proven offenses of these claims and/or for operating outside of his/her scope of practice.

Alternative Regulatory Schemes:

Registration of All Practitioners

Registration typically imposes baseline criteria for the practice of a skill or profession, but does not: 1) establish foundational training requirements; 2) provide a 'scope of practice;' 3) mandate continuing education; and 4) provide recourse for consumers. Although this alternative is low-cost, it has essentially no value to protecting the public because it does not distinguish capable from incapable practitioners. Further, this would not address the barriers to employment opportunities or the state's low genetic counselor workforce population, resulting in a lack of access to competent services and increased health care costs for patients.

Establishing a Protected Title for the Occupation via State Credentialing

A protected title presumably would identify practitioners who have graduated from an approved course of training, but would not require that they become board certified or maintain their skills and knowledge base through continuing education. This also would afford little protection to the public, given the rapid evolution of the genetic counseling field. This process would be preferable to registration and cost less than licensure, but would not provide the necessary level of oversight.

Further, this would not address the barriers to employment opportunities or the state's low genetic counselor workforce population, resulting in a lack of access to competent services and increased health care costs for patients.

Credentialing of All Practitioners

Local credentialing (*e.g.*, by employers) potentially could have a favorable effect on the quality of genetic counseling, but on an *ad hoc* basis. Some employers might require graduation from an accredited training program and certification by a national board, while others might not.

Without statutory licensure, a uniform scope of practice, and enforceable continuing education requirements, the public's interest cannot be adequately protected. For this reason, the majority of health care providers and hospital bylaws require state licensure to credential genetic counselors as independent practitioners. If the state were to require third-party credentialing for genetic counselors, the majority of health provider and hospital bylaws would still not allow the full benefit of credentialing genetic counselors as they specifically require state licensure.

Without a legal framework that the majority of health care providers accept for credentialing purposes, credentialing at the local level or via third-party would still not address the barriers to employment opportunities or the state's low genetic counselor workforce population. This results in a lack of access to competent services and increased health care costs for patients.

e) *Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.*

The economic benefit and cost savings realized through state licensure of genetic counselors far outweighs the administrative burden and fiscal impact to the state. Providing state licensure to genetic counselors will help to increase the number of genetic counselors employed within the state of Florida, which will: expand patient access to services, reduce out-of-pocket costs, reduce costs to health care systems, and provide a positive economic benefit to the state by increasing workforce opportunities for Floridians. Additionally, the administrative burden is minimal as the primary requirement for state licensure is to be certified by the American Board of Genetic Counselors. This is easily verifiable and, therefore, it provides a straightforward process for validation that requires minimal labor and time.

Currently, the state of Florida has by far one of the lowest patient:genetic counselor ratios in the country according to a 2020 Government Accountability Office report on Genetic Counselor and Medical Geneticist Workforces. The lack of state licensure is resulting in certified genetic counselors seeking employment outside of the state. Meanwhile, the demand for genetic counselors is rapidly growing, leaving providers with limited choices, including contracting with out-of-state services. The Bureau of Labor Statistics projected the genetic counselor workforce to grow at more than twice the rate of other similar technical and medical professions, however data collected by the NSGC on newly certified genetic counselors show the rate of growth is dramatically higher. The lack of state licensure places Florida at a competitive disadvantage at attracting new and retaining genetic counselors. Licensure will increase in-state employment and training opportunities for this fast growing state profession.

Licensure can reduce the costs to patients and payers for genetic counseling services. If a genetic counselor's services are billed under the genetic counselor's name, the cost for the same service is less than what a physician would bill for the same service. The lack of licensure for genetic counselors in Florida prevents these uniquely trained healthcare providers from being

credentialed within a hospital. As a result, many institutions bill “incident to” a physician for the routine genetic counseling services that employed genetic counselors provide. These services are then billed to third-party payers and self-paying clients at a physician rate. Physicians must also spend time directly overseeing these services that credentialed genetic counselors could otherwise provide in a more efficient, independent manner. Other hospitals use a “facility fee” to charge patients for genetic counselors' services. Often this can amount to \$300-\$400 not covered by the insurance. This makes genetic counseling services only accessible to those who financially can afford the high out of pocket cost to meet with a genetic counselor.

Third-party payers are more likely to cover clinically indicated tests, which leads to less out-of-pocket cost to the patient. Patients report fewer barriers to obtaining preventive screening, such as mammograms, following genetic counseling.

- Watson, M. Does genetic counseling have any impact on management of breast cancer risk? Genet Test 9, 167-74 (2005)

A genetic counselor is trained to identify the correct and most cost-effective test for the patient's clinical indication. Studies have shown genetic counselors can save hospital systems on average up to \$50,000 per month with the appropriate use of genetic testing

- - Miller C. Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing. Am J Med Genet A 164A, 1094-101 (2014); Riley, JD, et al. Improving Molecular Genetic Test Utilization through Order Restriction, Test Review, and Guidance. J Mol Diagnostics. 17(3), 225-9 (2015)

Further pursuant to Ch.11.63 F.S., the following information is put forward pertaining to the proposed legislation:

a) *The number of individuals or businesses that would be subject to the regulation;*

There are currently 130 genetic counselors registered in the state of Florida certified by the American Board of Genetic Counseling (www.abgc.net). All 130 ABGC certified genetic counselors would be subject to the regulation.

In addition, 62 genetic counselors are listed as providing services over-the-phone to patients in Florida (per www.FindAGeneticCounselor.com), and only 15 are currently included in the 130 genetic counselors with ABGC certification in Florida. This means as many as 47 additional providers would require licensure.

In addition to genetic counselors already providing services in Florida, many Florida healthcare organizations are hiring genetic counselors for the first time as demand continues to increase.

Since 2017, the University of South Florida has hosted the only accredited genetic counseling training program in Florida. The program currently graduates 5 board-eligible genetic counselors each year. However, state licensure is expected to grow the program by attracting more genetic counselors to the state who can provide supervision for clinical training. USF reported they receive 18-20 times more applicants than the program can accommodate. New applications for genetic counseling licenses are expected to be sustained with job growth and graduates from the current, as well as any future, in-state training program.

b) *The name of each association that represents members of the profession or occupation, together with a copy of its codes of ethics or conduct;*

The Florida Association of Genetic Counselors (FLAGC) represents all board certified and board eligible genetic counselors in the state of Florida. This is a state chapter of the national organization that represents genetic counselors--the National Society of Genetic Counselors. Their code of ethics is below.

Additional associations that represent genetic counselors among other medical professionals include the American Society of Human Genetics and the American College of Medical Genetics. The American Society of Human Genetics has a code of ethics also provided below, however the American College of Medical Genetics does not have a code of ethics.

FLAGC Code of Ethics: FLAGC abides by the same code of ethics as NSGC.
Download a PDF copy of the [NSGC Code of Ethics](#).

- **Preamble & Introduction**
- **SECTION I: Genetic Counselors Themselves**
- **SECTION II: Genetic Counselors and Their Clients**
- **SECTION III: Genetic Counselors and Their Colleagues**
- **SECTION IV: Genetic Counselors and Society**

Preamble

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. The National Society of Genetic Counselors (NSGC) is the leading voice, authority and advocate for the genetic counseling profession. Through this code of ethics, the NSGC affirms the ethical responsibilities of its members. NSGC members are expected to be aware of the ethical implications of their professional actions and work to uphold and adhere to the guidelines and principles set forth in this code.

Introduction

A code of ethics is a document that attempts to clarify and guide the conduct of a professional so that the goals and values of the profession are best served. The NSGC Code of Ethics is based upon the distinct relationships genetic counselors have with 1) themselves, 2) their clients, 3) their colleagues, and 4) society. Each section of this code begins with an explanation of the relevant relationship, along with the key values and characteristics of that relationship. These values are drawn from the ethical principles of autonomy, beneficence, nonmaleficence and justice, and they include the professional principles of fidelity, veracity, integrity, dignity and accountability.

No set of guidelines can provide all the assistance needed in every situation, especially when different values appear to conflict. In certain areas, some ambiguity remains, allowing for the judgment of the genetic counselor(s) involved to determine how best to respond to difficult situations.

Section I: Genetic Counselors Themselves

Genetic counselors value professionalism, competence, integrity, objectivity, veracity, dignity, accountability and self-respect in themselves as well as in each other. Therefore, genetic counselors work to:

1. Seek out and acquire balanced, accurate and relevant information required for a given situation.
2. Continue their education and training to keep abreast of relevant guidelines, regulations, position statements, and standards of genetic counseling practice.
3. Work within their scope of professional practice and recognize the limits of their own knowledge, expertise, and competence.
4. Accurately represent their experience, competence, and credentials, including academic degrees, certification, licensure, and relevant training.
5. Identify and adhere to institutional and professional conflict of interest guidelines and develop mechanisms for avoiding or managing real or perceived conflict of interest when it arises
6. Acknowledge and disclose to relevant parties the circumstances that may interfere with or influence professional judgment or objectivity, or may otherwise result in a real or perceived conflict of interest.
7. Assure that institutional or professional privilege is not used for personal gain.
8. Be responsible for their own physical and emotional health as it impacts their professional judgment and performance, including seeking professional support, as needed.

Section II: Genetic Counselors and Their Clients

The counselor-client relationship is based on values of care and respect for the client's autonomy, individuality, welfare, and freedom in clinical and research interactions. Therefore, genetic counselors work to:

1. Provide genetic counseling services to their clients within their scope of practice regardless of personal interests or biases, and refer clients, as needed, to appropriately qualified professionals.
2. Clarify and define their professional role(s) and relationships with clients, disclose any real or perceived conflict of interest, and provide an accurate description of their services.
3. Provide genetic counseling services to their clients regardless of their clients' abilities, age, culture, religion, ethnicity, language, sexual orientation and gender identity.
4. Enable their clients to make informed decisions, free of coercion, by providing or illuminating the necessary facts, and clarifying the alternatives and anticipated consequences.
5. Respect their clients' beliefs, inclinations, circumstances, feelings, family relationships, sexual orientation, religion, gender identity, and cultural traditions.
6. Refer clients to an alternate genetic counselor or other qualified professional when situations arise in which a genetic counselor's personal values, attitudes and beliefs may impede his or her ability to counsel a client.
7. Maintain the privacy and security of their client's confidential information and individually identifiable health information, unless released by the client or disclosure is required by law.
8. Avoid the exploitation of their clients for personal, professional, or institutional advantage, profit or interest.

Section III: Genetic Counselors and Their Colleagues

The genetic counselors' professional relationships with other genetic counselors, trainees, employees, employers and other professionals are based on mutual respect, caring, collaboration, fidelity, veracity and support. Therefore, genetic counselors work to:

1. Share their knowledge and provide mentorship and guidance for the professional development of other genetic counselors, employees, trainees and colleagues.
2. Respect and value the knowledge, perspectives, contributions, and areas of competence of colleagues, trainees and other professionals.
3. Encourage ethical behavior of colleagues.
4. Assure that individuals under their supervision undertake responsibilities that are commensurate with their knowledge, experience and training.
5. Maintain appropriate boundaries to avoid exploitation in their relationships with trainees, employees, employers and colleagues.
6. Take responsibility and credit only for work they have actually performed and to which they have contributed
7. Appropriately acknowledge the work and contributions of others.
8. Make employers aware of genetic counselors' ethical obligations as set forth in the NSGC Code of Ethics.

Section IV: Genetic Counselors and Society

The relationships of genetic counselors with society include interest and participation in activities that have the purpose of promoting the well-being of society and access to genetic services and health care. These relationships are based on the principles of veracity, objectivity and integrity. Therefore, genetic counselors, individually or through their professional organizations, work to:

1. Promote policies that aim to prevent genetic discrimination and oppose the use of genetic information as a basis for discrimination.
2. Serve as a source of reliable information and expert opinion on genetic counseling to employers, policymakers, payers, and public officials. When speaking publically on such matters, a genetic counselor should be careful to separate their personal statements and opinions made as private individuals from statements made on behalf of their employers or professional societies.
3. Participate in educating the public about the development and application of technological and scientific advances in genetics and the potential societal impact of these advances.
4. Promote policies that assure ethically responsible research in the context of genetics.
5. Adhere to applicable laws and regulations. However, when such laws are in conflict with the principles of the profession, genetic counselors work toward change that will benefit the public interest.

The American Society of Human Genetics code of ethics:

American Society of Human Genetics Code of Ethics

The American Society of Human Genetics (ASHG) is a membership organization that includes multidisciplinary professionals with a common interest in human genetic research and clinical practice. Society members contribute to the advancement of science for the benefit of health.

The Code of Ethics provides an ethical framework for members as they work to further the aims of ASHG. Members act in a manner consistent with the good reputation of the Society. Members do not represent the Society as such. This Code of Ethics does not replace the ethical

or legal obligations of individual members as set by their own professional bodies, employers, or applicable legislation.

Advancement of Science

Members advance both fundamental and applied knowledge in human genetics for the benefit of the public.

Improvement of health care

Promote public health, through the advancement of human genetic research and the provision of high quality genetic services.

Training

Educate employees, students, and professionals to follow responsible research practice and genetic services, consistent with the highest ethical standards. Treat trainees with respect and provide them with opportunities for professional growth and development.

Collaboration

Share knowledge in research, practice, and ethics through publication, professional meetings, and conferences. Encourage interprofessional and international collaboration for the benefit of health care. Meet applicable ethical and legal standards while conducting collaborations.

Integrity

Members comply with the highest ethical standards such as honesty and courtesy. They conduct themselves with appropriate behavior and attitudes.

Maintain professional competence

Advance their knowledge and understanding of new scientific developments and emerging areas of practice through ongoing education and training.

Respect professional codes of ethics

Abide by the prevailing ethical and legal norms of their profession.

Objectivity

Approach professional activities with an unbiased attitude, gathering evidence fairly and precisely.

Accountability

Act responsibly toward colleagues, government, corporate sponsors, the wider health care community and the public at large. Build public trust through accountability.

Collegiality

Treat colleagues and researchers with respect and courtesy, based on principles of equality and mutual respect for those with differing worldviews or from different cultures. Share ideas honestly, giving proper credit for others' contributions to their work.

Privacy

Members protect the privacy of the individual, especially in light of concerns over possible discrimination and confidentiality of medical information.

Confidentiality

Respect the confidential nature of all information entrusted to them. Disclose personal health information with proper and specific authority through the consent of the individual or where there is a legal, ethical or professional right or duty to disclose.

Storage and security

Maintain confidentiality in creating, storing, accessing, transferring, and disposing of personal health information.

Transparency

Members act fairly and provide complete, accurate and timely information to their colleagues, to the public, and to the media.

Professionalism

Claim expertise in fields where they have the necessary depth of knowledge, especially when interacting with patients, or contributing to public discussion or policy debate. Do not make statements that are false, deceptive, or fraudulent concerning research, practice, or other work activities, or those of persons or groups with whom they are affiliated.

Conflicts of interest

Disclose any potential conflicts of interest. Safeguard the quality and credibility of their professional judgment.

Diffusion of results

Report findings, accurately and completely, without distortion and in a timely manner. Present personal opinions as such and not as those of the Society.

Public education

Foster public understanding of the nature and objectives of human genetics consistent with open and responsible use of human genetic findings in science and health care.

c) *Documentation of the nature and extent of the harm to the public caused by the unregulated practice of the profession or occupation, including a description of any complaints that have been lodged against persons who have practiced the profession or occupation in this state during the preceding 3 years;*

Unfortunately due to the current lack of infrastructure for complaints to be filed against persons practicing genetic counseling in Florida, official documentation is unavailable. However, the practice of genetic counseling in general has been shown to risk harm when performed by unqualified individuals as reported in published literature.

The main responsibility of most genetic counselors is to provide direct patient care. As with any healthcare profession, inappropriate or inaccurate medical care could potentially harm clients with whom an inadequately trained genetic counselor has contact. Harm may also occur secondary to the client receiving the services from a non-genetics healthcare provider. Studies have shown that clinical errors are more likely in situations in which providers had less extensive knowledge, training, or certification in genetics.

Genetic counselor licensure requiring that genetic counselors maintain their certification through continuing education would reduce these types of errors. Additionally, licensure would allow action to be taken against a licensed genetic counselor who violates standard of practice. Below are some examples of harm to clients that may occur if genetic counseling services are provided inappropriately, erroneously, or incompetently. This includes documented cases from across the country as well as cases from Florida.

Incomplete Risk Assessment

- Harm may occur if practitioners do not take the time to elicit complete family history information. A client with a personal history of early-onset breast cancer and a family history of breast cancer may be considered at increased risk for hereditary breast/ovarian cancer syndrome and tested for BRCA1 and BRCA2 mutations. However, there are other breast cancer syndromes to consider as well, such as Cowden syndrome, which involves increased risk for breast, thyroid, and uterine cancers and has other physical features such as a large head circumference and benign skin and colon tumors.
 - A genetic counselor, who as standard practice reviews breast cancer family histories for such manifestations and identifies client medical information relevant to risk-assessment and consideration of differential diagnoses, may note that the patient has a large head and skin growths suggestive of this condition. Missing the possibility of Cowden syndrome may result in harm to the patient. The screening recommendations for Cowden syndrome include breast-cancer screening/medical management options, thyroid examinations, uterine and gastrointestinal cancer screening, and are different than the recommendations made for an individual with hereditary breast/ovarian cancer syndrome.
- A non-genetics provider diagnosed a patient with vision loss and muscle problems as having a mitochondrial disorder. This diagnosis remained with the patient for years. When the patient presented for genetic counseling, the genetic counselor took a detailed family history and determined that the patient was incorrectly diagnosed. The patient instead had an autosomal dominant-vision condition and his muscle problems were not believed to be of genetic etiology.
 - This impacts the prognosis for his children, who all inherited their father's vision condition and were fearful of developing muscle problems as well. This case demonstrates that a lack of complete family history, which genetic counselors provide as part of routine genetic counseling, can lead to a misdiagnosis. In this case, misdiagnosis led to incorrect risk assessment for this patient's children, causing unnecessary emotional stress. The children also underwent medical consultations related to the muscle problems and incurred associated financial costs that were likely not necessary given the non-hereditary nature of their father's symptom.
- A primary care provider referred a pregnant patient to a certified genetic counselor because of an incidental variant finding on an ultrasound that is not associated with increased risk. In reviewing her records prior to the consultation appointment, the genetic counselor found that the patient was a carrier of a chromosomal change that may place her pregnancy at increased risk for an unbalanced chromosome make-up.
 - In light of this finding, the patient's physician should have referred her for genetic counseling and offered the option of prenatal genetic testing. However, the primary care provider had not reviewed the records of the infertility specialist who had ordered the testing before the patient became pregnant. Although the laboratory report recommended genetic counseling, the infertility specialist had also not referred her for genetic counseling. This case attests to the critical importance of genetic counselors' specific training in medical records review and family history intake that leads to comprehensive evaluation and greater depth of information for the patient. Potential harm to the patient occurs when he/she is not correctly counseled for his/her risks. In this case, the baby could have had a potentially fatal diagnosis. Since this family received genetic counseling they had additional options available to them (such as an amniocentesis) that they may not have been offered if not for the genetic counselor.

- A pregnant woman had an increased risk for her baby to have a chromosome anomaly. She had received prenatal genetic counseling from an unlicensed genetic counselor in another state (genetic counselor state licensing not available at that time). The patient chose to have chorionic villus sampling (CVS) for the risk of aneuploidy (abnormal chromosome number). The baby was chromosomally normal on CVS, but the baby was born with a transverse limb defect resulting in severe malformation of the hand and lower arm.

- The family was emotionally devastated. The child would face physical challenges throughout life. Theoretically, the transverse limb defect could be a consequence of the CVS procedure. This should have been discussed as a potential risk before the test. The family did not recall getting this information and the family sued the hospital employing the genetic counselor for inadequate pre-test counseling. The genetic counselor, considered a very competent professional in the community, continued to practice. If licensure were in place, appropriate regulatory sanctions could have been taken against this genetic counselor.

Inaccurate Test Interpretation

- In 1997, *The New England Journal of Medicine* published several examples of incorrect counseling and test interpretation (Giardiello et al., NEJM, 1997, 336 (12):823-7). The authors reviewed 177 cases for individuals undergoing predisposition genetic testing for familial adenomatous polyposis (FAP), an inherited condition that leads to colon cancer at an unusually early age. This cancer can be prevented with appropriate surgical intervention, making accurate test-interpretation critical. Eighteen percent of the patients underwent genetic counseling prior to genetic testing and received accurate interpretations of their genetic test results. Thirty percent of the remaining patients who did not receive genetic counseling received the wrong test interpretation. In these cases, healthcare providers incorrectly interpreted inconclusive test results to mean that the patients did not have FAP mutations. The consequences of this misinterpretation are potentially devastating since these individuals would likely stop endoscopic screening because they were told that they were no longer at an elevated risk for colon cancer.

- A woman requested genetic counseling after her pregnant sister underwent carrier testing for cystic fibrosis (CF) and was found to carry the 5T allele, a harmless genetic variant in the gene responsible for CF. Although the patient's sister was told that the 5T allele is harmless, she did not receive adequate counseling. This caused the family unnecessary alarm. Fortunately, this woman sought genetic counseling to completely discuss the implications of this genetic finding, but other patients may be stranded with incomplete or inaccurate information.

- A physician referred a patient to a certified genetic counselor to help interpret a genetic test result. The client has a family history of Huntington disease (HD), an adult-onset neurological condition that affects movement, behavior, and thinking and is a fatal diagnosis. When the client mentioned her family history to her primary care physician, he ordered the HD genetic test without providing pretest counseling or obtaining adequate informed consent. The physician was unaware of the well-established HD presymptomatic testing protocol, which includes genetic counseling and psychiatrist and neurologist evaluations. The genetic test results were indeterminate, which the primary care physician had not discussed as a possibility with the client—and he could not interpret the results. The client experienced heightened anxiety and regretted that she had undergone genetic testing.

- A physician referred a pregnant woman to a certified genetic counselor because her nephew was affected with Duchenne muscular dystrophy (DMD), an X-linked genetic condition

affecting males and results in early death. Based on her family history, she was at risk to be a carrier—and at risk to have an affected child. She reported having had prenatal testing (amniocentesis) in a prior pregnancy that showed that the baby did not inherit DMD. As is customary, the genetic counselor requested records from the previous care provider. Records showed that an amniocentesis had been performed and chromosomes revealed a male fetus. Records did not show that a fetal sample had been sent to a reference laboratory for testing. Further investigation revealed that carrier testing on the patient had been uninformative, i.e. it could not be confirmed or denied that she is a carrier of DMD.

- Because her carrier status could not be determined, the prior pregnancy could not have been tested. The patient reported that the provider performing the amniocentesis told her that the testing indicated she would have an unaffected male child, although the testing on the pregnancy had not occurred. No genetic counselor was involved in her case. This exemplifies the misinformation that a patient can receive when a provider does not understand complex genetic information—and the provider's neglect for not referring the patient to a qualified genetics professional.

- A physician referred a pregnant patient who was older than 35 to a certified genetic counselor to discuss prenatal testing. The patient's history revealed a prior miscarriage that had been diagnosed as having Turner syndrome, a chromosomal condition caused by a missing sex chromosome. The records indicated that a physician had ordered chromosomal studies for both the patient and her husband. However, in this situation, chromosome studies of the parents were not indicated and provided no information regarding risks for future pregnancy.

- Turner syndrome has a low risk for recurrence and was not caused by a chromosomal problem in a patient or her partner. The patient had been falsely reassured that she had no risk of a chromosomally abnormal pregnancy reoccurring because her husband's and her test results were normal. However, her age placed her pregnancy at increased risk for other types of chromosomal anomalies. A genetic counselor gave her correct information regarding her risks that enabled her to make an informed decision about prenatal testing options.

- A 46-year-old woman of Polish, not Jewish, ancestry was referred to cancer genetic counseling because of her recent diagnosis of stage III ovarian cancer and strong family history of breast cancer (Fig. 1). She initially reported that one of her relatives who had breast cancer had BRCA testing in a different country and tested negative. At the end of her appointment, she recalled that she had BRCA testing through her gynecologist's office 16 months earlier at age 45 years and was told it was "normal." However, after discussing that she would now meet the testing company's criteria for large rearrangement testing (BART) in BRCA1/2 at no additional cost, the patient chose to proceed with testing. Upon receiving the request for this additional testing, the laboratory sent the genetic counselor a fax indicating that the patient would not qualify for free BART rearrangement testing because her initial testing was positive for a deleterious mutation in BRCA1. The counselor contacted the ordering gynecologist to determine what had occurred and what the patient had been told about her results. The gynecologist was shocked, and very upset, to learn that the patient carried a mutation and to realize that she had misinterpreted the result, which was clearly printed in capital letters in a box at the top of the page. The gynecologist had noticed only the wording listed next to the BRCA2 gene and a targeted rearrangement panel that indicated that no mutation was detected in that gene. The gynecologist contacted the patient about this error, and the patient was then seen for follow-up genetic counseling. The patient and her husband were painfully aware that if her results had been

read correctly 16 months earlier, she could have had a prophylactic BSO and probably avoided a likely fatal advanced ovarian cancer diagnosis. The patient and her husband indicated that they planned to sue her gynecologist. (Bierley, K. L. et al., (2012) Adverse Events in Cancer Genetic Testing, *The Cancer Journal*, 18(4): 304.)

Psychological and Financial Issues

- There are unique ethical and psychosocial issues associated with genetic testing. Genetic evaluations and detailed family histories may reveal information about family members and patients. Diagnosis may lead to psychological burdens such as guilt, blame, fear for the future, fear of being unable to cope, or anxiety regarding reproductive decisions. A genetic diagnosis may cause economic burdens, such as the cost of a chronic illness, as well as questions and concerns about employment and health insurance discrimination. Graduates of genetic counseling training programs are uniquely qualified to counsel on these issues. Most medical professionals do not provide the non-directive counseling that genetic counselors are trained to provide. Genetic counselors have extensive training and experience in this realm, which facilitates patient autonomy. Genetic testing can have far-reaching consequences—test results can affect family and personal relationships, psychological well-being, and future health.

- A client told her certified genetic counselor that a family member was pressuring her to undergo genetic testing by offering to pay for \$2,700 genetic testing for cancer predisposition. The genetic counselor asked about the client's reasons for testing and her feelings of coercion from the family member. The client decided to delay testing until she was ready to receive results, at a time when the results would benefit to her, and when she was ready to take action to reduce her risks. Non-directive counseling facilitated her autonomy.

- A couple underwent infertility treatment for 10 years. During this period, their physician neither referred them to a genetic counselor, nor took a family history, which would have revealed that the husband's sister had mental retardation. After taking a course in genetics, the wife realized the significance of her husband's family history. Several years later, a simple genetic test revealed that the husband carried a genetic rearrangement, called a balanced translocation, which explained their infertility. Prior to learning this, the wife underwent years of unnecessary surgical and hormonal treatments in an attempt to remedy the infertility. These treatments emotionally and financially drained the couple.

- Genetic counselors are trained to obtain detailed family histories (pedigrees) that assess for chromosomal and other genetic causes of infertility to guide appropriate diagnostic work-up, prevent inappropriate testing and treatment, and provide counseling to couples regarding technologies such as IVF and preimplantation genetic diagnosis that may enable them to achieve a successful and healthy pregnancy.

- A physician referred a woman for genetic counseling and detailed ultrasonography because of some concerns regarding the position and movements of her baby on her routine mid-trimester ultrasound. Amniocentesis was performed to rule out a chromosomal anomaly and chromosomal studies were normal. As the pregnancy progressed, serial ultrasound findings suggested arthrogryposis, a rare condition causing joint immobility.

- After the baby's birth, the genetic counselor involved with the case visited the newborn nursery to see the mother and baby. A neonatologist was present and examining the newborn. He told the genetic counselor that blood had been drawn and would be sent for chromosomes. When the genetic counselor explained that the amniocentesis results were

normal, he insisted that he wanted to check for a specific chromosome finding found in the Hispanic population. However, the previous study already ruled out this possibility. Additionally, the clinical findings did not match the chromosomal condition to which he was referring. His lack of correct genetic knowledge resulted in inappropriate tests that increased the cost to the family and third-party payer.

Inadequate Training Specializing in Genetics

- A 42-year-old patient with a confirmed diagnosis of FAP and an APC gene mutation was referred for genetic counseling by her gastroenterologist because she had had genetic testing several years earlier through her colorectal surgeon, but had never had formal genetic counseling. When the genetic counselor took the patient's personal history, she learned that the patient had had a total hysterectomy and bilateral salpingo-oophorectomy at age 41 years based on her surgeon's assessment that she "was at an increased risk for cancer there" because of her genetic test results. The surgeon had apparently confused the cancer risks associated with FAP with the ovarian and uterine cancer risks seen with Lynch syndrome. This patient had undergone unnecessary surgery and premature menopause because of this misinformation. (Bierley, K. L. et al., (2012) Adverse Events in Cancer Genetic Testing, *The Cancer Journal*, 18(4): 305.)

- Most medical professionals have very little training in medical genetics. A number of studies document that general practitioners are inadequately prepared in genetics. One survey of department of medicine chairs found that only 48 percent and 31 percent, respectively, agreed or strongly agreed that their internists or internal medicine subspecialists had enough knowledge about genetics to make accurate diagnoses and enough knowledge to provide appropriate genetic counseling. (Taylor, Genetics in Medicine, 2003, 5(4):328-331.)

Another survey of general practice providers reported that 25 percent of internists and 31 percent of family practitioners had referred a patient for genetic services in the previous year. One in six of the surveyed internists was unaware of the genetic services in their geographic area and saw no need to know this information. (Hayflick et al., Genetics in Medicine, 1998, 1(1): 13-21)

The various responses that surveyed physicians provided to basic genetics-related questions identified significant knowledge gaps. Over half of those surveyed did not recognize that family history of breast cancer on the paternal side increases a patient's risk. Most stated that they would provide the counseling rather than referring to a genetics provider.

- A study assessed the adequacy of genetic risk- assessment among primary care providers. This study found that in 35 percent of the 378 cases studied, significant genetic risk was identified in a subsequent genetic consultation that the referring physician missed. The authors reviewed the family history and the genetic consultation report and found that additional genetic testing and screening was indicated in approximately 10 percent of these patients.

- The authors concluded that providers should offer genetic counseling and risk assessment to all women considering prenatal genetic testing. Knowledge of risks ensures a patient access to genetic consultation, education, psychosocial support, and testing. Failure to identify significant genetic risks may lead to psychological distress, physical injury, or death. Genetic counselors involved with these cases understand the intricacies of genetic risk factors to provide education and psychosocial support, testing and test interpretation to avoid these mistakes and ensure that patients receive the most complete care. (Cohn et al., Journal of Perinatology, 1996, 16(5): 352-7)

- Allied health professionals often provide genetic counseling, although they have little or no genetics education within their training programs. Six allied health professions for whom genetic counseling is not considered within their typical scope of practice were surveyed regarding genetics in their practices. Seventy percent of surveyed dietitians, occupational therapists, physical therapists, psychologists, speech-language-hearing specialists, and social workers reported discussing the genetic component of their clients' problems with their clients. Thirty percent said that they had provided counseling about genetics to at least a few of their clients. Less than 10 percent of the health professionals reported having a high level of confidence in their ability to provide these services. (Lapham et al., *Genetics in Medicine*, 2000, 2(4): 226-31.

- Licensure of genetic counselors in Florida will help encourage allied health professionals to refer patients to genetic counseling services within the state of Florida.

- Commercial laboratory-developed genetic tests are increasingly marketed to non-genetics healthcare providers and to the general public. One laboratory used Denver and Atlanta as marketing test sites to evaluate the impact of direct-to-consumer marketing. The Colorado Department of Public Health and Environment and the Centers for Disease Control (CDC) studied the impact of such marketing and found that providers perceived an impact on their practice, but felt that they lacked the knowledge to advise patients about appropriate genetic counseling and testing. Their findings emphasize the need to educate providers and the public regarding appropriate use of genetic testing to maximize the public health benefit from genetic testing. (Centers for Disease Control and Prevention, *MMWR Morbidity and Mortality Weekly Report*, 2004, 53(27):603-6.

- Collecting complete histories, pedigrees, and genetic risk-assessment, as well as providing genetic counseling regarding genetic concepts, risks, testing options, informed consent, and related psychosocial concerns is time consuming. It is more cost-effective for a qualified genetic counselor to administer these duties rather than a physician. Primary care physicians in a busy practice do not have the time required to provide the complex patient education and in-depth counseling that patients most need. One study assessing the discussions between obstetrics providers and pregnant woman concluded that the information the providers give about genetic testing does not adequately ensure informed autonomous decision-making.

Examples specific to Florida:

- One common example is women who are told to terminate their pregnancies based on a potentially uncertain genetic test result called a variant of uncertain significance. Many medical providers incorrectly assume a variant of uncertain significance is pathogenic (disease causing). 85% of variants are reclassified as benign (not disease causing). Genetic counselors are highly trained to interpret variants of uncertain significance and what types of factors molecularly need to be considered to determine whether a variant could truly be pathogenic or not.

- One example of a case is that of a woman pregnant with her third child who chose to pursue prenatal genetic testing with no pre-test genetic counseling. Her initial screening results came back positive for a potential abnormality in the baby so she decided to pursue further diagnostic testing. The diagnostic testing showed the baby did NOT have the fatal genetic abnormality, but did carry a small variant of uncertain significance. They were incorrectly told by their maternal fetal medicine specialist this finding was significant and to consider

terminating the pregnancy. The couple sought an opinion from a certified genetic counselor who informed them this finding was insignificant and unlikely to cause any problems in the baby. The couple was relieved and continued the pregnancy. This couple was caused unnecessary emotional harm based on inaccurate test interpretation. (personal anecdote Kim Glaser, MS CGC).

- Other examples include a patient whose physician only interpreted a portion of their genetic testing report (specifically, their deletion/duplication results without ever looking at the sequencing portion) because the reports are sometimes delivered separately. The patient was told she was negative for BRCA1/2 the two most common hereditary breast and ovarian cancer genes. It was only after her sister developed ovarian cancer and she attended a genetic counseling appointment with her sister that she then sought genetic counseling for herself and her genetic counselor discovered she was actually BRCA1/2 positive, in need of additional screening, and was eligible for prophylactic surgeries (personal anecdote Talia Donennberg, MS CGC).

- Additionally there have been numerous cases of women removing their breasts and ovaries when they were incorrectly told a variant of uncertain significance put them at 80% life time risk to develop breast cancer and 40% lifetime risk to develop ovarian cancer when this in fact is only true of pathogenic variants. There are clear guidelines that state no medical management decisions should be made based off of variants of uncertain significance.

- Another case involves a male who has Charcot Marie Tooth disease, a genetic form of neuropathy that can be painful and debilitating. The man was told by his general practitioner that the type of CMT he had could only be passed on by females which indicates an X-linked inheritance pattern. The most common form of CMT, and the type in his family, is autosomal dominant, meaning both males and females can pass this on to both male and female children. Unfortunately this patient did not seek genetic counseling until after his daughter was born and affected with CMT. If this male had access to a genetic counselor prior to his daughter exhibiting developmental delays and frequent falls, he would have known he could have pursued in vitro fertilization using preimplantation genetic diagnosis and he could have PREVENTED CMT from being passed on to any of his future children (personal anecdote Kim Glaser MS CGC).

There are no known complaints filed against certified genetic counselors in the state of Florida. There is no way for a patient to file a complaint since the profession is unregulated. The patients can however consider personal lawsuits against the hospital/practice that provided the genetic counseling. We are aware of one currently pending legal case where the patient did not meet with a certified genetic counselor, was provided an inaccurate recurrence risk assessment by a geneticist, and is now suing the geneticist after they had a second affected child. There is another case we are aware of where a young woman was pregnant with an unplanned pregnancy and reported Ashkenazi Jewish ancestry. The OB/GYN did not order appropriate carrier screening for the patient and she was never identified as a carrier for Canavan disease during her pregnancy. Her partner ended up being a carrier too and they only found this out after their child was born with Canavan disease, a devastating neurologic disorder with an extremely shortened lifespan. This couple is now suing their OB/GYN for failure to refer them for genetic counseling and ordering appropriate genetic screening. These families could have been better prepared to cope with their circumstances and given proper education and emotional support had they received competent services from trained genetic counselors.

d) *A list of states that regulate the profession or occupation, and the dates of enactment of each law providing for such regulation and a copy of each law;*

States currently licensing genetic counselors: Alabama, Arkansas, California, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Nebraska, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Utah, Virginia, Washington.

For a complete list of dates of enactment and copies of each law you can visit:

<https://www.nsgc.org/p/cm/ld/fid=19>

e) *A list and description of state and federal laws that have been enacted to protect the public with respect to the profession or occupation and a statement of the reasons why these laws have not proven adequate to protect the public;*

There are no laws that we as an organization are aware of enacted to protect the public with respect to genetic counselors. Additionally, there is no specific regulation of the genetic counselor occupational group at the federal level. Perhaps the most recent federal legislation relevant to the provision of genetic testing and counseling is H.R. 493 (110th): The Genetic Information Nondiscrimination Act of 2008, (GINA) (Appendix C). GINA prohibits health insurers from using genetic information for enrollment, premium/contribution determinations, underwriting, and preexisting condition exclusions. GINA also prohibits an employer, employment agency, labor organization, or joint labor-management committee from discriminating against, limiting, segregating, classifying or otherwise adversely affecting an individual's status as an employee, individual, or family member because of genetic information. These along with other protections and penalties for violation have been in place since GINA was enacted.

However, there are significant limitations to GINA's protections that individuals should be aware of if they are to provide informed consent prior to genetic testing, as is required by Florida statute. As a component of their training and competency for practice, genetic counselors must be familiar with GINA, its protections, and its limitations as it relates to clients and their families.

The Affordable Care Act (ACA) requires health insurance plans to cover genetic counseling as a preventive service with no copay or deductible for women whose family history suggests an increased risk of mutations in *BRCA1* or *BRCA2*. The ACA-mandated coverage applies to genetic counseling but does not extend to genetic testing.

Florida does not specifically regulate the genetic counselor occupational group. However, the Florida State Board of Medicine has jurisdiction over other healthcare professionals who are licensed and may provide some types of genetic consultation within their scope. The regulatory boards that license these practitioners can investigate cases in which these professionals are accused of harming the public by providing inappropriate genetic consultation and/or practicing outside their scope, and can determine whether disciplinary action should be imposed.

As with GINA, genetic counselors are expected to be familiar with state laws pertaining to genetic nondiscrimination, their protections, and their limitations as they relate to clients and

their families. Genetic counselors should also be familiar with other state statutes pertaining to genetics practice, including but not limited to, newborn screening, employment nondiscrimination, and informed consent laws.

f) *A description of the voluntary efforts made by members of the profession or occupation to protect the public and a statement of the reasons why these efforts are not adequate to protect the public;*

The Florida Association of Genetic Counselors and National Society of Genetic Counselors try to promote public awareness with television interviews, magazine publications, and blog posts to try to inform the lay public. Both FLAGC and NSGC have websites where consumers can find a certified genetic counselor but most of the lay public is not aware that these resources exist. Even many medical doctors do not know these resources exist, especially if they trained before the era of genetics (early 2000's). These efforts are not adequate because there is no way to ensure we are reaching every consumer who may benefit from genetic counseling. There are many patients who *think* they met with a genetic counselor when in reality they did not and they were given incorrect information. Individuals finding themselves in such a situation are provided no path of recourse because the state of Florida does not regulate the profession. Some consumers do know our services exist, but since we are not licensed and therefore not recognized by insurance companies, hospitals charge very high self pay prices (as much as \$300-\$400) just to meet with a genetic counselor. This is a huge barrier for consumers because only those of certain financial status have access to genetic counseling. Licensure would allow genetic counselors to obtain recognition from more insurance companies so patients and facilities could be reimbursed for charges to meet with a genetic counselor.

g) *A copy of any federal legislation mandating regulation;*

- o Not applicable

h) *An explanation of the reasons why other types of less restrictive regulation would not effectively protect the public;*

As explained in section d) on pages 6-7 of this review, we explored alternative regulations. We found that, while these regulatory schemes may address patient harm, they do not provide the workforce growth opportunities and economic benefit to the state that state licensure provides. Licensure will provide the legal framework for genetic counselor's specific scope of practice that will allow them to be credentialed to practice independent of a physician and be fully integrated into health care systems. Thus while alternative regulation may perhaps appear "less restrictive" administratively the end result is added regulation without removing barriers to opportunity that licensure provides. Therefore, licensure provides the mechanism to remove restrictions on economic opportunity as board certification of genetic counselors already establishes initial competency and ongoing education.

i) *The cost, availability, and appropriateness of training and examination requirements;*

The American Board of Genetic Counseling (ABGC)-certification is granted to qualified individuals who take and pass the ABGC certification examination and/or American Board of Medical Genetics and Genomics (ABMGG), and for temporary licensure, active-candidate status

for the ABGC-certification examination. Board certification is obtained by a national standardized examination that ABGC administers after graduating from an accredited genetic counseling training program. The ABGC examination takes place twice annually, during February/March and August/September testing windows at specific computer-based testing centers worldwide. Certification is time-limited, and is renewed by re-examination or continuing education pathways.

- The ABGC certification, CGC® credential, is the gold standard for clinical competency in the genetic counseling profession. Certification or Active Candidate Status is already required as a condition of licensure to practice as a genetic counselor in other states. While health care employers are not required to hire certified genetic counselors in Florida, employers generally seek to hire genetic counselors who are board-certified due to the increasing need for trained specialists in genetics. Therefore, state licensure need not necessarily impose additional requirements than a quality credential already established which applicants would already be working towards or have obtained and are maintaining regardless of the existence of state licensure.

The Standards for Graduate Programs in Genetic Counseling Seeking Accreditation by ACGC (the Standards) includes a separate section detailing the Practice-Based Competencies for entry-level genetic counselors. The Standards require genetic counseling master's degree-granting programs to reside in a graduate degree-granting institution that is accredited by a regional accrediting association recognized by the U.S. Department of Education (or the equivalent provincial authority for Canadian educational institutions). Program duration must be a minimum of 21 months or two academic years. Instructional content must cover established and evolving medical and clinical genetics principles and how genetic counselors apply this knowledge to patient care. This content must be sufficient in breadth and depth to prepare the student for the clinical practice of genetic counseling.

The Standards specify that the curriculum content areas required to develop practice-based competencies in genetic counseling must, at a minimum, include:

- *Principles of Human Genetics* (Mendelian and non-Mendelian inheritance, population and quantitative genetics, human variation and disease susceptibility, family history and pedigree analysis, normal/abnormal human development, human reproduction, personalized genomic medicine).
- *Applicability of Related Sciences to Medical Genetics* (cytogenetics, biochemical genetics, molecular genetics, embryology/developmental genetics, teratology, cancer genetics, adult genetics, cardiovascular genetics, neurogenetics, and, pharmacogenetics).
- *Principles and Practice of Clinical/Medical Genetics* (clinical features and natural history of a broad range of genetic and complex diseases and syndromes, the diagnostic process including dysmorphology/syndromology, modalities/methods/applications of cytogenetic, molecular and biochemical tests and new/emerging technologies, risk assessment, and use of genetics literature, databases and other bioinformatics tools).
- *Psychosocial Content* (counseling theories, interviewing techniques, psychosocial development, family dynamics, grief and bereavement dynamics, multicultural sensitivity and competency, disability awareness, and crisis intervention).
- *Social, Ethical, and Legal Issues in Genetics* (facilitating informed-decision making via informed consent, patient and research subject privacy issues [e.g. HIPAA], genetic

discrimination and related legislation, health disparities, and the genetic counseling Code of Ethics).

- *Health Care Delivery Systems and Principles of Public Health* (health and social policy, community/ regional/national resources, financial/reimbursement issues, population-based screening [e.g. newborn screening, carrier screening], and genetics as a component of public health services).
- *Education* (identification of the genetics educational needs of clients, patients, community and lay groups, students, and health and human service professionals; developing appropriate educational tools and materials for a given audience; and delivering and evaluating educational tools and materials).
- *Research Methods* (clinical and laboratory research methodologies and protocols using both quantitative and qualitative methods; funding and publication topics including grant writing, data analysis, abstract development, and preparing a manuscript for publication).
- *Professional Development/Self-Care* (interviewing and job-seeking skills, stress management, ABGC-certification exam readiness, structure and purpose of genetics-related professional societies, and self-care topics to prepare students for the emotional and intellectual challenges of clinical practice).

Substantial clinical training and fieldwork experience is also required to train genetic counseling graduate students. This training provides students with first-hand experience working in a variety of practice settings with individuals and families affected by a broad range of genetic conditions. A minimum of 50 “core cases” is required to develop fundamental genetic counselor skills that they can effectively apply in a wide variety of clinical settings and service-delivery models. An experienced, board-certified geneticist and/or board-certified genetic counselor must directly supervise these cases.

Cases must expose students to a variety of genetic issues throughout the life cycle, including preconception counseling, prenatal counseling, pediatric genetics, and adult and pre-symptomatic genetics. A subset of core cases must include direct work with individuals symptomatic for genetic conditions, as well as experience in conducting family sessions in which multiple family members are evaluated and/or counseled. To further enhance students’ clinical training, the core cases are augmented with additional fieldwork experiences in settings such as diagnostic laboratories, telemedicine clinics, research programs, public health clinics, and healthcare settings that include interacting with non-geneticists (non-geneticist physicians, nurses, nutritionists, etc.).

Because genetic counselors play a significant role in educating patients, other health professionals, students, and the public, graduate programs must include teaching opportunities with a variety of learners for their students. Programs are also required to provide students with instruction, observation, and participation in genetic laboratory activities so that they may become proficient in genetic-testing utilization, learn to choose appropriate clinical and research laboratories to send patient samples, and understand the analytic and clinical validity and clinical utility of various types of genetic testing. Students are also required to conduct research or other scholarly activities through a formal thesis, capstone project, or other independent-research project.

The Standards’ Practice-Based Competencies recognize that genetic counselors work in various settings and provide services to diverse clients, including patients and their families in healthcare

settings, other healthcare professionals, research subjects, and the public. An entry-level genetic counselor must demonstrate the practice-based competencies to successfully practice as a genetic counselor. The didactic and experiential training components of a graduate genetic counseling curriculum must help develop these competencies. The Competencies are organized into the following domains, which can be applied in the varied practice settings in which genetic counselors serve their clients: (I) Genetics Expertise and Application; (II) Genetic Counseling Skills; (III) Education; and (IV) Professional Development & Professional Practice. Specific learning objectives accompany each competency and illustrate the skills that reflect achievement of the competency.

Graduates of ACGC-accredited genetic counseling training programs are expected to have achieved these entry-level competencies and are thus eligible to apply for Active Candidate Status (ACS) to sit for the national certification examination that ABGC administers. By requiring certification or ACS as a condition of licensure to practice as a genetic counselor in Florida, a quality standard would be established and a regulatory mechanism would be implemented to report and investigate suspected substandard practice and take disciplinary action, if necessary.

A certified genetic counselor graduates from one of 47 accredited training programs in the US or Canada accredited by the Accreditation Counseling for Genetic Counseling. There is currently one genetic counseling training program in the state of Florida at the University of South Florida which is a Masters of Science in Public Health with a concentration in Genetic Counseling (MSPH-GC). Students in the program receive their didactic and clinical training from faculty of the University of South Florida and other board-certified clinicians at Nemours Children's Hospital, Arnold Palmer Children's Hospital, Moffitt Cancer Center, and other affiliated institutions and organizations providing genetic counseling services in Florida. The program is fully accredited by the Accreditation Council for Genetic Counseling (ACGC).

The MSPH-GC at the University of South Florida is completed during five semesters (two academic years, including the interim summer) of full-time study. The cost depends upon a student's residency status during each year of the program; per university policy, non-resident domestic students may petition for resident status after one year of attendance. Currently, the genetic counseling degree requires students to successfully complete 42 credit hours of graduate-level coursework. Per-credit hour tuition and fees for the 2019-2020 academic year is \$431.43 for Florida residents and \$877.17 for non-residents. Estimated total tuition costs for the two-year program, based on current tuition rates, are: roughly \$18,120.06 Florida residents, \$27,480.63 for non-residents who achieve residency in year two, and \$36,841.14 for international students and other students who remain non-residents throughout the program. In addition, all students pay approximately \$1000 in university fees and \$500-\$1000 for program books/supplies. Students are also required to obtain their own health insurance, purchased through a university or private plan, as well as their own living and transportation arrangements. For those attending out-of-state programs the cost of their Masters degree varies greatly from \$10,000 to \$70,000.

- State licensure is expected to further expand in-state workforce education and training opportunities for genetic counselors. Program capacity at USF is severely capped due to the lack of available genetic counselors that can provide supervision during clinical training. The program can accommodate only up to 5 students per year despite having had consistently 18-20 times more applicants than available positions. As state licensure will help attract new and retain

genetic counselors, the program may expand to accommodate more students. The growth in clinical training opportunities has been demonstrated in other states which have implemented state licensure.

The ABGC Certification Examination development and administration process follows the National Organization for Competency Assurance (NOCA) quality standards for credentialing organizations. NOCA identifies five characteristics that should define a professional certification examination: 1) A professional role delineation or job analysis is conducted and periodically validated; 2) A demonstration of how the examination is linked to a defined body of knowledge, based on the professional role delineation or job analysis, is provided; 3) A demonstration of reliability and validity of the examination, based on psychometrically accepted statistical methods, is provided; 4) A minimum passing score is developed using psychometrically accepted statistical methods; and 5) A demonstration that alternate forms (versions) of the examination are parallel in construction and content coverage, and equated for difficulty using psychometrically sound techniques, is provided.

ABGC conducts a Practice Analysis every three – five years (most recently in 2017) to develop a detailed description of the skills and activities associated with the current practice of the genetic counseling profession. ABGC uses information derived from the Practice Analysis to develop all phases of the ABGC Certification Examination by providing a detailed content outline and test specifications that are used to direct item writing and examination content. The Practice Analysis ensures that the exam content aligns with the most recent developments within the genetic counseling field. This ensures that the examination reflects the current practice of the genetic counseling profession and remains the foundation for examination validity.

Only individuals seeking ABGC certification in genetic counseling take the ABGC Certification Examination. The examination consists of 200 multiple-choice questions (170 scored items; 30 pre-test items used for future test development). These questions are derived from the most recent version of the content outline based on the current Practice Analysis the results. At the conclusion of each examination administration window, the psychometrician conducts a statistical analysis on the examinees' responses to the pre-test items. Based on this analysis, items that did not perform well (i.e. generated statistical red flags that indicate a possible flaw in quality) are removed, and items that performed well are retained for further validation or use on future examinations. Once an item is fully validated, it may be used as one of the scored items on an examination.

ABGC uses a criterion-referenced methodology to score examinations, which is a certification examination industry standard. With this type of scoring methodology, there is no "curve." Candidates do not compete against one another. The "bar" for performance level is the same for each candidate—minimally competent practice. In this method of scoring, it is theoretically possible for all examinees to pass the examination or for all examinees to fail the examination. Since candidates are compared to the criterion of competent practice, there is no minimum percentage of examinees that must fail the exam.

Prior to the institution of instant scoring with the August 2013 examination administration, the Angoff scoring method was used to set the performance level required to pass the examination. This is the most common methodology for establishing passing scores for credentialing exams. This process was overseen by a psychometrician and was based on a combination of statistical

analysis and the expert judgment of the CEC to determine what constituted the minimum qualification to pass the exam. This performance level established using the Angoff method is retained with instant scoring through a statistical process known as equating. As mentioned above, all items used to calculate a person's score on the examination have been previously used and, therefore, have known statistical performance characteristics. This information allows the CEC to develop new forms that are parallel to previous forms, with consistent levels of difficulty and score reliability. A psychometrician uses each item's statistical performance characteristics to project results on the new form, and an equitable passing score is determined. Because score equating occurs before the examination is administered, this procedure is characterized as pre-equating.

Equating controls for slight variations in difficulty can occur among multiple test forms and thus helps ensure that all candidates are held to the same standard (aka performance level). A great deal of time and effort is spent ensuring an exam's passing score is derived fairly for each examinee. Careful adherence to this process yields a rationally determined score that can be used with confidence to make pass/fail decisions. The ABGC certification examination development process follows established psychometric principles and industry standards.

The ABGC certification exam is offered twice each year, in February and August. The cost to sit for the exam is \$900 for first-time applicants and \$800 for repeat applicants. Graduates of a training program accredited by ACGC after January 1, 2008 are eligible for up to three examination attempts within five years after graduation.

j) *The cost of regulation, including the indirect cost to consumers, and the method proposed to finance the regulation;*

The cost of this regulation is expected to be budget-neutral or minimal. Costs will be limited by administering licenses through the Department of Health, through simple verification of board certification, rather than creating a Board of Genetic Counseling. In addition, any costs incurred by the state, while nominal, may be off-set by application and renewal fees paid by genetic counselors or covered by their employers. Fee legislation has been proposed in the 2021 Legislative Session. As explained in sections above and below, consumers are expected to realize both direct and indirect cost savings. Additionally, the state would realize economic benefits from increasing opportunities for Florida's workforce within an in-demand STEM career. This benefit will easily outweigh the cost of the proposed licensure on the state as well as consumers.

k) *The cost imposed on applicants or practitioners or on employers of applicants or practitioners as a result of the regulation;*

The only cost imposed on applicants may be a small fee to obtain and renew their licenses every two years. Linked fee legislation has been proposed with a cost of \$25 per application. Some employers may choose to cover the licensure fee so instead of this being a cost to the practitioner this would be a cost to the employer. There would be no additional cost imposed to the practitioner or employer. Costs proposed are minimal as the primary requirement proposed for state licensure is board certification with no restrictions on which state the genetic counselor is certified. As such, the process for verifying an application is straightforward, involving minimal

labor and costs. Licensure renewals would involve verifying that continuing education hours have been completed, a requirement already in place to maintain board certification.

Regulation of the genetic counseling profession in Florida will likely reduce overall healthcare costs. It will also help to increase the number of genetic counselors employed in Florida, which will expand patient access to services and ensure that the genetic tests ordered for patients are appropriate and necessary.

Licensure may reduce the costs to patients and to payers for genetic counseling services. If a genetic counselor's services are billed under the genetic counselor's name, the cost for the same service is less than what a physician would bill for the same service. The lack of licensure for genetic counselors in Florida often prevents these uniquely trained healthcare providers from being credentialed within a hospital. As a result, many institutions bill "incident to" a physician for the routine genetic counseling services that employed genetic counselors provide. These services are then billed to third-party payers and self-paying clients at a physician rate. Physicians must also spend time directly overseeing these services that credentialed genetic counselors could otherwise provide in a more efficient, independent manner.

Additionally, genetic counseling services often include discussing and/or ordering genetic tests. Hundreds of new genetic tests have been developed over the past few years—sometimes hitting the market daily. These tests are widely available for ordering by clinicians who may not have specific or sufficient training in cytogenetics, biochemical genetics, molecular genetics, genetic risk assessment, selection of appropriate genetic testing, or genetic-test interpretation. Further, genetic testing laboratories have aggressively marketed tests to physicians who do not have the time or expertise to determine the best test for an individual.

Inappropriate and unnecessary genetic testing contributes to increasing societal healthcare costs. Recent evidence-based research demonstrates that genetic counselors provide a net savings when they are involved in the genetic testing process. Examples include:

- Priority Health, a private insurance company in Michigan, mandated the use of genetic counselors prior to the approval of certain genetic tests. This program prevented over \$10 million worth of inappropriate tests and a net savings of \$7.2 million.
- The Department of Veterans Affairs Genomic Medicine Service recently conducted a cursory chart review of their first 100 genetic referrals, in which testing was ordered for 19 patients by a practitioner other than a licensed genetic counselor. These tests would have cost taxpayers \$109,369 and after review by a genetic counselor, only \$18,345 of genetic tests were determined to be medically indicated for a cost savings of \$91,024.
- A 2013 review study by ARUP laboratories showed that by having licensed genetic counselors review genetic testing requests, 26% of all genetic testing orders received by the laboratory had to be modified by the genetic counselors. In total they saved an average of \$48,000 per month to their referring institutions by modifying the genetic test orders to more appropriate testing (Miller CE, Krautscheid P, Baldwin EE, Tvrdik T, Openshaw AS, Hart K, LaGrave D. 2014. Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing. *Am J Med Genet Part A* 9999:1–8.)
- At Seattle Children's Hospital, laboratory GCs reviewed 3441 genetic tests' send-out orders from hospital and ambulatory clinics over a 57-month period, resulting in a 32% test modification rate and \$972,000 total cost savings.

- At the Regions Hospital/HealthPartners care system in Minnesota and western Wisconsin, laboratory GCs reviewed 904 genetic test send-out orders from June 2015 to May 2016, resulting in an overall 13.5% test modification/cancellation rate and a total of \$263,000 in cost savings for all genetic test order requests. (Haidle, J. et al Genetic Counselors Save Costs Across the Genetic Testing Spectrum. Evidence Based Oncology August 2017). Additional examples can be found in this paper.

These studies show that genetic counselors ensure the appropriate utilization of genetic tests. Genetic counselors ensure that the right person receives the right test at the right time. They help to confirm that a genetic test is clinically indicated, and can provide the appropriate clinical justification for the test based on their specific knowledge of genetic conditions and how the testing will impact the patient's care. Third-party payers are more likely to cover clinically indicated tests, which leads to less out-of-pocket cost to the patient.

A genetic counselor is trained to identify the correct and most cost-effective test for the patient's clinical indication. For instance, a test seeking a specific gene mutation already identified in another affected family member may cost \$300, while full-sequence analysis of the gene may cost \$3,000. Another provider might order the full-sequence analysis, assuming that it is a "better" test, while a genetic counselor would deem it unnecessary.

This diligence derived from expertise saves patients from spending money on unnecessary genetic tests that third-party payers may not cover. In turn, it saves private third-party payers as well as federal and state programs, such as Medicare and Medicaid, from spending healthcare dollars on inappropriate laboratory tests.

Healthcare institutions also benefit from genetic counselors. By involving them in their genetic testing process, the institution will less likely have to absorb the cost of unnecessary or inappropriate genetic tests that its laboratory sends out and is subsequently not reimbursed.

Hospital systems around the country have begun incorporating genetic counselors into their pathology departments to help develop policies and protocols for clinically appropriate and cost-effective genetic testing utilization. Licensure will provide genetic counselors the opportunity to be credentialed, which will increase the likelihood that a hospital will staff genetic counselors. As more hospitals employ genetic counselors, more patients, third-party payers, institutions, and state/federal programs will realize the benefits of cost savings related to appropriate genetic testing selection and utilization.

1) The details of any previous efforts in this state to implement regulation of the profession or occupation; and

During the 2002, 2003, and 2004 legislative sessions, sponsors for a bill requiring licensure of genetic counselors filed bills in both the House and Senate. In 2004 the Senate bill passed through 5 committees and the full Senate unanimously. In the house, the bill passed through the Health Standards subcommittee, the Health Care committee, and the full House unanimously. The bill was received by the Governor in June and vetoed on June 24, 2004 due to reasons that we believe are no longer valid given the current state of genetic testing and increasing medical reliance on genetic counselors. In 2005, bills were again submitted. Prior to the 2005 legislative session, meetings with staff members from the Governor's office and with the Secretary of Health were arranged to address concerns raised in the 2004 veto. Both bills died in committee

when the session ended. The decision was made not to submit bills in the 2006 or 2007 legislative sessions. Each year our organization has continued to work with lobbyists who advised us not to move forward due to unfavorable political climates, though we have had ongoing meetings with key officials since 2004.

Legislation was not reintroduced until the 2020 Legislative Session as the need for Florida to license genetic counselors has grown more clear and pressing. The legislation was not heard in a committee in 2020 as we focused our efforts on exploring alternative methods of regulation, such as third-party credentialing, in an effort to draft a more favorable bill. Despite this good-faith effort, as explained in sections above, we found that these alternative methods would only add more barriers to opportunity without addressing the key issues that state licensure alone provides.

In light of the expansion of genetics within the field of medicine, the increase in demand for genetic counseling services by providers and patients alike, and the ever-growing complexity of testing options and result interpretation, we can no longer delay this important step in protecting the residents of Florida.

m) *Any other information the agency or the committee considers relevant to the analysis of the proposed legislation.*

Important Note: The Sunrise Review largely requests information specific to the direct harm caused to patients by the unregulated practice. However, it is important to note that a main consequence of state licensure is to remove rather than construct barriers to opportunity while encouraging state workforce growth and retention for an in-demand field. Regulation of the practice of genetic counseling can be as simple as verifying the genetic counselor is board-certified by the American Board of Genetic Counselors. The point is that state licensure provides a legal framework which enables genetic counselors to be credentialed as independent practitioners and fully serve patients to their maximum capacity and competency. By not providing licensure, Florida is at a competitive disadvantage in retaining and attracting new genetic counselors. This has led to Florida having one of the lowest genetic counselor workforce to patient populations in the country. While demand grows at a rapid pace, board-certified genetic counselors in Florida are unable to: pursue careers independent of physician supervision; maximize patient access to services; save patients on out-of-pocket costs; reduce costs to health care systems; supply a competitive workforce that meets demands of our current healthcare era; and, most importantly, improve patient outcomes by ensuring they can access and receive critical services from competent professionals.

With that, direct harm from unregulated genetic counseling is well-documented and state licensure does provide an important mechanism for accountability that does not currently exist. Answers provided herein focus on the specific information requested, which is largely from the perspective of patient harm and regulation vs. no regulation. It also underscores the important role genetic counselors fulfill in the delivery of health care services.

Genetic counselors care about state licensure as it will enable them to better provide Floridians with access to affordable, competent services that have a direct impact on their life. We want to reach as many potential patients as possible and have more awareness of our profession so those who need genetic counseling are able to obtain services whatever their financial or educational background.

Since 2005, the field of genetics has expanded dramatically. Research and technology have advanced scientific progress, and personalized medicine is becoming a reality. As the number and availability of genetic tests has increased, so has the level of complexity and subsequent need for interpreting results. For example, the genetic testing field has moved from chromosome testing based on a karyotype or “picture” of the chromosomes to a current standard of microarray testing (array comparative genomic hybridization), which is a molecular genetic technique with a much higher sensitivity for detecting both pathogenic and benign copy number variants and that requires more specialized training to correctly interpret clinically.

While single-gene testing still occurs, multi-gene panels have become more prevalent and whole exome sequencing is now clinically available. Without the guidance of a qualified healthcare professional, test results could be misinterpreted, risks miscalculated, and incorrect health and lifestyle changes pursued. Appropriate informed consent is also essential prior to such testing and appropriate genetic counseling is critical to the genetic testing process. Licensure would require genetic counselors to maintain their certification, which ensures participation in continuing education and remaining up-to-date with advances in the rapidly changing field of genetics.

The areas of genetic counselor-practice have also expanded. Many genetic counselors who practice in hospital settings function as the genetics expert on multidisciplinary teams that represent the spectrum of medical specialties. Almost one-third of genetic counselors practice outside of a hospital or medical center. With the advent of new genetic tests and direct-to-consumer options, genetic counselors work in a wider variety of settings, including private companies or other non-hospital environments in which internal genetic counselor monitoring may not be enforced. Licensure would protect the public and identify qualified genetic counselors regardless of the area of practice.

Genetic counseling is one of the few healthcare occupations recognized by the federal Bureau of Labor Statistics that requires a Master’s degree or higher. However, genetic counseling is the only one of these occupations not regulated by the state of Florida, despite genetic counseling having similar specialized training and potential for harm as each of the other occupations. Because of this as well as the myriad reasons laid out in this document, licensure of genetic counseling is of the utmost importance. If these efforts are unsuccessful in the 2021 Legislative Session, we plan to continue working on this effort until Florida joins the other 29 states which already license genetic counselors.

- (5) The agency shall provide the Legislature with information concerning the effect of proposed legislation that provides for new regulation of a profession or occupation regarding:
 - (a) The departmental resources necessary to implement and enforce the proposed regulation;
 - (b) The technical sufficiency of the proposal for regulation, including its consistency with the regulation of other professions and occupations under existing law; and
 - (c) If applicable, any alternatives to the proposed regulation which may result in a less restrictive or more cost-effective regulatory scheme.
- (6) When making a recommendation concerning proposed legislation providing for new regulation of a profession or occupation, a legislative committee shall determine:

- (a) Whether the regulation is justified based on the criteria specified in subsection (3), the information submitted pursuant to request under subsection (4), and the information provided under subsection (5);
- (b) The least restrictive and most cost-effective regulatory scheme that will adequately protect the public; and
- (c) The technical sufficiency of the proposed legislation, including its consistency with the regulation of other professions and occupations under existing law.

THE FLORIDA SENATE
APPEARANCE RECORD

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

03/24/2021

Meeting Date

SB 1770

Bill Number (if applicable)

Topic Genetic Counseling

Amendment Barcode (if applicable)

Name Lauren Jackson

Job Title lobbyist

Address 205 S. Adams St

Street

Phone 931-265-8999

Tallahassee

City

FL

State

32301

Zip

Email lauren@tsecgov.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing FLORIDA ASSOCIATION OF GENETIC COUNSELORS

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

3/24/2021

Meeting Date

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



SB1770

Bill Number (if applicable)

Topic Genetic Counseling Licensure

Amendment Barcode (if applicable)

Name Debi Cragun

Job Title Assistant Professor

Address 1738 W. Ferris Ave

Phone 813-466-4111

Street

Tampa

City

FL

State

33603

Zip

Email

Speaking: ☒ For ☐ Against ☐ Information

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

Representing University of South Florida Public Health

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 1772

INTRODUCER: Health Policy Committee and Senator Jones

SUBJECT: Fees/Genetic Counselor Licenses

DATE: March 24, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Brown	HP	Fav/CS
2.			AP	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1772 creates s. 483.919, F.S., to require the Department of Health (DOH) to adopt by rule procedures for the issuance and annual renewal of a genetic counselor license, including an application fee for such license and annual renewal not to exceed \$25. The bill provides that the DOH may waive the payment of the fee by rule. The bill also provides that such fees will be deposited into DOH's administrative trust fund and used for the administration of genetic counselor licensure.

The State Constitution requires that legislation that imposes or authorizes new state taxes or fees,¹ or that raises existing state taxes or fees,² must be approved by two-thirds of the membership of each house of the Legislature and that the tax or fee provisions must be passed in a separate bill that contains no other subject.³ CS/SB 1772 authorizes the imposition of a new fee on a person who makes application to become a licensed genetic counselor or who applies for renewal of such a license. As such, the State Constitution may require that such a fee provision must be approved in a stand-alone bill by two-thirds of the membership of each house of the Legislature.

The bill has an indeterminate fiscal impact on the Department of Health (DOH). See section V of this analysis.

¹ FLA. CONST. art. VII, s. 19(a).

² FLA. CONST. art. VII, s. 19(b).

³ FLA. CONST. art. VII, s. 19(e).

The bill provides an effective date that is the same date that SB 1770, or other similar legislation, takes effect if such legislation is adopted in the same legislative session or extension thereof and becomes a law.

II. Present Situation:

Genetic Counseling

Under current law, there is no license issued by the DOH for a health care practice specific and exclusive to genetic counseling. However, CS/SB 1770, entitled “An act relating to genetic counseling,” creates part III of ch. 483, F.S., to require the DOH to begin issuing such licenses and regulating the practice of genetic counselors.

Under CS/SB 1770, the “practice of genetic counseling” means the process of advising an individual or a family affected by or at risk of genetic disorders, including:

- Obtaining and evaluating individual, family, and medical histories to determine genetic risk for genetic or medical conditions and diseases in a patient, his or her offspring, and other family members.
- Discussing the features, natural history, means of diagnosis, genetic and environmental factors, and management of risk for genetic or medical conditions and diseases.
- Identifying, ordering, and coordinating genetic laboratory tests and other diagnostic studies as appropriate for a genetic assessment.
- Integrating genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic or medical conditions and diseases.
- Explaining the clinical implications of genetic laboratory tests and other diagnostic studies and their results.
- Evaluating the client’s or family’s responses to the condition or risk of recurrence and providing client-centered counseling and anticipatory guidance.
- Identifying and using community resources that provide medical, educational, financial, and psychosocial support and advocacy.
- Providing written documentation of medical, genetic, and counseling information for families and health care professionals.
- Referring patients to a physician for diagnosis and treatment.

CS/SB 1770 also provides requirements for licensure, renewal, and continuing education, as well as grounds for disciplinary action and penalties, relating to the practice of genetic counseling. CS/SB 1770 provides an effective date of July 1, 2021. See the staff analysis for CS/SB 1770 for more details.

Health Care Practitioner Licensure

The DOH is responsible for the regulation of health care practitioners and certain health care facilities in Florida for the preservation of the health, safety, and welfare of the public. The

Division of Medical Quality Assurance (MQA), working in conjunction with 22 boards⁴ and four councils, licenses and regulates seven types of health care facilities, and more than 200 license types, in more than 40 health care professions.⁵ Any person desiring to be a licensed health care professional in Florida must apply to the MQA in writing.⁶ Most health care professions are regulated by a board or council in conjunction with the DOH, and all professions have different requirements for initial licensure and licensure renewal.⁷

Under current law, the costs of regulation of health care practitioners must be borne by the licensees and licensure applicants.⁸ The definition of “license” includes any permit, registration, certificate, or license, including a provisional license, issued by the DOH.⁹ Regulatory boards, in consultation with the DOH, must set licensure renewal fees by rule, and renewal fees must be:¹⁰

- Based on revenue projections prepared using generally accepted accounting procedures;
- Adequate to cover all expenses relating to that board identified in the DOH long-range policy plan;
- Reasonable, fair, and not serve as a barrier to licensure;
- Based on potential earnings from working under the scope of the license;
- Similar to fees imposed on similar licensure types; and
- No more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.

III. Effect of Proposed Changes:

CS/SB 1772 creates s. 483.919, F.S., to:

- Require the DOH to adopt by rule procedures for the issuance and annual renewal of a genetic counselor license, including an application fee for such license and annual renewal not to exceed \$25;
- Authorize the DOH to waive the payment of the fee by rule; and
- Require that proceeds from such fees must be deposited into the DOH’s administrative trust fund and used for the administration of genetic counselor licensure.

The bill provides an effective date that is the same date that SB 1770, or other similar legislation, takes effect if such legislation is adopted in the same legislative session or extension thereof and becomes a law.

⁴ Under s. 456.001(1), F.S., the term “board” is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the MQA.

⁵ Florida Department of Health, Medical Quality Assurance, *Annual Report and Long Range Plan, 2019-2020*, available at <http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/documents/2019-2020-annual-report.pdf> (last visited Feb. 3, 2021).

⁶ Section 456.013, F.S.

⁷ See chs. 401, 456-468, 478, 480, 483, 484, 486, 490, and 491, F.S.

⁸ Section 456.025(1), F.S.

⁹ Section 456.001(5), F.S.

¹⁰ *Supra*, note 8.

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:

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

CS/SB 1772 authorizes the imposition of a new fee on a person who makes application to become a licensed genetic counselor or who applies for renewal of such a license. As such, the State Constitution may require that such a provision must be approved in a stand-alone bill by two-thirds of the membership of each house of the Legislature.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Under CS/SB 1772, persons who make application to become licensed genetic counselors in Florida may be subject to an application fee of up to \$25, both for an initial application and for annual licensure renewal, unless the DOH waives the fees.

C. Government Sector Impact:

The DOH has not provided an estimated fiscal impact for the bill. The DOH will experience the costs of rule-making required under the bill. The DOH may also experience an increase in revenue if the department does not waive the fees that the bill

authorizes for initial licensure applications and renewals. The extent of these fiscal impacts is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 483.919 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 24, 2021:

The CS makes a technical correction so that the bill takes effect on the same date that CS/SB 1770, or similar legislation, takes effect if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

- B. Amendments:

None.



695202

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/24/2021	.	
	.	
	.	
	.	

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

Senate Amendment

Delete line 24
and insert:
SB 1770 or similar legislation takes effect if such legislation

By Senator Jones

35-01760-21

20211772__

A bill to be entitled

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

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

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

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

Section 2. This act shall take effect on the same date that SB ____ or similar legislation takes effect if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: March 5th, 2021

I respectfully request that **Senate Bill #1772**, relating to Fees/Genetic Counselor Licenses, be placed on the:

- ☒ committee agenda at your earliest possible convenience.
- ☐ next committee agenda.

A handwritten signature in black ink, appearing to be "Shev" followed by a stylized "Jones".

Senator Shevrin D. "Shev" Jones
Florida Senate, District 35

THE FLORIDA SENATE
APPEARANCE RECORD

03/24/2021
Meeting Date

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

SB 1772
Bill Number (if applicable)

Topic Fees - Genetic Counseling

Amendment Barcode (if applicable)

Name Lauren Jackson

Job Title Lobbyist

Address 205 S. Adams St.
Street

Phone 931-265-8999

Tallahassee FL 32301
City State Zip

Email lauren@tsecgov.com

Speaking: ☒ For ☐ Against ☐ Information
→ FOR QUESTIONS

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

Representing FLORIDA ASSOCIATION OF GENETIC COUNSELORS

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 1242

INTRODUCER: Health Policy Committee and Senator Book

SUBJECT: Program of All-Inclusive Care for the Elderly

DATE: March 24, 2021

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1242 codifies the Program of All-Inclusive Care for the Elderly (PACE) in s. 430.84, F.S. The bill:

- Establishes a statutory process for the review, approval, and oversight of future and current PACE organizations.
- Authorizes the Agency for Health Care Administration (AHCA), in consultation with the Department of Elder Affairs (DOEA), to approve entities that have submitted the required application and data to the federal Centers for Medicare & Medicaid Services (CMS) as PACE organizations pursuant to federal regulations.
- Requires all PACE organizations to meet specific quality and performance standards established by the federal CMS and the state administering agency.
- Provides that the AHCA has the responsibility to oversee and monitor Florida's PACE and the contracted organizations.
- Exempts all PACE organizations from the requirements of ch. 641, F.S., which regulates health maintenance organizations, prepaid health clinics, and other health care service programs.

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

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

II. Present Situation:

Program of All-Inclusive Care for the Elderly

The Program of All-Inclusive Care for the Elderly (PACE) is a capitated benefit model authorized by the federal Balanced Budget Act of 1997 (BBA)¹ that features a comprehensive service delivery system and integrated federal Medicare and state Medicaid financing mechanism. The model, which was tested through federal CMS demonstration projects beginning in the mid-1980s,² was developed to address the needs of long-term care clients, providers, and payers.

The PACE operates as a three-way agreement between the federal government, the state administering agency, and a PACE organization. In Florida, the PACE is a Florida Medicaid long-term care managed care plan option providing comprehensive long-term and acute care services which support Medicaid and Medicare enrollees who would otherwise qualify for Medicaid nursing facility services.³

The PACE is a unique federal/state partnership. The BBA established the PACE model of care as a permanent entity within the Medicare program and enabled states to provide PACE services to Medicaid beneficiaries as an optional state plan service without a Medicaid waiver.

The federal government established the PACE organization requirements and application process; however, the state is responsible for oversight of the application process, which includes reviewing the initial application and providing an on-site readiness review before a PACE organization can be authorized to serve participants. An approved PACE organization must sign a contract with the federal CMS and the state Medicaid agency.

The PACE is administered by the DOEA in consultation with the AHCA. The DOEA oversees the contracted PACE organizations but is not a party to the contract between the federal CMS, the AHCA, and the PACE organizations.⁴ The DOEA, the AHCA, and the federal CMS must approve any applications for new PACE organizations if expansion is authorized by the Legislature through the necessary appropriation of the state matching funds.

A PACE organization must be part of either a city, county, state, or tribal government; a private not-for-profit 501(c)(3) organization; or for-profit entity that is primarily engaged in providing PACE services and must also:

- Have a governing board that includes participant representation;
- Be able to provide the complete service package regardless of frequency or duration of services;

¹ Specifically, services under the PACE are authorized under Section 1905(a)(26) of the Social Security Act.

² United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, *CMS Manual System: Pub. 100-11 Programs of All-Inclusive Care for the Elderly (PACE) Manual* (issued June 9, 2011), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pace111c01.pdf> (last visited Mar. 16, 2021).

³ Department of Elder Affairs and Agency for Health Care Administration, *Program of All-Inclusive Care for the Elderly and Statewide Medicaid Managed Care Long-term Care Program Comparison Report* (January 14, 2014), available at https://ahca.myflorida.com/Medicaid/recent_presentations/PACE_Evaluation_2014.pdf (last visited Mar. 16, 2021).

⁴ *Id.*

- Have a physical site and staff to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals;
- Have a defined service area;
- Have safeguards against conflicts of interest;
- Have a demonstrated fiscal soundness;
- Have a formal participant bill of rights; and
- Have a process to address grievances and appeals.⁵

Eligibility and Benefits

PACE participants must be at least 55 years of age, live in the PACE center service area, meet eligibility requirements for nursing home care, pursuant to a Comprehensive Assessment and Review for Long-Term Care Services (CARES) pre-admission screening, and be able to live in a community setting without jeopardizing their health or safety. The PACE becomes the sole source of services for these Medicare and Medicaid eligible enrollees. Additionally, by electing to enroll in the PACE, the participant agrees to forgo other options for medical services and receive all of their services through the PACE organization.⁶

Under the PACE, an interdisciplinary team consisting of professional and paraprofessional staff assesses participants' needs, develops care plans, and delivers all services, including acute care and nursing facility services when necessary, which are integrated to provide a seamless delivery model. In most cases, a PACE organization provides social and medical services in a health center with supplemental services through in-home and referral services as necessary. The PACE service package must include all Medicare and Medicaid covered services and other services determined necessary by the multidisciplinary team for the care of the PACE participant.⁷

Before being approved to operate and deliver services, PACE organizations are required to provide evidence of the necessary financial capital to deliver the benefits and services, which include a combined adult day care center and primary care clinic, transportation, and full range of clinical and support staff with the interdisciplinary team of professionals.⁸

By federal law, the first three contract years for a PACE organization are considered a trial period, and the PACE organization is subject to annual reviews to ensure compliance.⁹ The site visit reviews include:

- A comprehensive assessment of an organization's fiscal soundness;
- A comprehensive assessment of the organization's capacity to provide all PACE services to all enrolled participants;
- A detailed analysis of the PACE organization's substantial compliance with all the federal statutory requirements and accompanying federal regulations; and

⁵ *Supra* note 2.

⁶ *Id.*

⁷ *Id.*

⁸ *Supra* note 3, at 4.

⁹ See 42 U.S.C. s. 1395eee(e)(4)(A) (2020).

- Compliance with any other elements the Secretary of the U.S. Department of Health and Human Services (Secretary) or the state's administering agency considers necessary and appropriate.¹⁰

Review of the PACE organization may continue after the trial period by the Secretary or the administering state agency as appropriate, depending upon the PACE organization's performance and compliance with requirements and regulations.

No deductibles, copayments, coinsurance, or other cost-sharing can be charged by a PACE organization. No other limits relating to amount, duration, or scope of services that might otherwise apply in Medicaid are permitted.¹¹ The PACE enrollee must accept the PACE center physician as his or her new Medicare primary care physician, if enrolled in Medicare.¹²

Quality of Care Requirements

Each PACE organization is required to develop, implement, maintain, and evaluate an effective data-driven Quality Assurance and Performance Improvement (QAPI) program. The program must incorporate all aspects of the PACE organization's operations, which allows for the identification of areas that need performance improvement. The organization's written QAPI plan must be reviewed by the PACE organization's governing body at least annually. At a minimum, the plan should address the following areas:

- Utilization of services in the PACE organization, especially in key services;
- Participant and caregiver satisfaction with services;
- Data collected during patient assessments to determine if individual and organizational-level outcomes were achieved within a specified time period;
- Effectiveness and safety of direct and contracted services delivered to participants; and
- Outcomes in the organization's non-clinical areas.¹³

Florida PACE

The original Florida PACE project was authorized in ch. 98-327, Laws of Florida, under the administration of the DOEA operating in consultation with the AHCA.¹⁴ Florida's first PACE organization, located in Miami-Dade County, began serving enrollees in February 2003 with a total of 150 slots. Since then, the Legislature has approved additional slots either as part of the General Appropriations Act (GAA) or general law.

In 2011, the Legislature moved administrative responsibility for the PACE from the DOEA to the AHCA as part of the expansion of Medicaid managed care into the Statewide Medicaid Managed Care (SMMC) program.¹⁵ Participation by the PACE in the SMMC program is not subject to the procurement requirements or regional plan number limits normally applicable to

¹⁰ *Id.*

¹¹ *Supra* note 2.

¹² *Supra* note 3.

¹³ *Id.*

¹⁴ Chapter 2011-135, s. 24, Laws of Fla., repealed s. 430.707, F.S., effective October 1, 2013, as part of the expansion of Medicaid managed care.

¹⁵ Chapter 2011-135, s. 24, Laws of Fla., repealed s. 430.707, F.S., effective October 1, 2013.

SMMC plans. Instead, PACE plans may continue to provide services to individuals at such levels and enrollment caps as authorized by the GAA.¹⁶

Currently, five PACE organizations operate in Florida and provide services to participants within specific zip codes Broward, Charlotte, Collier, Duval, Hillsborough, Lee, Miami-Dade, Palm Beach, and Pinellas counties.¹⁷ As of December 2020, there are 2,396 individuals enrolled in the five Florida PACE organizations.¹⁸

The current PACE approval process for a new PACE project authorized by the Legislature requires any entity interested in becoming a PACE organization to submit a comprehensive PACE application to the AHCA, which sets forth details about the adult day care center, staffing, provider network, financial solvency and pro forma financial projections, and policies and procedures, among other elements. The application is similar in detail to the provider applications submitted by managed care plans seeking to provide medical care to Medicaid recipients. PACE providers operating in the same geographic region must establish that there is adequate demand for services so that each provider will be viable. The application requires that documentation be submitted demonstrating that PACE providers in the same geographic region are not competing for the same potential enrollees.

The AHCA and the DOEA review the application and, when the entity has satisfied all requirements, conduct an on-site survey of the entity's readiness to serve PACE enrollees. Once all requirements are met, including full licensure of the PACE center, staffing for key positions, and signed provider network contracts, the AHCA certifies to the federal CMS that the PACE site is ready. At that time, the federal CMS reviews the application and readiness certification and, if all requirements are satisfied, executes a three-way agreement with the PACE provider and the AHCA. The PACE provider may then begin enrolling members, subject to an appropriation to fund the slots.

Enrollment and Organizational Slots

Slots are authorized by the Legislature for a specific PACE area; however, slots may not always be fully funded in the same year the program is authorized. Some PACE providers need additional time to complete the application process, obtain necessary licensures, or to finalize operations.

Funding and Rates

Each year since the PACE's inception, the Legislature has appropriated funds for PACE organizations through proviso language in the GAA or through one of the GAA's accompanying implementing or conforming bills.¹⁹ These directives provide specific slot increases or decreases by county or authorization for implementation of a new program. In 2013, Governor Rick Scott vetoed all county allocations with the exception of Palm Beach County, noting that the state's

¹⁶ Section 409.981(4), F.S.

¹⁷ Agency for Health Care Administration, *House Bill 905 Fiscal Analysis* (Feb. 12, 2021) (on file with Senate Committee on Health Policy).

¹⁸ *Id.*

¹⁹ Chapter 2013-40, Laws of Fla.

focus should be on the implementation of the SMMC and that effectiveness and the need for additional PACE slots should be re-evaluated after that transition was completed.²⁰

PACE organizations receive a capitated Medicaid payment for each enrolled Medicaid long-term care recipient and an enhanced Medicare payment for Medicare enrollees for acute care services from the federal government. The payment amount is established in the GAA and is based on estimates that have been forecast by the Social Services Estimating Conference for the PACE.

Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership between the federal and state governments where the federal government establishes the structure for the program and pays a share of the cost. Each state operates its own Medicaid program under a state plan that must be approved by the federal CMS. The plan outlines current Medicaid eligibility standards, policies, and reimbursement methodologies.

To qualify for nursing home care under Medicaid, both an individual's income and assets are reviewed. Additionally, a personal needs allowance is applied as part of the eligibility determination process.²¹ The current standard income limit in Florida for institutional care or services under the home and community based services waiver is \$2,382 for an individual and \$4,764 for a couple. There is also an asset limit for either category of \$2,000 for an individual or \$3,000 for a couple.²²

In Florida, the Medicaid program is administered by the AHCA. The AHCA, however, delegates certain functions to other state agencies, including the Department of Children and Families (DCF), the Agency for Persons with Disabilities (APD), and the DOEA. The AHCA has overall responsibility for the program and qualifies providers, sets payment levels, and pays for services.

The DCF is responsible for determining financial eligibility for Medicaid recipients. The APD operates one of the larger waiver programs under Medicaid, the Home and Community-Based Services (HCBS) Waiver program, serving individuals with developmental disabilities.

Pursuant to s. 409.985, F.S., the DOEA assesses Medicaid recipients to determine if they require nursing home level of care. Specifically, the DOEA determines whether an individual:

- Requires nursing home placement as evidenced by the need for medical observation throughout a 24-hour period and requires medically complex care to be performed on a daily basis under the direct supervision of a health professional because of mental or physical incapacitation;

²⁰ Governor Rick Scott, *Veto Message - SB 1500* (May 20, 2013), p. 28, available at <http://www.flgov.com/wp-content/uploads/2013/05/Message1.pdf> (last visited Mar. 16, 2021).

²¹ The personal needs allowance (PNA) of an individual is defined as that portion of an individual's income that is protected to meet the individual's personal needs while in an institution. See Department of Children and Families, *Glossary (Chapter 4600) "Personal Needs Allowance,"* p. 19, available at <http://www.dcf.state.fl.us/programs/access/docs/esspolicymanual/4600.pdf> (last visited Mar. 16, 2021).

²² Department of Children and Families, *SSI-Related Program-Financial Eligibility Standards: Apr. 1, 2021*, available at https://www.myflfamilies.com/service-programs/access/docs/esspolicymanual/a_09.pdf (last visited Mar. 16, 2021).

- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires care to be performed on a daily basis under the supervision of a health professional because of mental or physical incapacitation; or
- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires limited care to be performed on a daily basis under the supervision of a health professional because of mild mental or physical incapacitation.

Floridians who need nursing home care, but do not qualify for Medicaid, must pay from their own funds or through insurance.

Long-Term Care Managed Care

In 2011, CS/HB 7107²³ was signed into law, increasing the use of managed care plans in Medicaid. The law required both Medicaid LTC services and Managed Medical Assistance (MMA) services to be provided through managed care plans.

LTC Managed Care plans participating in SMMC are required to provide minimum benefits that include nursing home care as well as home and community based services. The minimum benefits include:

- Nursing home care;
- Services provided in assisted living facilities;
- Hospice;
- Adult day care;
- Medical equipment and supplies, including incontinence supplies;
- Personal care;
- Home accessibility adaptation;
- Behavior management;
- Home delivered meals;
- Case management;
- Therapies, including physical, respiratory, speech, and occupational;
- Intermittent and skilled nursing;
- Medication administration;
- Medication management;
- Nutritional assessment and risk reduction;
- Caregiver training;
- Respite care;
- Transportation; and
- Personal emergency response system.

²³ Chapter 2011-134, Laws of Fla.

III. Effect of Proposed Changes:

Section 1 creates s. 430.84, F.S., and codifies the Program of All-Inclusive Care for the Elderly (PACE) within the Florida Statutes. Currently, the program does not have an implementing statute and has been operationalized through annual appropriations, proviso, or bills designed to implement the state budget or conform statute to provisions of the state budget.

Program Creation

The bill authorizes the AHCA, in consultation with the DOEA, to approve entities that have submitted the required application and data to the federal CMS as PACE organizations pursuant to 42 U.S.C. s. 1395eee. Applications, as required by the federal CMS, will be reviewed by the AHCA on an ongoing basis, in consultation with the DOEA for initial approval as PACE organizations. Notice of applications must be published in the Florida Administrative Register.

A prospective PACE organization must submit an application to the AHCA before submitting a request for program funding. An applicant must meet the following requirements:

- Provide evidence that the applicant can meet all of the federal regulations and requirements established by the federal CMS by the proposed implementation date;
- Provide market studies which include an estimate of the potential number of participants and which show the geographic area the applicant proposes to serve;
- Develop and provide a business plan of operation, including pro forma financial statement and projections based on the planned implementation date;
- Show evidence of regulatory compliance and meet market studies requirements, if the applicant is an existing PACE organization which seeks to expand to an additional service area;
- Serve a unique and defined geographic service area without duplication of services or target populations. No more than one PACE organization may be authorized to provide services within any unique and defined geographic area; and
- Submit its complete federal PACE application to the AHCA and the federal CMS within 12 months after date of initial state approval. If the organization fails to timely meet this requirement, the state approval of the application is void.

Quality and Reporting

All PACE organizations are required to meet specific quality and performance standards established by the federal CMS and the state administering agency (the AHCA). The AHCA has the responsibility to oversee and monitor Florida's PACE and the contracted organizations through the data and reports submitted periodically to the AHCA and the federal CMS.

The bill exempts all PACE organizations from the requirements of chapter 641, the chapter of Florida law that regulates health maintenance organizations, prepaid health clinics, and other health care service programs.

Section 2 provides an effective date of July 1, 2020.

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:

Additional private sector providers that meet the criteria to be a Program of All-Inclusive Care for the Elderly (PACE) organization and achieve eligibility confirmation status could be approved as PACE sites. Expansion of PACE sites would also mean additional individuals in the community would have access to the PACE model for medical care and long-term care.

C. Government Sector Impact:

The bill has no fiscal impact on state revenues or expenditures.²⁴

VI. Technical Deficiencies:

None.

VII. Related Issues:

In subsection (4) of section 430.84, the bill directs the AHCA to oversee and monitor the PACE by using data and reports that the PACE organizations submit periodically to the AHCA and

²⁴ *Supra* note 17.

CMS. This subsection requires PACE organizations to meet standards established by the CMS. Because the bill limits the AHCA's oversight to only CMS standards, the AHCA has indicated that it may not be able to compare PACE and the Statewide Medicaid Managed Care Long-Term Care (LTC) program under the bill to ensure comparable quality and patient outcomes.²⁵

VIII. Statutes Affected:

This bill creates section 430.84 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 24, 2021:

The CS requires all PACE organizations to meet specific quality performance standards established by the CMS and the state administering agency (the AHCA), rather than just the CMS.

- B. **Amendments:**

None.

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

²⁵ *Id.*



284458

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/24/2021	.	
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	.	
	.	

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

Senate Amendment (with title amendment)

Delete line 92
and insert:
CMS and the state administering agency for the PACE program. The
agency shall oversee and monitor

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

And the title is amended as follows:

Delete line 18
and insert:



284458

12 PACE organizations meet certain federal and state
13 quality and

By Senator Book

32-01322-21

20211242__

1 A bill to be entitled

2 An act relating to the Program of All-Inclusive Care

3 for the Elderly; creating s. 430.84, F.S.; defining

4 terms; authorizing the Agency for Health Care

5 Administration, in consultation with the Department of

6 Elderly Affairs, to approve entities applying to

7 deliver PACE services in the state; requiring

8 applications to be reviewed and considered on a

9 continuous basis; requiring notice of applications to

10 be published in the Florida Administrative Register;

11 providing specified application requirements for such

12 prospective PACE organizations; requiring existing

13 PACE organizations to meet specified requirements

14 under certain circumstances; requiring prospective

15 PACE organizations to submit a complete application to

16 the agency and the Centers for Medicare and Medicaid

17 Services within a specified period; requiring that

18 PACE organizations meet certain federal quality and

19 performance standards; requiring the agency to oversee

20 and monitor the PACE program and organizations;

21 providing that a PACE organization is exempt from

22 certain requirements; providing an effective date.

23

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

25

26 Section 1. Section 430.84, Florida Statutes, is created to

27 read:

28 430.84 Program of All-Inclusive Care for the Elderly.—

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

Page 1 of 4

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

32-01322-21

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30 (a) "Agency" means the Agency for Health Care

31 Administration.

32 (b) "Applicant" means an entity that has filed an

33 application with the agency for consideration as a Program of

34 All-Inclusive Care for the Elderly (PACE) organization.

35 (c) "CMS" means the Centers for Medicare and Medicaid

36 Services within the United States Department of Health and Human

37 Services.

38 (d) "Department" means the Department of Elderly Affairs.

39 (e) "PACE organization" means an entity under contract with

40 the agency to deliver PACE services.

41 (f) "Participant" means an individual receiving services

42 from a PACE organization who has been determined by the

43 department to need the level of care required under the state

44 Medicaid plan for coverage of nursing facility services.

45 (2) PROGRAM CREATION.—The agency, in consultation with the

46 department, may approve entities that have submitted

47 applications required by the CMS to the agency for review and

48 consideration which contain the data and information required in

49 subsection (3) to provide benefits pursuant to the PACE program

50 as established in 42 U.S.C. s. 1395eee and in accordance with

51 the requirements set forth in this section.

52 (3) PACE ORGANIZATION SELECTION.—The agency, in

53 consultation with the department, shall, on a continuous basis,

54 review and consider applications required by the CMS for PACE

55 that have been submitted to the agency by entities seeking

56 initial, state approval to become PACE organizations. Notice of

57 such applications shall be published in the Florida

58 Administrative Register.

Page 2 of 4

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

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(a) A prospective PACE organization shall submit application documents to the agency before requesting program funding. Application documents submitted to and reviewed by the agency, in consultation with the department, must include all of the following:

1. Evidence that the applicant has the ability to meet all of the applicable federal regulations and requirements, established by the CMS, for participation as a PACE organization by the proposed implementation date.

2. Market studies, including an estimate of the number of potential participants and the geographic service area in which the applicant proposes to serve.

3. A business plan of operation, including pro forma financial statements and projections, based on the proposed implementation date.

(b) Each applicant must propose to serve a unique and defined geographic service area without duplication of services or target populations. No more than one PACE organization may be authorized to provide services within any unique and defined geographic service area.

(c) An existing PACE organization seeking authority to serve an additional geographic service area not previously authorized by the agency or Legislature shall meet the requirements set forth in paragraphs (a) and (b).

(d) Any prospective PACE organization that is granted initial state approval by the agency, in consultation with the department, shall submit its complete federal PACE application, in accordance with the application process and guidelines established by the CMS, to the agency and the CMS within 12

32-01322-21

20211242__

months after the date of initial state approval, or such approval is void.

(4) ACCOUNTABILITY.—All PACE organizations must meet specific quality and performance standards established by the CMS for the PACE program. The agency shall oversee and monitor the PACE program and organizations based upon data and reports periodically submitted by PACE organizations to the agency and the CMS. A PACE organization is exempt from the requirements of chapter 641.

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



The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: February 24, 2021

I respectfully request that **Senate Bill 1242**, relating to Program of All-Inclusive Care for the Elderly, be placed on the:

- ☐ committee agenda at your earliest possible convenience.
- ☒ next committee agenda.

Thank you for your consideration.

A handwritten signature in cursive script that reads "Lauren Book".

Senator Lauren Book
Florida Senate, District 32



2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION

BILL NUMBER:	HB 905
BILL TITLE:	Program of All-Inclusive Care for the Elderly
BILL SPONSOR:	Representative Rommel
EFFECTIVE DATE:	July 1, 2021

COMMITTEES OF REFERENCE

1)
2)
3)
4)
5)

CURRENT COMMITTEE

SIMILAR BILLS

BILL NUMBER:	SB 1242
SPONSOR:	Senator Book

PREVIOUS LEGISLATION

BILL NUMBER:	SB 778
SPONSOR:	Senator Baxley
YEAR:	2019
LAST ACTION:	Died in Appropriations

IDENTICAL BILLS

BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?

Y ___ N X

BILL ANALYSIS INFORMATION

DATE OF ANALYSIS:	February 12, 2021
LEAD AGENCY ANALYST:	Kimberly Quinn
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

HB 905 creates section 430.84, Florida Statutes (F.S.), which codifies requirements for an organization seeking approval to operate a Program of All-Inclusive Care for the Elderly (PACE) program in Florida, which are not currently in statute. The bill also establishes requirements related to organization selection and accountability.

The language requires prospective PACE organizations to apply to the Agency for Health Care Administration (Agency) for state approval prior to receiving program funding. The bill provides a list of materials applicants must submit as part of the application process and requires the Agency to notice the application in the Florida Administrative Register. Each PACE applicant must also propose to serve a unique and defined geographic service area, with no more than one PACE organization authorized to provide services within any unique and defined service area. This is a new requirement, as currently there is no language that would allow the Agency to deny an application because it overlaps with another PACE organization's geographic service area. Also, a PACE applicant must submit its complete federal PACE application to the Agency and CMS within 12 months after initial state approval, or such approval is void. These changes would provide clarity to the application process.

The bill states that the PACE organization must meet quality and performance standards established by CMS and that the Agency will oversee and monitor the PACE program using data and reports that the PACE organizations submit periodically to the Agency and CMS. The Agency is in the process of developing additional standards for PACE organizations that will allow comparisons and evaluation between the PACE and the Statewide Medicaid Managed Care Long-Term Care (LTC) programs. If the bill is intended to limit the Agency's oversight to only reports submitted to CMS, then the Agency may not be able to compare PACE and the LTC managed care program and ensure comparable quality and patient outcomes.

HB 905 requires minor changes to the Agency's processes related to PACE application review, however, the workload can be completed using current Agency resources.

This act will take effect on July 1, 2021.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

PACE is a Medicare and Medicaid program that helps people meet their health and long-term care needs in the community instead of going to a nursing home or other care facility. PACE programs primarily organize their services in a PACE Center, which in Florida is licensed as an adult day care center. Participants come to the center, often several times a week, for primary care, nursing, recreation, therapy, supervision, and socialization.

In order to enroll in PACE, federal law requires individuals meet the following criteria:

- Individuals age 55 years or older
- Individuals determined by the state to need the level of care required under the State Medicaid plan for coverage of nursing facility services
- Individuals who reside in the service area of the PACE organization
- Individuals who are able to live in a community setting without jeopardizing his or her health or safety

Individuals who choose to enroll in PACE have both their medical and long-term care needs managed through a single organization. Here are some of the services PACE covers:

- Adult day care (including doctor, recreational therapy, and nursing services)
- Dentistry
- Emergency services
- Home care

- Hospital care
- Laboratory/x-ray services
- Meals (home-delivered meals and meals provided at the Adult Day Care Center)
- Medical specialty services
- Nursing home care
- Nutritional counseling
- Occupational therapy
- Physical therapy
- Prescription drugs
- Primary care

The Agency is the single state agency responsible for the administration of the Florida Medicaid and PACE programs; both programs are authorized under Title XIX of the Social Security Act. This authority includes establishing and maintaining a Medicaid state plan, approved by the federal Centers for Medicare and Medicaid Services (CMS). A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs. Within the Medicaid state plan, states establish and maintain a PACE Program Agreement plan that is approved by CMS. The PACE Program Agreement is an agreement between a state administering agency, the PACE organization, and the federal government describing how that state administers the PACE program. It establishes the group of individuals covered by each PACE organization and details covered services, payment methodologies, and other administrative and organizational requirements. The Agency must also maintain compliance with federal regulations necessary to operate the PACE program as funded through the General Appropriations Act and directed by the Florida Legislature.

In addition to services covered under Medicaid, PACE includes all Medicare-covered services for individuals eligible for Medicare (known as dual eligibles). For dual eligibles, PACE organizations receive both Medicare and Medicaid capitated payments and are responsible for providing the full continuum of medical and long-term care services. Individuals receive all their services from providers in the PACE network, including their primary care.

Currently, five PACE organizations operate in Florida and provide services to participants within specific ZIP codes in Ge counties. There are 2,396 individuals enrolled in the 5 Florida PACE organizations as of December 2020.

Current Application/Enrollment Process for PACE Organizations

In order to operate as a PACE organization in any state, the PACE organization must meet the requirements as outlined in the Code of Federal Regulations (CFR), 42 CFR 460. Federal regulations require a PACE organization to receive approval from CMS to operate.

In order to operate the PACE program in Florida, each service area must have funds appropriated through the General Appropriations Act (GAA) as passed by the Legislature and approved by the Governor each fiscal year. The GAA also includes an allocation of "slots," which is the maximum number of individuals that may be served in each service area. There is currently no formal process for estimating or designating new slots specific to each PACE organization or service location. The lack of methodology needed to accurately determine the appropriate number of slots can complicate the approach of prospective PACE organizations when applying, expanding, and managing current operations. Problems occur when the state funds are appropriated prior to the organization's approval or ability to operate, or the organization has the approval and ability to operate, but does not have the funds appropriated.

The following outlines the current process by which PACE program applicants recognized by the Legislature can enroll as a PACE provider in Florida:

- The PACE program applicant must have slots designated by the Legislature prior to application.

- The applicant must notify the Agency, in writing, regarding its intent to apply and must provide a copy of the application to the Agency prior to submitting the application to the CMS Health Plan Management System.
- The applicant must send the Agency all supplemental documentation required in 42 CFR 460 for the application review process. The Agency and the Department of Elder Affairs (DOEA) review all documents and verify that the applicant meets all the requirements. The Agency then forwards the application to the prospective PACE organization for submission to CMS with a certification that the State has reviewed and certifies the application is complete and in compliance.
 - Please note that no state application submission timelines currently exist, but CMS has an annual application submission window. To meet the CMS application submission deadline, applicants must send the notification, application, and all supplemental documentation to the Agency for review prior to the established CMS quarterly deadline.
- Per 42 CFR 460.18, CMS evaluates an application for approval as a PACE organization on the basis of the following information: (a) Information contained in the application; (b) Information obtained through onsite visits conducted by CMS or the state administering agency; (c) Information obtained by the state administering agency.
- CMS will either approve or deny the application. CMS may also request additional information to make a determination.
- In addition to federal approval, all PACE organizations must enroll as a Medicaid provider and receive an Adult Day Care License through the Agency.

In fiscal year 20/21, the Agency and DOEA have received, or expect to receive, at least five PACE applications. Presently, the Agency and DOEA have received one PACE application from a prospective PACE organization that would overlap service areas with another PACE applicant. Additionally, the Agency anticipates imminent receipt of another PACE application that would overlap service areas with an existing PACE organization. At this time, the Agency and DOEA do not have the ability to deny an application that overlaps with another PACE organization's geographic service area. The Agency instead is conducting market feasibility studies to look at whether the geographic service area has the potential to sustain two PACE programs along with the Statewide Medicaid Managed Care Long-Term Care plans.

Administration of PACE

To administer PACE, the Agency works with DOEA and coordinates the reviews for initial and service area expansion applications and any proposed amendments to the PACE Program Agreement (see 42 CFR 460). The Agency and DOEA also collaborate in the oversight, monitoring, and data collection activities of PACE organizations. DOEA compiles funding and population projections on a monthly basis to ensure the program has reasonable growth capacity. The Agency, in collaboration with CMS, conducts audits of each PACE organization. The PACE organization also submits quarterly reports to CMS on the organization's quality and performance.

The Agency requires prospective participants to be determined medically and financially eligible prior to enrollment in PACE. In almost all cases, an individual who meets the PACE enrollment criteria will also qualify for the Statewide Medicaid Managed Care Long-Term Care (LTC) program (authorized under Part IV of Chapter 409, F.S.). The LTC program provides comprehensive home and community-based services to help eligible members remain in the community and avoid institutionalization in a nursing facility. The LTC program is available statewide and serves over 100,000 individuals ages 18 and older who are elderly or have a disability and meet the qualifications for nursing facility care. Health plans providing LTC services are competitively selected to provide the best value to the State and the Medicaid recipients. These plans are held to national quality standards and are comprehensively and continuously monitored by the Agency to ensure contract compliance and quality. While engaging in the independent choice counseling process, prospective PACE and/or LTC participants are educated about both programs, if a PACE organization serves their area, and they can choose to enroll in either program.

2. EFFECT OF THE BILL:

HB 905 creates section 430.84, F.S., which codifies the requirements for an organization seeking approval to operate a PACE program in Florida. The bill also establishes requirements related to organization selection and accountability.

The language requires prospective PACE organizations to apply to the Agency for state approval prior to receiving program funding. In addition, the bill provides a list of materials applicants must submit as part of the application process. Each PACE applicant must also propose to serve a unique and defined geographic service area, with no more than one PACE organization authorized to provide services within any unique and defined service area. This poses a change to the current application review process, as currently there is no language that exists that would allow the Agency to deny an application because it does not propose to serve a unique and defined geographic service area. Also, a PACE applicant must submit their complete federal PACE application to the Agency and CMS within 12 months after initial state approval, or such approval is void. These changes would provide clarity to the application process.

The bill states that the PACE organization must meet quality and performance standards established by CMS and that the Agency will oversee and monitor the PACE program using data and reports that the PACE organizations submit periodically to the Agency and CMS. The Agency is in the process of developing additional reporting requirements and standards for PACE organizations that will allow comparisons and evaluation between the PACE and LTC programs. If the bill is intended to limit the Agency's oversight to only CMS standards, then the Agency may not be able to compare PACE and the LTC managed care program and ensure quality of care and positive member outcomes.

The bill clarifies in the section related to accountability that PACE organizations are exempt from Chapter 641, F.S., which is the primary regulatory statute for health maintenance organizations, prepaid health clinics, and health care services. All of the LTC plans operating under the SMMC program are regulated under Chapter 641, F.S. This change has no impact on the Agency's operational procedures as the Agency does not currently apply the requirements codified in Chapter 641, F.S. to PACE organizations.

HB 905 poses a minor operational impact to the Agency; however, the workload can be completed using current Agency resources. Although this bill does not direct the Agency to initiate rulemaking in conjunction with the new statutory language, the Agency would need to utilize existing statutory authority to promulgate an administrative rule to clearly outline the Agency's expectations regarding the PACE application process. Rulemaking is part of the Agency's standard business operations and can be completed using existing Agency resources.

This act will take effect on July 1, 2021.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y x N

If yes, explain:	Although this bill does not direct the Agency to initiate rulemaking in conjunction with the new statutory language, the Agency would need to utilize existing statutory authority to promulgate an administrative rule to clearly outline the Agency's expectations regarding the PACE application process.
Is the change consistent with the agency's core mission?	Y <u>x</u> N <u> </u>
Rule(s) impacted (provide references to F.A.C., etc.):	

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	
Opponents and summary of position:	

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ___ N X

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQUIRED BY THIS BILL? Y ___ N X

Board:	
Board Purpose:	
Who Appointments:	
Appointee Term:	
Changes:	
Bill Section Number(s):	

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y ___ N X

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees? If yes, explain.	
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y ___ N X

Revenues:	
Expenditures:	
Does the legislation contain a State Government appropriation?	
If yes, was this appropriated last year?	

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y ___ N X

Revenues:	

Expenditures:	
Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y ___ N X

If yes, explain impact.	
Bill Section Number:	

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y ___ N X

If yes, describe the anticipated impact to the agency including any fiscal impact.	

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y ___ N X

If yes, describe the anticipated impact including any fiscal impact.	

ADDITIONAL COMMENTS

The bill as written could be interpreted as requiring PACE organizations to only meet quality standards established by federal CMS. This would preclude AHCA from establishing standards that would allow it to measure PACE performance and compare PACE to the performance of managed LTC plans.

As a result, the Agency would like to recommend the following amendment. The purpose of this amendment is to ensure that the state can set minimum quality standards to be able to compare PACE organizations' performance to that of the Long-Term Care (LTC) managed care program.

Proposed Amendment

Remove lines 89 and 90 and insert:

specific quality and performance standards established by the CMS and the state administering agency for the PACE program. The agency shall oversee and monitor

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/21

Meeting Date

1242

Bill Number (if applicable)

Topic PACE Bill

Amendment Barcode (if applicable)

Name Matt Hudson

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Speaking: ☐ For ☐ Against ☒ Information

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

Representing Florida PACE Providers Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/20

Meeting Date

1242

Bill Number (if applicable)

Topic Program of All Inclusive Care for the Elderly

Amendment Barcode (if applicable)

Name Kelly Mallette

Job Title _____

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Miami Jewish Health System

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: SB 1268

INTRODUCER: Senator Baxley

SUBJECT: Coverage for Hearing Aids for Children

DATE: March 23, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	Favorable
2.	Smith	Brown	HP	Favorable
3.			AP	

I. Summary:

SB 1268 requires an individual health insurance policy or individual health maintenance organization (HMO) contract that provides major medical coverage for a dependent child of an insured or subscriber, respectively, to provide hearing aid coverage for children from birth through age 18 who have been diagnosed with hearing loss by a licensed physician or a licensed audiologist. The term “hearing aid” means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing, and includes ear molds. The term does not include cochlear implants.

The bill requires such policies or contracts to provide a minimum coverage limit of \$3,500 per ear within a 24-month period. The insured or subscriber remains responsible for the additional cost of hearing aids that exceed the coverage limit provided for in their policy or contract. If a child experiences a significant and unexpected change in his or her hearing or experiences a medical condition requiring an unexpected change in the prescription for the hearing aid before the existing 24-month period expires, and alterations to the existing hearing aid do not, or cannot, meet the needs of the child, the bill requires that a new 24-month period must begin with full benefits and coverage.

The bill applies to individual policies or contracts issued on or after January 1, 2022. The provisions of the bill do not apply to the State Group Insurance program; therefore, there is no fiscal impact to that program.

II. Present Situation:

One in eight people in the United States (13 percent, or 30 million) age 12 years or older has hearing loss in both ears, based on standard hearing examinations.¹ Hearing loss is one of the most common birth defects² in the United States, with approximately two or three out of every 1,000 children in the United States are born with a detectable level of hearing loss in one or both ears.³

Many people who are deaf or hard-of-hearing have some hearing. In some instances, a hearing aid may help a child with hearing loss to make the most of their residual hearing.⁴ Hearing aids make sounds louder and can be worn by people of any age, including infants. Babies with hearing loss may understand sounds better using hearing aids. There are many styles of hearing aids. They can help many types of hearing loss. A young child is usually fitted with behind-the-ear style hearing aids because they are better suited to growing ears.⁵

Hearing loss may be in one ear (unilateral loss) or in both ears (bilateral loss). The degree of hearing loss can range from mild to profound, as described below:⁶

- Mild Hearing Loss (26-40 decibels). A person with a mild hearing loss may hear some speech sounds, but soft sounds are hard to hear.
- Moderate Hearing Loss (41-70 decibels). A person with a moderate hearing loss may hear almost no speech when another person is talking at a normal level.
- Severe Hearing Loss (71-90 decibels). A person with severe hearing loss will hear no speech when a person is talking at a normal level and only hear some loud sounds.
- Profound Hearing Loss (91 decibels or more). A person with a profound hearing loss will not hear any speech and will hear only very loud sounds.⁷

Hearing loss can affect a child's ability to develop communication, language, and social skills. Early detection of hearing loss can help infants and children with learning and reaching developmental milestones, according to recent research. In the United States, researchers have reported that children have more favorable language outcomes, such as greater vocabulary and reading abilities, when hearing loss is identified sooner and the child receives hearing aids and

¹ See National Institutes for Health, National Institute on Deafness and Other Communication Disorders *available at* <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing> (last visited Mar. 18, 2021).

² Florida Newborn Screening, Early Hearing and Intervention Program *available at* <https://floridanewbornscreening.com/hearing/early-hearing-and-intervention-programs/> (last visited Mar. 18, 2021).

³ *Id.*

⁴ Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disorders (Jun. 8, 2020) *available at* <https://www.cdc.gov/ncbddd/hearingloss/treatment.html> (last visited Mar. 18, 2021). The amount of hearing a deaf or hard-of-hearing person has is referred to as “residual hearing.”

⁵ *Id.* A plastic ear mold is connected to a behind-the-ear hearing aid and is fitted for the child's ear. It directs sound from the hearing aid into the ear canal. Each person's ear is shaped differently, and a child's ear will change as he or she grows. An audiologist uses a soft material to make a copy of the child's outer ear canal. This is used to make an ear mold that will fit the child. As the child grows, new ear molds can be made and attached to the same hearing aid.

⁶ Florida Department of Health and Children's Medical Services, *A Florida Parent's Guide to Hearing* (Apr. 2020 Edition) *available at* <http://floridanewbornscreening.com/wp-content/uploads/Hearing-Guide-English-FINAL-1.pdf> (last visited Mar. 18, 2021).

⁷ See Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disorders (Jun. 8, 2020), *available at* <https://www.cdc.gov/ncbddd/hearingloss/types.html> (last visited Mar. 18, 2021).

interventions at an earlier age.⁸ A second study similarly found that children who received hearing aids and cochlear implants earlier had better language outcomes, comparing language skills with the provision of a hearing aid at three months compared to 24 months.⁹ The authors' state:

The younger the child received intervention, the better the language outcome. In addition, more substantial benefits of earlier access to useful HAs (hearing aids) and CI (cochlear implants) were obtained by those with worse hearing. Earlier intervening, rather than access to UNHS (universal newborn hearing screening), improved outcomes.¹⁰

Florida Newborn Hearing Screening Program

Florida has a universal newborn hearing-screening program¹¹ that requires all Florida-licensed facilities that provide maternity and newborn care to screen, or refer for screening, all newborns prior to discharge for hearing loss, unless a parent objects to the screening.¹² All test results, including recommendations for any referrals or follow-up evaluations by a licensed audiologist, a physician licensed under chs. 458 or 459, F.S., or other newborn hearing screening providers in the hospital facility, must be placed in the newborn's medical records within 24 hours after the completion of the screening procedure.¹³ For babies born in a facility other than a hospital, the parents are to be instructed on the importance of having a screening conducted, information must be provided, and assistance must be given to make an appointment within three months.¹⁴

The initial newborn screening and any necessary follow-up and evaluation are covered benefits reimbursable by Medicaid, health insurers, and health maintenance organizations, with some limited exceptions.¹⁵ For those newborns and children found to have a permanent hearing loss, the law also provides for referral to the state's Part C program of the federal Individuals with Disabilities Education Act¹⁶ and Children's Medical Services' Early Intervention Program, Early Steps.¹⁷

⁸ Christine Yoshinaga-Itano, Ph.D., et al, *Early Hearing Detection and Vocabulary of Children with Hearing Loss*, PEDIATRICS, (Aug. 2017, Vol. 140, No. 2), available at <https://pediatrics.aappublications.org/content/140/2/e20162964> (last visited Mar. 18, 2021).

⁹ Teresa Y.C. Ching, Ph.D., *Age at Intervention for Permanent Hearing Loss and 5-Year Language Outcomes*, Pediatrics, (Sept. 2017, Vol. 140, Issue 3), available at <https://pediatrics.aappublications.org/content/140/3/e20164274> (last visited Mar. 18, 2021).

¹⁰ *Id.*

¹¹ Florida's Early Hearing Detection and Intervention Program (EHDI) is Florida's newborn hearing-screening program available at <https://floridanewbornscreening.com/hearing/early-hearing-and-intervention-programs/> (last visited Mar. 18, 2021).

¹² See s. 383.145, F.S.

¹³ Section 383.145(3)(e), F.S.

¹⁴ Section 383.145(3)(i), F.S.

¹⁵ Section 383.145(3)(j), F.S.

¹⁶ See Pub. L. No. 108-446. The Part C program provides benefits and services for infants and toddlers from birth to age 36 months. Florida's Part C program is known as Early Steps and is administered by the Children's Medical Services within the Department of Health.

¹⁷ The Early Steps program services children with disabilities, developmental delays, or children with a physical or mental condition known to create a risk of a developmental delay. See http://www.cms-kids.com/families/early_steps/early_steps.html (last visited Mar. 18, 2021).

Hearing Aid Coverage in Public Insurance Programs

Medicaid

Florida Medicaid provides hearing services for eligible recipients under the age of 21, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. This coverage includes diagnostic services, treatment, equipment, supplies, and other measures described in 42 U.S.C. 1396d(a).¹⁸ Medicaid recipients under the age of 21 have coverage for the following hearing related services:

- Recipients who have documented, profound, severe hearing loss in one or both ears have coverage for:
 - An implanted device for recipients age five years and older; or
 - A non-implanted (softband) device for recipients under age five.
- Cochlear implants for recipients age 12 months and older who have documented, profound to severe, bilateral sensorineural hearing loss.
- For recipients who have moderate hearing loss or greater, the coverage is:
 - One new, complete, (not refurbished) hearing aid device per ear, every three years, per recipient;
 - Up to three pairs of ear molds per year, per recipient; and
 - One fitting and dispensing service per ear, every three years, per recipient.
- A recipient under the age of 12 months may receive up to two newborn screenings. A second screening may be conducted only if the recipient did not pass the test in one or both ears.
- An eligible recipient may receive one hearing assessment every 3 years for the purposes of determining hearing aid candidacy and the most appropriate hearing aid.¹⁹

Medicaid also covers repairs and replacement of both Medicaid and non-Medicaid provided hearing aids, up to two hearing aid repairs every 366 days, after the one-year warranty period has expired.²⁰

State Children's Health Insurance Program²¹

The Children's Health Insurance Program (CHIP) was enacted as part of the Balanced Budget Act of 1997, and it created Title XXI of the federal Social Security Act as a joint state-federal funding partnership to provide health insurance to children in low to moderate income households.²² The Florida Healthy Kids Corporation²³ is one component of Florida's Title XXI program, known as Florida KidCare, and is the only program component utilizing a non-Medicaid benefit package.²⁴ The other program components, Medicaid for children, Medikids, and Children's Medical Services Network, follow the Medicaid benefit package.²⁵

¹⁸ See Fla. Admin. Code R. 54G-4.110 (2021). The hearing services coverage policy from the Agency for Health Care Administration available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-06744> (last visited Mar. 18, 2021).

¹⁹ See Agency for Health Care Administration, *Hearing Services Coverage Policy* (June 2016), available at http://ahca.myflorida.com/medicaid/review/specific_policy.shtml (last visited Mar. 18, 2021).

²⁰ *Id.*

²¹ 42 U.S.C. 1397aa-1397mm.

²² Pub. L. No. 105-33, 111 Stat. 251 (1997).

²³ See ss. 624.91-624.915, F.S.

²⁴ See ss. 409.810-409.821, F.S.

²⁵ See s. 409.815(2)(a), F.S., and s. 391.0315, F.S.

In order for health benefits coverage to qualify for premium assistance payments, KidCare enrollees must receive hearing screenings as a covered, preventative health service.²⁶ Additionally, s. 409.815(2)(h), F.S., provides that the benefits for durable medical equipment include within covered services equipment and devices that are medically indicated to assist in the treatment of a medical condition, and specifically prescribed as medically necessary. Hearing aids are covered only when medically indicated to assist in the treatment of a medical condition. There are no out of pocket costs for the well-child hearing screening and the provision of hearing aids for subsidized Title XXI eligible children.²⁷

Hearing Aid Coverage in the Private Health Insurance Market

The Office of Insurance Regulation (OIR) is responsible for the regulation of all activities of insurers and other risk-bearing entities that do business in Florida.²⁸ Florida law does not require health insurance policies or HMO contracts to provide coverage for hearing aids. According to the OIR, some of the plans offered by UnitedHealthcare (All Savers, Neighborhood Health, etc.) cover hearing aids if recommended by a physician, and bone-anchored hearing aids are covered with some restrictions. Molina and Health First cover implant type hearing aids, if medically necessary.²⁹

Currently, 19 states appear to mandate health benefit plans to provide coverage for hearing aids for children only.³⁰ Coverage requirements range from authorizing coverage of a hearing aid every 24 months to every five years. Many states include caps on the amount the insurer must pay. These caps range from \$1,000 to \$4,000.³¹

State Mandated Health Insurance Coverage

Prior to 2012, the OIR identified 18 state mandated benefits.³² Subsequently, Florida has not enacted any mandated benefits. Examples of benefits mandated under Florida law include:

- Treatment for temporomandibular joint disorders;
- Coverage for bone marrow transplants;
- Coverage for certain cancer drugs;
- Diabetes treatment services;
- Osteoporosis;
- Certain coverage for newborn children;
- Child health supervision services; and

²⁶ Section 409.815(2)(a), F.S.

²⁷ Florida Healthy Kids Corporation, *Medical Benefits available at* <https://www.healthykids.org/benefits/medical/> (last visited Mar. 18, 2021).

²⁸ The OIR is under the Financial Services Commission, which is composed of the Governor, the Attorney General, the Chief Financial Officer, and the Commissioner of Agriculture, which serves as the agency head of the commission. Section 20.121(3), F.S.

²⁹ Office of Insurance Regulation correspondence (Dec. 8, 2020) (on file with Senate Committee on Health Policy).

³⁰ See information gathered by the American Speech-Language-Hearing Association *available at* https://www.asha.org/advocacy/state/issues/ha_reimbursement/ (last visited Mar. 18, 2021). In addition, five states require coverage for adults and children.

³¹ *Id.*

³² Centers for Medicare & Medicaid Services, *Florida – State Required Benefits, available at* https://downloads.cms.gov/ccio/State%20Required%20Benefits_FL.pdf (last visited Mar. 18, 2021).

- Treatment of cleft lip and cleft palate in children.³³

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal, which would mandate a health coverage or the offering of a health coverage by an insurer, to submit to the Agency for Health Care Administration and the legislative committees having jurisdiction, a report that assesses the social and financial impacts of the proposed coverage. Proponents have submitted a report to Senate Banking and Insurance Committee staff which indicates that less than 7,200 children under the age of 18 in Florida are deaf.³⁴ Hearing aids and the services necessary to prescribe, evaluate, fit, and manage children with hearing loss generally cost an average of \$3,500 per ear depending on the technology and enhancements selected by the audiologist based on the individual needs of the child.³⁵ (See Section V, Fiscal Impact Statement, Private Sector Impact of the Bill Analysis.)

Advocates of the bill note that untreated hearing loss may lead to tremendous expense for the taxpayer, as described below:

- Untreated pediatric hearing loss costs \$420,000 in special education costs per child and \$1 million over the lifetime of the individual.
- Longitudinal, peer-reviewed studies have shown that healthcare costs are significantly higher for individuals with untreated vs treated hearing loss.
- Increased costs are not confined to the medical bills in the studies. Medical providers must absorb (and pass on via increased overall costs) costs incurred from longer visit times due to communication difficulties, increased risk of malpractice lawsuits from communication difficulties, and necessary accommodations like interpreter services.
- Communication difficulties in deaf and hard of hearing patients, which would be mitigated by appropriate access to sound, result in more physician visits and overuse of emergency rooms and urgent care centers.
- Patients with untreated hearing loss are more likely to be misdiagnosed when visiting providers for unrelated health issues and are more difficult to treat due to communication difficulties.³⁶

Federal Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA)³⁷ does not require health insurance policies to cover hearing aids for adults or for children. Under PPACA, individuals and small businesses can obtain health insurance coverage on or off the federal marketplace exchanges.³⁸

³³ *Id.*

³⁴ Florida Coalition for Spoken Language Options, *SB 1268 Mandate Report* (on file with Senate Committee on Health Policy).

³⁵ *Id.*

³⁶ *Id.*

³⁷ The PPACA (Pub. Law No. 111-148) was enacted on March 23, 2010. On March 30, 2010, PPACA was amended by Pub. Law No. 111-152, the Health Care and Education Reconciliation Act of 2010. The two laws are collectively referred to as the “Patient Protection and Affordable Care Act” or “PPACA.”

³⁸ Exchanges are entities established under PPACA through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs). Many individuals who enroll in QHPs through individual market exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. 42 U.S.C. s. 18031.

All non-grandfathered health plans³⁹ must offer qualified health plans meeting certain federal mandates, including the provisions of the following 10 essential health benefits (EHB):

- Ambulatory services (outpatient care);
- Emergency services;
- Hospitalization (inpatient care);
- Maternity and newborn care;
- Mental health and substance abuse disorder services;
- Prescription drugs;
- Rehabilitative services and rehabilitative services and devices;
- Laboratory services;
- Preventive care and chronic disease management; and
- Pediatric services, including oral and vision care.⁴⁰

States may modify the EHB offered in their states by mandating additional coverage. However, states must defray the associated costs such benefits imposed on qualified health plans coverage, and those costs should not be included in the percentage of premium attributable to the coverage of EHB for calculating the premium tax credit for eligible enrollees⁴¹ on the exchange.⁴² The State of Florida may be required to defray the costs of any additional benefits beyond the required EHB put in place after 2011.⁴³

Reporting of Additional State-Required Benefits and Cost Analysis

For plan years beginning on or after January 1, 2020, each state must identify and report to the federal Department of Health and Human Services (HHS) benefits mandated by state law and identify which of those benefits are in addition to EHB. The first annual submission deadline for states to notify the HHS of their state-mandated benefits is July 1, 2021.⁴⁴ Each QHP issuer in the state must quantify cost attributable to each additional required benefit and then report this to the state.⁴⁵ In May 2020, HHS clarified existing rules to provide that it would also be permissible for issuers to choose to rely on another entity, such as the state, to produce the cost analysis, provided the issuer remains responsible for ensuring that the quantification complies with

³⁹ A “grandfathered health plan” is a plan that maintains coverage that were in place prior to the passage of the PPACA or in which the enrollee was enrolled on March 23, 2010 while complying with the consumer protection components of the PPACA. If a group health plan enters a new policy, certificate, or contract of insurance, the group must provide the new issuer the documentation from the prior plan so it can be determined whether there has been a change sufficient to lose grandfather status. See s. 627.402, F.S.

⁴⁰ 42 U.S.C. s. 18022(b)(1)(A)-(J).

⁴¹ In Florida, 1,705,902 or 95 percent of the total marketplace exchange enrollees receive premium tax credits. KFF, Marketplace Effectuated Enrollment and Financial Assistance (2020) available at <https://www.kff.org/other/state-indicator/effectuated-marketplace-enrollment-and-financial-assistance/?currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D,%22states%22:%7B%22florida%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited Mar. 18, 2021).

⁴² HealthCare.gov, Subsidized Coverage, available at <https://www.healthcare.gov/glossary/subsidized-coverage/> (last visited Mar. 18, 2021). Household income must be between 100 percent and 400 percent of the federal poverty level to qualify for a premium tax credit.

⁴³ See 42 U.S.C. s. 18031(d)(3)(B)(ii).

⁴⁴ CFR 156.111.

⁴⁵ CFR 155.170(c).

existing rules.⁴⁶ Further, the HHS noted that this calculation should be done prospectively to allow for the offset of an enrollee's share of premium and for purposes of calculating the PTC and reduced cost sharing.⁴⁷

III. Effect of Proposed Changes:

Sections 1 and 2 create ss. 627.6413 and 641.31(48), F.S., respectively, to require an individual health insurance policy or individual HMO contract that provides major medical or similar coverage for a dependent child, age 18 or younger, of the insured or subscriber to provide coverage for hearing aids prescribed, fitted, and dispensed by a physician licensed under ch. 458 or 459, F.S., or an audiologist licensed under part I of ch. 468, F.S.

The term, "hearing aid," is defined to include any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing, and includes ear molds. The term does not include cochlear implants.

The policy or contract is required to provide a minimum coverage limit of \$3,500 per ear within a 24-month period. The bill provides that the insured or subscriber remains responsible for the cost of hearing aids and related services that exceed the coverage limit provided for in their policy or contract.

The bill provides that, if a child experiences a significant and unexpected change in his or her hearing or a medical condition requiring an unexpected change in the prescription for the hearing aid before the existing 24-month period expires, and alterations to the existing hearing aid do not or cannot meet the needs of the child, the bill requires that a new 24-month period must begin with full benefits and coverage.

The bill applies to policies or contracts that are issued or renewed on or after January 1, 2022.

Section 3 provides an effective date of January 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

⁴⁶ 85 Fed. Reg. 29218 (May 14, 2020).

⁴⁷ *Id.*

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:

Advocates of the Florida Coalition for Spoken Language Options provided the following analysis of the fiscal impact of SB 1268 on individual policies or contracts.⁴⁸ According to the Florida Coalition for Spoken Language Options, approximately 461 children will benefit from the mandated coverage, and the resulting increases in costs are estimated to be \$0.74 annually or .06 monthly per covered life, as described below:

Florida Population	21,477,737
Florida Population Under 0-18 (19.7%)	4,231,114
All Floridians with individual major medical plans ⁴⁹	1,765,807
19.7% of all covered lives on individual major medical plans are under 18	347,864
0.17% of children have hearing loss	7,193
0.17% of the children who have individual major medical plans	591
2% of .17% slight loss/no hearing aid needed	-12
30% of .17% severe to profound sensorineural or mixed loss/cochlear implant candidate	-177
.17% of 16,170 Children Receiving Early Steps	-11
Impacted Hearing Aid Candidates	461
39% unilateral	180
61% bilateral	281
Cost per Unilateral (\$3500 per ear over 24 months)	\$630,000
Cost Per Bilateral (\$3500 per ear over 24 months)	\$1,967,000
Total Cost Over 24 Months	\$2,597,000
Cost per Year	\$1,298,500

⁴⁸ Florida Coalition for Spoken Language Options, *SB 1268 Mandate Report* (on file with Senate Committee on Health Policy).

⁴⁹ Office of Insurance Regulation correspondence (Dec. 8, 2020) (on file with Senate Committee on Health Policy).

Annual Cost per Plan (\$1,298,500 spread over 1,765,807 covered lives)	\$0.74
Cost Per Month Per Covered Life	\$0.06

C. Government Sector Impact:

None. The bill's requirements do not apply to the State Group Insurance Program since the bill does not mandate that group or employer coverage provide the benefit.

VI. Technical Deficiencies:

The bill does not define “significant and unexpected change” in hearing requiring an unexpected change in the prescription or what criteria will be used to make that determination. Defining this term in the bill or through rulemaking should reduce disputes over whether a change in hearing is “significant and unexpected.”⁵⁰

VII. Related Issues:

Generally, insurance policies and HMO contracts are issued with a one-year duration. It may be difficult to implement a coverage requirement that lasts for 24 months, as proposed in the bill.⁵¹

VIII. Statutes Affected:

This bill substantially amends section 641.31 of the Florida Statutes.

This bill creates section 627.6413 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.

⁵⁰ Office of Insurance Regulation, *Senate Bill 1268 Fiscal Analysis* (Feb. 18, 2021) (on file with Senate Committee on Health Policy).

⁵¹ *Id.*

By Senator Baxley

12-00744B-21

20211268__

A bill to be entitled

An act relating to coverage for hearing aids for children; creating s. 627.6413, F.S.; defining the term "hearing aid"; requiring certain individual health insurance policies to provide coverage for hearing aids for children 18 years of age or younger, under certain circumstances; requiring the hearing aids to be prescribed, fitted, and dispensed by specified health care providers; specifying certain coverage requirements; providing an exception; providing that an insured is responsible for certain costs that exceed the policy limit; providing applicability; amending s. 641.31, F.S.; requiring certain individual health maintenance organization contracts to provide coverage for hearing aids for children 18 years of age or younger, under certain circumstances; requiring the hearing aids to be prescribed, fitted, and dispensed by specified health care providers; specifying certain coverage requirements; providing an exception; providing that a subscriber is responsible for certain costs that exceed the contract limit; defining the term "hearing aid"; providing applicability; providing an effective date.

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

Section 1. Section 627.6413, Florida Statutes, is created to read:

Page 1 of 4

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

12-00744B-21

20211268__

627.6413 Coverage for hearing aids for children.—

(1) As used in this section, the term "hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing, and includes ear molds. The term does not include a cochlear implant.

(2) A health insurer issuing an individual policy that provides major medical or similar comprehensive coverage for a dependent child of the insured must provide coverage for a hearing aid for any such child 18 years of age or younger who is diagnosed with hearing loss by a physician licensed under chapter 458 or chapter 459 or an audiologist licensed under part I of chapter 468, and for whom the hearing aid is prescribed as medically necessary. Coverage for a hearing aid prescribed to a child 18 years of age or younger must require the hearing aid to be prescribed, fitted, and dispensed by a physician licensed under chapter 458 or chapter 459 or an audiologist licensed under part I of chapter 468.

(3) The policy must provide benefits in any 24-month period of at least \$3,500 per ear. The policy may limit coverage for ear molds to six ear molds in any 24-month period. However, if a child experiences a significant and unexpected change in his or her hearing or a medical condition requiring an unexpected change in the prescription for the hearing aid before the existing 24-month period expires, and alterations to the existing hearing aid do not or cannot meet the needs of the child, a new 24-month period must begin with full benefits and coverage.

(4) An insured is responsible for the cost of hearing aids

Page 2 of 4

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

12-00744B-21 20211268__

and related services which exceeds the coverage limit provided by his or her policy.

(5) This section applies to a policy that is issued or renewed on or after January 1, 2022.

Section 2. Subsection (48) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(48) (a) A health maintenance organization issuing an individual contract that provides major medical or similar comprehensive coverage for a dependent child of the insured must provide coverage for a hearing aid for any such child 18 years of age or younger who is diagnosed with hearing loss by a physician licensed under chapter 458 or chapter 459 or an audiologist licensed under part I of chapter 468, and for whom the hearing aid is prescribed as medically necessary. Coverage for a hearing aid prescribed to a child 18 years of age or younger must require the hearing aid to be prescribed, fitted, and dispensed by a physician licensed under chapter 458 or chapter 459 or an audiologist licensed under part I of chapter 468.

(b) The contract must provide benefits in any 24-month period of at least \$3,500 per ear. The policy may limit coverage for ear molds to six ear molds in any 24-month period. However, if a child experiences a significant and unexpected change in his or her hearing or a medical condition requiring an unexpected change in the prescription for the hearing aid before the existing 24-month period expires, and alterations to the existing hearing aid do not or cannot meet the needs of the child, a new 24-month period must begin with full benefits and

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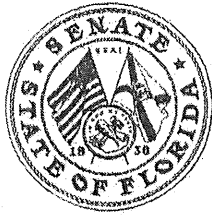
coverage.

(c) A subscriber is responsible for the cost of hearing aids and related services which exceeds the coverage limit provided by his or her contract.

(d) As used in this section, the term "hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing, and includes ear molds. The term does not include a cochlear implant.

(e) This subsection applies to a contract that is issued or renewed on or after January 1, 2022.

Section 3. This act shall take effect January 1, 2022.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Ethics and Elections, *Chair*
Appropriations Subcommittee on Criminal and
Civil Justice
Community Affairs
Criminal Justice
Health Policy
Judiciary
Rules

JOINT COMMITTEE:

Joint Legislative Auditing Committee,
Alternating Chair

SENATOR DENNIS BAXLEY
12th District

The Honorable Chair Manny Diaz
306 Senate Office Building
Tallahassee, Florida 32399

Dear Chair Diaz,

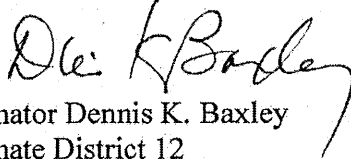
I would like to request that SB 1268 Insurance Coverage for Children with Hearing Aids be heard in the next Health Policy Committee meeting.

This would require a private health insurance policy that provides coverage on an expense-incurred basis for a member of the family of the insured must provide health insurance benefits that include coverage for children diagnosed with hearing loss from birth through 18 years of age for hearing aids prescribed, fitted, and dispensed by a licensed audiologist.

An insurer must provide a minimum coverage amount of \$3,500 per ear within a 24-month period. However, if a child experiences a significant and unexpected change in his or her hearing or a medical condition requiring an unexpected change in the hearing aid before the existing 24-month period has expired, and alterations to the existing hearing aid do not or cannot meet the needs of the child, a new 24-month period shall begin with full benefits and coverage. Also, the insured is responsible for the cost of hearing aids and related services that exceed the coverage provided by his or her policy.

Thank you for your favorable consideration.

Onward & Upward,


Senator Dennis K. Baxley
Senate District 12

DKB/dd

cc: Allen Brown, Staff Director

REPLY TO:

- ☐ 206 South Hwy 27/441, Lady Lake, Florida 32159 (352) 750-3133
- ☐ 315 SE 25th Avenue, Ocala, Florida 34471 (352) 789-6720
- ☐ 322 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5012

Senate's Website: www.flsenate.gov

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore

From: Phillips, Grant <Grant.Phillips@flor.com>
Sent: Tuesday, December 8, 2020 3:47 PM
To: Johnson, Lisa <JOHNSON.LISA@flsenate.gov>
Subject: Inquiries

Good Afternoon Lisa,

Please see the figures you requested below.

2019 Numbers- These numbers include all Major Med plans we regulate.

Individual- 1,765,807

Total Group- 1,968,873 (338k small group ACA)

For your second question regarding which companies offer coverage for hearing aids. Currently, UnitedHealthcare (All Savers, Neighborhood Health, etc.) covers hearing aids if recommended by a physician, and bone-anchored hearing aids are covered with some restrictions. Molina and Health First cover implant type hearing aids if medically necessary.

Please let me know if there is anything else you need!

Best Regards,

Grant Phillips | Deputy Director of Government Affairs
Florida Office of Insurance Regulation
Tallahassee, FL 32301
Office Phone-850-413-2427
Grant.Phillips@flor.com



**FLORIDA OFFICE OF
INSURANCE REGULATION**

Twenty-five states (AK, CT, CO, DE, GA, ID, KY, LA, MA, MD, ME, MN, MO, NH, NJ, NM, NC, OH, OK, OR, RI, TN, TX, WI) require health benefit plans cover hearing aids for children. The proposed Florida requirement has adopted the best parts of those existing in other states and will make Florida a model for pediatric hearing care in the country.

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0600-0699/0624/Sections/0624.215.html

...Guidelines for assessing the impact of a proposed mandated or mandatorily offered health coverage, to the extent that information is available, shall include:

(a) To what extent is the treatment or service generally used by a significant portion of the population.

There is no known registry or recent survey data that estimated overall hearing loss in Florida's pediatric population. However, it is possible to estimate the number of children with hearing loss needing hearing aids from various sources including data from the CDC, the U.S. Census, and Early Hearing Detection and Intervention reports.

Florida Population ¹	21,477,737
Florida Population Under 0-18 (19.7%) ²	4,231,114
All Floridians with individual major medical plans	1,765,807
19.7% of all covered lives on individual major medical plans are under 18	347,864
0.17% of children have hearing loss ³	7,193.00
0.17% of the children who have individual major medical plans	591
2% of of .17% slight loss/no HA needed ⁴	-12
30% of .17% severe to profound sensorineural or mixed loss/ CI candidate ⁵	-177
.17% of 16,170 Children Receiving Early Steps ⁶	-11
Impacted HA Candidates	461

¹ US Census 2019 <https://www.census.gov/quickfacts/FL>

² US Census 2019 <https://www.census.gov/quickfacts/FL>

³ See Documented Diagnosis Section. This is the most recent available data (2018).

⁴ <https://www.cdc.gov/ncbddd/hearingloss/2018-data/01-data-summary.html>

⁵ https://www.cdc.gov/ncbddd/hearingloss/2018-data/documents/12_2018-HSFS_Type-and-Severity-Table.pdf

⁶ https://www.cdc.gov/ncbddd/hearingloss/2018-data/documents/12_2018-HSFS_Type-and-Severity-Table.pdf

⁶ http://www.cms-kids.com/providers/early_steps/reports/Earlystepsannualreport.pdf

(b) To what extent is the insurance coverage generally available.

There is no existing law mandating coverage for hearing aids for private insurance. Despite this, in recent years some private insurance policies have begun to include hearing aid coverage. For children ages 0-18 years in Florida, hearing aids for children are covered by the Early Steps Program (ages 0-3 years), Medicaid, the Children's Health Insurance Programs (CHIP), and Tricare/Other Public Insurance. With the exception of Early Steps, these children have been excluded from this evaluation. Data is not available for the percentage of individual major medical plans that already include hearing aid coverage for children. Therefore, some children are included who will already have coverage.

(c) If the insurance coverage is not generally available, to what extent does the lack of coverage result in persons avoiding necessary health care treatment.

There is no known registry or recent survey data that estimates the percentage of children with hearing loss that avoid hearing aids due to lack of coverage. The most recent survey of the general United States population that may provide some insight to the extent non-coverage has on hearing aid adoption was completed 6 years ago (Abrams & Kihm, 2015). This study found that 51% of people with hearing loss that did not have hearing aids ("non-owners") said that having insurance coverage would facilitate buying hearing aids.

(d) If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship.

Hearing aids and the services to properly prescribe, evaluate, fit, and manage children with hearing loss generally cost an average of \$3,500 per ear depending on the technology and enhancements selected by the audiologist based on the individual needs of the child. The associated costs to families of children with hearing loss include, for example, services for frequent adjustments; fittings of new ear molds necessary to accommodate the child's growth—up to 4 times per year for children until at least age 10 years; and, the on-going management required for children to assure their hearing aids are working optimally to maximize their ability to acquire communication and educational skills.

Today's hearing aids are complex computer programmed digital technology that must be individually fit to every child. They not only restore audibility based on individual needs but offer beneficial features such as noise and feedback management and various programs based on the listening environment. The hearing aids also feature wireless streaming permitting the child to audio-stream directly to the hearing aids as well as communicate with classroom and large group amplification systems, e.g., theaters, classrooms, churches. These features increase accessibility of essential services such as education, telemedicine, religious services, and the ability to communicate with emergency services via telephone.

The fitting process is verified by the audiologist using probe tube measurements of the child's ear canal to ensure that the child is being properly amplified based on their individual needs and the individual anatomical

and physiologic measurements of the child's auditory system. For young children, they must return to the audiologist at least monthly while adolescents may return to the audiologist quarterly.

(e) The level of public demand for the treatment or service.

See section A above.

(f) The level of public demand for insurance coverage of the treatment or service.

See section C above.

(g) The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.

Collective bargaining agents typically advocate for broader benefits than what is proposed in this bill. Collective bargaining agents for private insurance companies do not appear to have advocated specifically for the inclusion of this benefit in their health benefit packages.

(h) To what extent will the coverage increase or decrease the cost of the treatment or service.

Treatment services (hearing aids) should remain roughly the same; it is a small population that would fall into this coverage and should not impact the overall costs. Hearing aid costs range from practice to practice based on each practice's buying power from manufacturers and their sales model (which is why there is a range in cost). This bill should not change how much a service provider charges for their services and goods related to hearing aids.

(i) To what extent will the coverage increase the appropriate uses of the treatment or service.

There are no available studies to determine a specific amount of increase in appropriate use of hearing aids and their related services. It is believed that having coverage will increase the number of children using hearing aids and their related services.

(j) To what extent will the mandated treatment or service be a substitute for a more expensive treatment or service.

Untreated hearing loss leads to tremendous expense for the taxpayer.

- Untreated pediatric hearing loss costs \$420,000 in special education costs per child and \$1 million over the lifetime of the individual.⁷

⁷ Johnson, J.L., Mauk, G.W., Takekawa, K.M., Simon, P.R., Sia, C.C.J. and Blackwell, P.M. Implementing a statewide system of services for infants and toddlers with hearing disabilities. *Seminars in Hearing*. 1993; 14:105-119

- Longitudinal, peer-reviewed studies have shown that healthcare costs are significantly higher for individuals with untreated vs treated hearing loss.^{8,9}
- Increased costs are not confined to the medical bills in the studies. Medical providers must absorb (and pass on via increased overall costs) costs incurred from longer visit times due to communication difficulties¹⁰, increased risk of malpractice lawsuits from communication difficulties¹¹, and necessary accommodations like interpreter services.^{12 13 14 15}
- Communication difficulties in deaf and hard of hearing patients, which would be mitigated by appropriate access to sound, result in more physician visits and overuse of emergency rooms and urgent care centers.¹⁶
- Patients with untreated hearing loss are more likely to be misdiagnosed when visiting providers for unrelated health issues and are more difficult to treat due to communication difficulties.¹⁷

⁸ Reed, N., Altan, A., Deal, J., Yeh, C., Kravetz, A., Wallhagen, M., & Lin, F. (2019). Trends in Health Care Costs and Utilization Associated With Untreated Hearing Loss Over 10 Years. *JAMA Otolaryngology-Head & Neck Surgery*, 145(1), 27. doi: 10.1001/jamaoto.2018.2875

⁹ Simpson, A., Simpson, K., & Dubno, J. (2016). Higher Health Care Costs in Middle-aged US Adults With Hearing Loss. *JAMA Otolaryngology-Head & Neck Surgery*, 142(6), 607. doi: 10.1001/jamaoto.2016.0188

¹⁰ Fagan, M., Diaz, J., Reinert, S., Sciamanna, C., & Fagan, D. (2003). Impact of interpretation method on clinic visit length. *Journal Of General Internal Medicine*, 18(8), 634-638. doi: 10.1046/j.1525-1497.2003.20701.x

¹¹ Legal Risks of Ineffective Communication. (2007). *Virtual Mentor*, 9(8), 555-558. doi: 10.1001/virtualmentor.2007.9.8.hlaw1-0708

¹² Jacobs, B., Ryan, A., Henrichs, K., & Weiss, B. (2018). Medical Interpreters in Outpatient Practice. *The Annals Of Family Medicine*, 16(1), 70-76. doi: 10.1370/afm.2154

¹³ Questions and Answers for Health Care Providers. (2019). Retrieved from <https://www.nad.org/resources/health-care-and-mental-health-services/health-care-providers/questions-and-answers-for-health-care-providers/>

¹⁴ Flores, G., Abreu, M., Barone, C., Bachur, R., & Lin, H. (2012). Errors of Medical Interpretation and Their Potential Clinical Consequences: A Comparison of Professional Versus Ad Hoc Versus No Interpreters. *Annals Of Emergency Medicine*, 60(5), 545-553. doi: 10.1016/j.annemergmed.2012.01.025

¹⁵ Juckett, G., & Unger, K. (2019). Appropriate Use of Medical Interpreters. Retrieved from <https://www.aafp.org/afp/2014/1001/p476.html>

¹⁶ Position Statement On Health Care Access For Deaf Patients. (2019). Retrieved from <https://www.nad.org/about-us/position-statements/position-statement-on-health-care-access-for-deaf-patients/>

¹⁷ Position Statement On Health Care Access For Deaf Patients. (2019). Retrieved from <https://www.nad.org/about-us/position-statements/position-statement-on-health-care-access-for-deaf-patients/>

- Secondarily developing language, cognitive, behavioral and mental health diagnoses^{18 19 20} lead to increased covered physician and therapy visits.
- Even a mild untreated hearing loss doubles the risk of dementia and cognitive decline. A severe to profound loss causes five times the risk.²¹
- Increased costs compound over time. Children with untreated hearing loss miss the window to develop effective spoken language and risk factors and secondary medical costs build. Even in post lingual hearing loss for adults, increased costs go from 26% more after two years to 46% more after ten years.²²
- Deaf and hard of hearing children have a narrow window to develop effective spoken language.²³ Better outcomes are associated with earlier amplification and access to auditory oral services.^{24 25} Most increased medical costs associated with hearing loss are a result of ineffective communication. Developing effective language in childhood results in a lifetime of savings in educational, healthcare, and disability related costs.
- The median reading level for deaf adults has long been 3rd grade, limiting access to health and safety information, job prospects, and other opportunities.²⁶
- Deaf adults without adequate spoken language access face staggering unemployment rates.²⁷

¹⁸ Hogan, A., Shipley, M., Strazdins, L., Purcell, A., & Baker, E. (2011). Communication and behavioural disorders among children with hearing loss increases risk of mental health disorders. *Australian And New Zealand Journal Of Public Health*, 35(4), 377-383. doi: 10.1111/j.1753-6405.2011.00744.x

¹⁹ FELLINGER, J., HOLZINGER, D., SATTEL, H., LAUCHT, M., & GOLDBERG, D. (2009). Correlates of mental health disorders among children with hearing impairments. *Developmental Medicine & Child Neurology*, 51(8), 635-641. doi: 10.1111/j.1469-8749.2008.03218.x

²⁰ Arlinger, S. (2003). Negative consequences of uncorrected hearing loss—a review. *International Journal Of Audiology*, 42(sup2), 17-20. doi: 10.3109/14992020309074639

²¹ Lin, F., Metter, E., O'Brien, R., Resnick, S., Zonderman, A., & Ferrucci, L. (2011). Hearing Loss and Incident Dementia. *Archives Of Neurology*, 68(2). doi: 10.1001/archneurol.2010.362

²² Reed, N., Altan, A., Deal, J., Yeh, C., Kravetz, A., Wallhagen, M., & Lin, F. (2019). Trends in Health Care Costs and Utilization Associated With Untreated Hearing Loss Over 10 Years. *JAMA Otolaryngology-Head & Neck Surgery*, 145(1), 27. doi: 10.1001/jamaoto.2018.2875

²³ Supporting Success For Children With Hearing Loss | Brain Development & Hearing Loss. (2019). Retrieved from

<https://successforkidswithhearingloss.com/for-professionals/brain-development-hearing-loss/>

²⁴ Goldblat, E., & Pinto, O. (2017). Academic outcomes of adolescents and young adults with hearing loss who received auditory-verbal therapy. *Deafness & Education International*, 19(3-4), 126-133. doi: 10.1080/14643154.2017.1393604

²⁵ Ching, T., Dillon, H., Leigh, G., & Cupples, L. (2017). Learning from the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study: summary of 5-year findings and implications. *International Journal Of Audiology*, 57(sup2), S105-S111. doi: 10.1080/14992027.2017.1385865

²⁶ Qi, S., & Mitchell, R. (2011). Large-Scale Academic Achievement Testing of Deaf and Hard-of-Hearing Students: Past, Present, and Future. *Journal Of Deaf Studies And Deaf Education*, 17(1), 1-18. doi: 10.1093/deafed/enr028

²⁷ Deaf Employment Reports. (2019). Retrieved from

<https://www.gallaudet.edu/research-support-and-international-affairs/research-support/research-resources/demographics/deaf-employment-reports>

- “The estimated cost in lost earnings due to untreated hearing loss is \$122 billion while the cost to society in terms of unrealized Federal Taxes is \$18 billion.”²⁸
- Children who receive both appropriate amplification and timely, qualified auditory oral services achieve language scores²⁹, literacy³⁰, and academic success comparable to hearing peers while educated in mainstream classrooms³¹. They no longer qualify for social security disability³² and face better job prospects upon entering the workforce.

²⁸ (2019). Retrieved from

http://hearingaidsterrehaute.com/uploads/MarkeTrak7_ImpactUntreatedHLLIncome.pdf

²⁹ Rhoades, E. (2006). Research Outcomes of Auditory-Verbal Intervention: Is the Approach Justified?. *Deafness & Education International*, 8(3), 125-143. doi: 10.1179/146431506790560157

³⁰ Robertson, C. (2019). Reading Development: A Parent Survey of Children with Hearing Impairment Who Developed Speech and Language through the Auditory-Verbal Method. Retrieved from <https://eric.ed.gov/?id=EJ474410>

³¹ Lim, S., Goldberg, D., & Flexer, C. (2018). Auditory-Verbal Graduates—25 Years Later: Outcome Survey of the Clinical Effectiveness of the Listening and Spoken Language Approach for Young Children with Hearing Loss. *The Volta Review*, 118(1.2), 5-40. doi: 10.17955/tvr.118.1.2.790

³² 2.00-Special Senses and Speech-Adult. (2019). Retrieved from <https://www.ssa.gov/disability/professionals/bluebook/2.00-SpecialSensesandSpeech-Adult.htm>

(k) To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.

Florida Population ³³	21,477,737
Florida Population Under 0-18 (19.7%) ³⁴	4,231,114
All Floridians with individual major medical plans	1,765,807
19.7% of all covered lives on individual major medical plans are under 18	347,864
0.17% of children have hearing loss ³⁵	7,193.00
0.17% of the children who have individual major medical plans	591
2% of of .17% slight loss/no HA needed ³⁶	-12
30% of .17% severe to profound sensorineural or mixed loss/ CI candidate ³⁷	-177
.17% of 16,170 Children Receiving Early Steps ³⁸	-11
Impacted HA Candidates	461
39% unilateral ³⁹	180
61% bilateral ⁴⁰	281
Cost per Unilateral (\$3500 per ear over 24 months)	\$630,000
Cost Per Bilateral (\$3500 per ear over 24 months)	\$1,967,000
Total Cost Over 24 Months	\$2,597,000
Cost per Year	\$1,298,500
Annual Cost per Plan (\$1,298,500 spread over 1,765,807 plans)	\$0.74
Cost Per Month Per Plan	\$0.06

³³ US Census 2019 <https://www.census.gov/quickfacts/FL>

³⁴ US Census 2019 <https://www.census.gov/quickfacts/FL>

³⁵ See Documented Diagnosis Section. This is the most recent available data (2018).

<https://www.cdc.gov/ncbddd/hearingloss/2018-data/01-data-summary.html>

³⁶ https://www.cdc.gov/ncbddd/hearingloss/2018-data/documents/12_2018-HSFS_Type-and-Severity-Table.pdf

³⁷ https://www.cdc.gov/ncbddd/hearingloss/2018-data/documents/12_2018-HSFS_Type-and-Severity-Table.pdf

³⁸ http://www.cms-kids.com/providers/early_steps/reports/Earlystepsannualreport.pdf

³⁹ https://www.cdc.gov/ncbddd/hearingloss/2018-data/documents/12_2018-HSFS_Type-and-Severity-Table.pdf

⁴⁰ https://www.cdc.gov/ncbddd/hearingloss/2018-data/documents/12_2018-HSFS_Type-and-Severity-Table.pdf

(I) The impact of this coverage on the total cost of health care."

The proposed mandate is not expected to have a significant impact on total cost of healthcare in the state of Florida. The insurance companies will likely experience an increase in costs; however, the projected increase is negligible relative to the overall lifetime costs associated with children needing special education and loss of earning potential. A World Health Organization report⁴¹ in 2017 "shows that unaddressed hearing loss poses substantial costs to the health-care system and to the economy as a whole." The report further concludes that "provision of hearing devices is a cost-effective strategy, especially when used regularly and supported with rehabilitation services."

There is a preponderance of evidence supporting the positive effects and benefits of hearing aids and the Florida Hearing Care for Children Act. There is clear evidence in the literature demonstrating that fitting children with hearing aids is associated with greater gains in their development of speech and language. Risk for language delays in children with hearing loss may be mitigated from early age of fitting and consistent use of hearing aids.

The Florida Hearing Care for Children Act will benefit the families of children with hearing loss while ensuring children will be provided with hearing aid technology that meets their educational and communication needs so that they can reach their full potential.

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<https://apps.who.int/iris/bitstream/handle/10665/254659/9789241512046-eng.pdf;jsessionid=4C6885EEED6E0752817A93B62E5B033B?sequence=1>

Prepared by The Florida Coalition For Spoken Language Options



2021 LEGISLATIVE SESSION

AGENCY: Office of Insurance Regulation

BILL INFORMATION

BILL NUMBER:	SB 1268
BILL TITLE:	Coverage for Hearing Aids for Children
BILL SPONSOR(S):	Sen. Dennis Baxley
EFFECTIVE DATE:	03/01/2021

COMMITTEES OF REFERENCE

#	COMMITTEE
1	Banking and Insurance
2	Health Policy
3	Appropriations

CURRENT COMMITTEE

Banking and Insurance

PREVIOUS LEGISLATION

BILL NUMBER	SPONSOR	YEAR	LAST ACTION
N/A			

SIMILAR BILLS

BILL NUMBER	SPONSOR
N/A	

IDENTICAL BILLS

BILL NUMBER	SPONSOR
N/A	

BILL ANALYSIS INFORMATION

DATE OF ANALYSIS:	2/18/2021
LEAD AGENCY ANALYST:	Christopher Struk
ADDITIONAL ANALYSTS:	Christina Jackson
LEGAL ANALYST:	Sarah Berner, Tyler Parks

FISCAL ANALYST:

Richard Fox

POLICY ANALYSIS**1. EXECUTIVE SUMMARY**

This bill creates section 627.6413, Florida Statutes, and modifies section 641.31, Florida Statutes, to require individual health insurance policies and health maintenance organization ("HMO") contracts to provide coverage for hearing aids for children from birth until their 19th birthday. The minimum coverage is \$3,500 per ear within any 24-month period, although a policy or contract can limit coverage to six ear molds over a 24-month period.

2. SUBSTANTIVE BILL ANALYSIS**1. PRESENT SITUATION:**

Florida Statutes do not require health insurance policies to provide coverage for hearing aids.

2. EFFECT OF THE BILL:

This bill creates section 627.6413, Florida Statutes, and modifies section 641.31, Florida Statutes, to define the term "hearing aid" and to require individual health insurance policies and HMO contracts to provide coverage for hearing aids for any child from birth until their 19th birthday who is diagnosed with hearing loss by a physician licensed under chapter 458 or 459 or an audiologist licensed under part I of chapter 468 and is prescribed as medically necessary. Coverage must require the hearing aid to be prescribed, fitted, and dispensed by a physician licensed under chapter 458 or 459 or an audiologist licensed under part I of chapter 468. The minimum benefit is \$3,500 per ear within a 24-month period although a policy or contract can limit coverage for ear molds to six ear molds in any 24-month period. However, if a covered child experiences a significant and unexpected change in his or her hearing or a medical condition requiring an unexpected change in the prescription for the hearing aid before the existing 24-month period has expired and alterations to the existing hearing aid do not or cannot meet the needs of the child, a new 24-month period shall begin with full benefits and coverage. The bill specifies that the insured or subscriber is responsible for the cost of hearing aids and related services that exceed the coverage limit in their policy or contract.

This coverage requirement applies to all policies and contracts issued or renewed after January 1, 2022.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Yes

If yes, explain:	The Office of Insurance Regulation will need to amend its form review procedures to incorporate this new requirement.
Is the change consistent with the agency's core mission?	N/A
Rule(s) impacted (provide references to F.A.C., etc.):	

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	
Opponents and summary of position:	

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? No

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

6. ARE THERE ANY NEW GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSIONS, ETC. REQUIRED BY THIS BILL? No

Board:	
Board Purpose:	
Who Appoints:	
Changes:	
Bill Section Number(s):	

FISCAL ANALYSIS**1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? No**

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Yes

Revenues:	
Expenditures:	In accordance with federal law at 45 CFR 155.170, Florida may be required to defray the cost of any new coverage mandate that raises the cost of subsidies paid by the federal government.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	No

3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR? Yes

Revenues:	
Expenditures:	Adding an additional mandated benefit will likely result in an increase in premium costs.

Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? No

If yes, explain impact.	
Bill Section Number:	

TECHNOLOGY IMPACT**1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? No**

If yes, describe the anticipated impact to the agency including any fiscal impact.	

FEDERAL IMPACT**1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Yes**

If yes, describe the anticipated impact including any fiscal impact.	In accordance with federal law at 45 CFR 155.170, Florida may be required to defray the cost of any new coverage mandate that raises the cost of subsidies paid by the federal government.

ADDITIONAL COMMENTS

Health insurance policies and HMO contracts are typically for one year. Therefore, it may be difficult to implement a coverage requirement that lasts two years.

The bill does not provide a definition for "significant and unexpected change" in hearing; it also does not specify who may determine whether the existing hearing aid meets the child's needs, what criteria will be used to make that determination, or whether the determination is subject to appeal. It may be necessary to provide clarification in the bill or to provide the Office of Insurance Regulation with rulemaking authority to provide these details.

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

THE FLORIDA SENATE
APPEARANCE RECORD

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

1268

Bill Number (if applicable)

Meeting Date

Topic HEARING Aids for Children

Amendment Barcode (if applicable)

Name Mason Rodriguez

Job Title [Child] who is deaf

Address 3450 sw 23rd terrace

Phone 786 - 478 - 7042

Miami, FL 33145
City State Zip

Email NA

Speaking: ☒ For ☐ Against ☐ Information

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

Representing SELF and other children

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/21

Meeting Date

SB 1268

Bill Number (if applicable)

Topic Hearing aids for Children

Amendment Barcode (if applicable)

Name Jennifer Manso Farrell

Job Title _____

Address 215 35th Avenue N

Phone 954-560-2845

Street

St. Petersburg, FL

City

State

Zip

Email jen.menso1@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing self

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

3/24/2021
Meeting Date

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

SB # 1268
Bill Number (if applicable)

Topic Hearing Q&A for Kids

Amendment Barcode (if applicable)

Name Ginger Farrell

Job Title _____

Address 402 Live Oak Lane West

Phone 850 - 545 - 5760

Street

Havana
City

Fl.
State

32333
Zip

Email gb.farrell@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

March 24, 2021
Meeting Date

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

1268
Bill Number (if applicable)

Topic Hearing Aids for Children

Amendment Barcode (if applicable)

Name Angelica Martinez

Job Title Teacher of the Deaf

Address 3540 SW 23rd Terrace

Phone 786 - 478 - 7042

Street

Miami,
City

FL,
State

33145
Zip

Email Aaangie0412@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Self

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

3/24/21

Meeting Date

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

SB 1268

Bill Number (if applicable)

Topic COVERAGE FOR HEARING AIDS FOR CHILDREN

Amendment Barcode (if applicable)

Name THERESA BULGER (pronounced Bowl-jer)

Job Title Lobbyist

Address 1700 N. MONROE ST. Suite #11 Box #182 Phone 904-880-9063

Street

Tallahassee

City

FL

State

32303

Zip

Email tb@leafkidscan.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Academy of Audiology

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/21
Meeting Date

SB 1268
Bill Number (if applicable)

Topic SB 1268 Coverage for Hearing Aids for Children

Amendment Barcode (if applicable)

Name Edeline Joseph-Theophile (^{Pronounced}
Theo-Phil)

Job Title _____

Address 413 Old Village Way Phone 954-543-3569
Street

Oldsmar FL 34677 Email edelinejt.pta@gmail.com
City State Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida PTA

Appearing at request of Chair: ☐ Yes ☒ No Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/21

Meeting Date

1268

Bill Number (if applicable)

Topic COVERAGE For Hearing Aids for Children

Amendment Barcode (if applicable)

Name Tripp FARREN

Job Title _____

Address 215 35th Avenue N

Street

St. Petersburg, FL 33704

City

State

Zip

Phone 850 - 345 - 7260
954 - 560 - 2845

Email Tripp.Farrell@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing self

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/24/21
Meeting Date

SB 1268
Bill Number (if applicable)

Topic HEARING Aids for Kids

Amendment Barcode (if applicable)

Name Daniela Berrios

Job Title Speech Language Pathologist

Address 1923 SW 5th Blvd.

Phone 954-559-5383

Street
Fort Lauderdale, FL 33312
City State Zip

Email Daniela.berrios7@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/24/2021

Meeting Date

SB#1268

Bill Number (if applicable)

Topic Hearing Aid for Kids

Amendment Barcode (if applicable)

Name Debra Golinski

Job Title CEO Sertoma Speech & Hearing Foundation

Address 6728 Driftwood Drive Phone 727-808-2612
Street

Hudson, FL 34667 Email debra@familyhearinghealth.org
City State Zip

Speaking: ☒ For ☐ Against ☐ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

3/24/21

Meeting Date

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

SB #1268

Bill Number (if applicable)

Topic HEARING AIDS FOR CHILDREN

Amendment Barcode (if applicable)

Name Whit Ferrell

Job Title Child who is Deaf

Address 215 35th Avenue N

Phone 954-560-2845

Street

St Petersburg, Fl. 33704

City

State

Zip

Email

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Children who are deaf

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

Meeting Date _____

1268
Bill Number (if applicable)

Topic SB 1268

Amendment Barcode (if applicable)

Name William Farrell III

Job Title NA Merchandise Mgr

Address 215 35th Ave N

Phone 850 545 7260

St Pete FL 33701
City State Zip

Email TRIPP.Farrell@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 1292

INTRODUCER: Health Policy Committee and Senator Bean

SUBJECT: Medicaid

DATE: March 24, 2021

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1292 updates or repeals outdated or obsolete language relating to the:

- Expansion of the mail order delivery of pharmacy products;
- Reimbursement of prescribed drugs based on average wholesale price;
- Implementation of, including increases and decreases to, a variable pharmacy dispensing fee;
- Review of certain drugs by the Medicaid Pharmaceutical and Therapeutics Committee;
- Definition of “medical necessity;”
- Medicaid reimbursement of drugs prescribed to treat erectile dysfunction;
- Duties of the Department of Children and Families regarding Medicaid Fair Hearings; and
- The Organ Transplant Advisory Council (OTAC).

The bill also eliminates requirements that the Agency for Health Care Administration (AHCA) submit the following to the Legislature:

- Annual report related to the Pharmaceutical Expense Assistance Program;
- Quarterly reports related to the Medicaid Reform 1115 Waiver; and
- Quarterly reports related to fee-for-service pharmaceutical spending.

The AHCA reports that the bill will not have a fiscal impact on the Medicaid program, nor have any impact on recipients or providers.¹

¹ Agency for Health Care Administration, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

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

II. Present Situation:

Due to the diverse issues within the bill, additional background information is provided within the effect of proposed changes section of this analysis for the reader's convenience.

The Agency for Health Care Administration

The 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 40 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 48,000 providers.²

Florida Medicaid Program

The Medicaid program is a joint federal-state program that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults and persons with disabilities.³ The Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) is responsible for administering the federal Medicaid program. Florida Medicaid is the health care safety net for low-income Floridians. Florida's program is administered by the AHCA and financed through state and federal funds.⁴

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.

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. The AHCA may seek an amendment to the state plan as necessary to comply with federal or state laws or to implement program changes. States send state plan amendments to the federal CMS for review and approval.⁵

Medicaid enrollees generally receive benefits through one of two service-delivery systems: fee-for-service (FFS) or managed care. Under FFS, health care providers are paid by the state Medicaid program for each service provided to a Medicaid enrollee. Under managed care, the AHCA contracts with private managed care plans for the coordination and payment of services

² See Agency for Health Care Administration, Division of Health Quality Assurance available at <http://ahca.myflorida.com/MCHQ/index.shtml> (last visited Jan. 23, 2020).

³ Medicaid.gov, *Medicaid*, available at <https://www.medicaid.gov/medicaid/index.html> (last visited Mar. 3, 2021).

⁴ Section 20.42, F.S.

⁵ Medicaid.gov, *Medicaid State Plan Amendments*, available at <https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html> (last visited Mar. 3, 2021).

for Medicaid enrollees. The state pays the managed care plans a capitation payment, or fixed monthly payment, per recipient enrolled in the managed care plan.

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.⁶ The SMMC program has two components, the Managed Medical Assistance (MMA) program and the Long-term Care program. Florida's SMMC offers a health care package covering both acute and long-term care.⁷ The SMMC benefits are authorized by federal authority and are specifically required in ss. 409.973 and 409.98, F.S.

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 August 2014, and was re-procured for a period beginning December 2018 and ending in 2023.⁸

III. Effect of Proposed Changes:

Pharmaceutical Expense Assistance Program Report

The Pharmaceutical Expense Assistance Program was established within the AHCA in 2006 to provide pharmaceutical expense assistance to individuals diagnosed with cancer or individuals who have received organ transplants who were medically needy recipients prior to January 1, 2006, and who are eligible for Medicare.⁹ Using Medicaid payment policies, the AHCA pays Medicare Part B prescription drug coinsurance and deductibles for Medicare Part B medications that treat eligible cancer and organ transplant patients.¹⁰

Section 1 of the bill amends s. 402.81, F.S., to eliminate the requirement that the AHCA report to the Legislature by January 1 of each year on the operation of Pharmaceutical Expense Assistance Program. Currently, the annual report must include information on the number of individuals served, use rates, and expenditures under the program.

The program currently pays pharmacy expenses for approximately 20 individuals who meet that criteria, requiring a total expenditure of \$4,457 during Fiscal Year 2019-2020.¹¹

Drug Pricing Formula

The AHCA is required to reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in agency rule.¹² Currently, ss. 409.908(14) and 409.912(5)(a), F.S., specify that a provider of prescribed drugs must be reimbursed the least of

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ Chapter 2006-28, s. 20, Laws of Fla., Section 402.81(1) and (2), F.S.

¹⁰ Section 402.81(3), F.S.

¹¹ *Supra* note 1.

¹² Section 409.908, F.S.

the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the AHCA, plus a dispensing fee.

On February 1, 2016, the federal Centers for Medicare & Medicaid Services (CMS) published the Covered Outpatient Drug final rule, CMS-2345-FC, effective April 1, 2017. This rule required states to submit a State Plan Amendment by June 30, 2017, to update reimbursement methodologies for covered outpatient drugs in the Medicaid program.¹³ The requirements of this rule included a revised requirement from 42 CFR s. 447.512(b) for states to reimburse at an aggregate upper limit based on actual acquisition cost plus a professional dispensing fee established by the state Medicaid agency.

While states retained the flexibility to establish reimbursement methodologies consistent with the requirements of this final rule, Florida's statutory reimbursement methodology does not align with the new federal requirements. In response, the AHCA amended its reimbursement methodology for covered outpatient drugs.¹⁴ Changes in the bill would update the statutory reimbursement methodologies so they are in line with the federal rules and with the AHCA's current practice.¹⁵

Section 3 of the bill amends s. 409.908(14), F.S., and **Section 5** of the bill amends s. 409.912(5)(a), F.S., to make changes to provisions setting reimbursement rates for providers of prescribed drugs. Currently, a provider of prescribed drugs must be reimbursed the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee. The Medicaid maximum allowable fee for ingredient cost must be based on the lowest of: the average wholesale price minus 16.4 percent, the wholesaler acquisition cost plus 1.5 percent, the federal upper limit, the state maximum allowable cost, or the usual and customary charge billed by the provider. Under the bill, a provider of prescribed drugs will be reimbursed in an amount not to exceed the lesser of the actual acquisition cost based on the CMS 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.

Section 4 of the bill reenacts s. 409.91195(4), F.S., to incorporate the changes made to s. 409.912(5)(a), F.S.

Variable Dispensing Fee

In addition to reimbursement for a prescription drug's cost, Medicaid pays pharmacies a professional dispensing fee for filling the prescription.

Currently, paragraph (b) of s. 409.908(14), F.S., requires the AHCA to implement a variable dispensing fee for prescribed drugs. Paragraph (c) of that subsection authorizes the AHCA to increase the dispensing fee by \$0.50 for the dispensing of a drug on the Medicaid preferred drug list and to reduce the dispensing fee by \$0.50 for drugs not on the preferred drug list.

¹³ *Supra* note 1.

¹⁴ Fla. Admin. Code R. 59G-4.251 (2020).

¹⁵ *Supra* note 1.

Effective April 1, 2017, federal CMS implemented the use of the term “professional dispensing fee” and mandated that certain criteria be met in setting the dispensing fee.¹⁶ In response, the AHCA updated the Medicaid state plan with a new professional dispensing fee that does not conform to s. 409.908(14)(b) and (c), F.S. **Section 3** of the bill deletes these obsolete paragraphs.

Prior Consultation and Prior Authorization

Prior authorization means a process by which a health care provider must qualify for payment coverage by obtaining advance approval from a health plan before a specific service is delivered to the patient.¹⁷

Currently, s. 409.912(5)(a), F.S., requires the AHCA to establish procedures ensuring that there is a response to a request for prior consultation by telephone or other communication device within 24 hours after receipt of a request for prior consultation. **Section 5** of the bill amends that provision to change prior “consultation” to prior “authorization.” The AHCA does not provide pharmacy consultations (that is the role of the pharmacist), and legal counsel for the agency has recommended that this be interpreted to mean prior authorization and not prior consultation.¹⁸

Home Delivery of Pharmacy Products

Section 5 of the bill deletes outdated provisions requiring the AHCA to expand home delivery of pharmacy products. These provisions have been in place since 2011, predating the implementation of the SMMC program and the current Medicaid Pharmacy services rule.¹⁹ The AHCA reports that this language is no longer needed because Medicaid FFS and managed care plans already provide for mail order delivery of drugs.

Erectile Dysfunction Drugs

In 2005, Section 1903(i) of the Social Security Act was amended to prohibit Medicaid federal financial participation for drugs used for the treatment of sexual or erectile dysfunction, unless such drugs were approved by the federal FDA to treat a different condition.²⁰ Subparagraph 9. of s. 409.912(5)(a), F.S., authorizes Medicaid to reimburse any drug prescribed to treat erectile dysfunction, limited to one dose per month. This subparagraph predates the federal prohibition.

Medicaid FFS Pharmaceutical Quarterly Report

Section 5 of the bill amends s. 409.912(5)(c), F.S., to eliminate the requirement that the AHCA report quarterly to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the progress made on implementing s. 409.912(5), F.S., relating to Medicaid prescribed drug spending and its effect on expenditures. The quarterly report applies only to the FFS delivery system, which excludes the majority of Medicaid recipients in managed care. FFS

¹⁶ *Supra* note 1.

¹⁷ Riley, Hannah, Gistia Healthcare, *Making Sense of Prior Authorization, What is it?* (Apr. 21, 2020) available at <https://www.gistia.com/insights/what-is-prior-authorization> (last visited Mar. 22, 2021).

¹⁸ *Supra* note 1.

¹⁹ *Id.*

²⁰ *Id.*

Medicaid recipients are typically not enrolled in managed care due to specific health needs, the presence of other insurance, or because they are living in a facility that provides their prescription drugs. Because of this, the AHCA reports that the results of the report are not generally reflective of the Medicaid population.

Medicaid Preferred Drug List and Patient Safety

Established in 2000, the Medicaid Pharmaceutical and Therapeutics Committee (Committee) as authorized in s. 409.91195, F.S., is composed of four allopathic physicians, one osteopathic physician, five pharmacists, and a consumer representative, each appointed by the Governor.²¹ The Committee must meet at least quarterly and is responsible for developing, implementing, updating, and providing the AHCA with the Medicaid Preferred Drug List.²²

Section 4 of the bill also amends s. 409.91195(9), F.S., to remove language requiring the AHCA to ensure that any therapeutic class of drugs, including drugs that have been removed from distribution to the public by their manufacturer or the federal Food and Drug Administration (FDA) or have been required to carry a black box warning label by the federal FDA because of safety concerns, is reviewed by the Committee at the “next regularly scheduled meeting.” Under current law, after such review, the Committee must recommend whether to retain the therapeutic class of drugs or subcategories of drugs within a therapeutic class on the Medicaid preferred drug list and whether to institute prior authorization requirements necessary to ensure patient safety.

If drugs covered by Florida Medicaid are removed from distribution for safety reasons or because of an FDA-mandated black box warning, the AHCA does not wait for the quarterly committee meetings or for its recommendations because the safety of enrollees could be at stake.²³

Medicaid Fair Hearings

Individuals who have been turned down for a Medicaid service, or who were receiving a Medicaid service, that has been reduced or stopped, should receive a letter explaining why Medicaid will not pay for or cover the service.²⁴ In these cases, the individual has the right to challenge that determination in a Medicaid fair hearing.²⁵ Medicaid fair hearing responsibilities were moved from the Department of Children and Families (DCF) to the AHCA in the 2016 Legislative session.²⁶ **Section 4** of the bill amends s. 409.91195(10), F.S., to reflect that the AHCA is responsible for Medicaid fair hearings in which preferred drug formulary decisions are appealed, rather than the DCF.

²¹ Agency for Health Care Administration, Medicaid Pharmaceutical & Therapeutics Committee *available at* https://ahca.myflorida.com/medicaid/prescribed_drug/pharm_thera/ (last visited Mar. 22, 2021). See s. 409.91195, F.S.

²² *Id.*

²³ *Supra* note 1.

²⁴ Agency for Health Care Administration, Medicaid Fair Hearings *available at* https://ahca.myflorida.com/medicaid/complaints/fair_hrng.shtml (last visited Mar. 22, 2021).

²⁵ *Id.*

²⁶ Ch. 2016-65, Laws of Fla.

Medicaid Reform 1115 Waiver Report

Section 6 of the bill repeals s. 409.91213, F.S., to eliminate the requirement that the AHCA submit a quarterly progress report and an annual report relating to the 1115 Managed Medical Assistance waiver to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Minority Leader of the Senate, the Minority Leader of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability. The Medicaid Reform 1115 waiver is tied to the original 2006 Medicaid Reform waiver authority. The Medicaid Reform pilot program ended in 2014 with the full implementation of the Statewide Medicaid Managed Care Program. Because of this, the AHCA considers this report to be obsolete.²⁷ The AHCA notes that all CMS-mandated reports regarding the SMMC waiver are posted on its website.²⁸

Medical Necessity

Federal law specifies that state Medicaid programs do not have to cover services that are not medically necessary.²⁹ Each state has adopted its own definition of “medical necessity.”³⁰ Section 409.913(1)(d), F.S., specifies that the AHCA is the final arbiter of medical necessity for purposes of medical reimbursement. Further, that paragraph requires determinations of medical necessity to be made by a licensed physician employed by or under contract with the AHCA, based upon information available *at the time the goods or services are provided*.

Pursuant to Rule 59G-1.010 of the Florida Administrative Code, care, goods, and services are medically necessary if they are:

- Necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- Individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient’s needs;
- Consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
- Reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
- Furnished in a manner not primarily intended for the convenience of the recipient, the recipient’s caretaker, or the provider.

Section 7 of the bill amends s. 409.913, F.S., to create an exception to the requirement that determinations of medical necessity must be made by a licensed physician employed by or under contract with the AHCA. The exception enables doctoral-level, board-certified behavior analysts to make determinations of medical necessity for behavior analysis services in addition to licensed physicians. The bill also requires a determination of medical necessity to be based on

²⁷ *Supra* note 1.

²⁸ *Id.*

²⁹ 42 U.S.C. s. 1395y.

³⁰ Dickey, Elizabeth, NOLO, Getting Approval for Medicaid Services: Medical Necessity *available at* <https://www.nolo.com/legal-encyclopedia/getting-approval-medicaid-services-medical-necessity.html> (last viewed Mar. 22, 2021).

information available at the time the goods or services are requested, rather than when they are provided.

Organ Transplant Advisory Council

Section 765.53, F.S., establishes the Organ Transplant Advisory Council (OTAC) to consist of 12 physician members who are appointed to represent the interests of the public and the clients of the Department of Health (DOH) or the AHCA. All members are appointed by the Secretary of Health Care Administration for two-year terms. The OTAC is responsible for recommending indications for adult and pediatric organ transplants to the AHCA and formulating guidelines and standards for organ transplants and for the development of End Stage Organ Disease and Tissue/Organ Transplant programs. The OTAC's recommendations, guidelines, and standards are limited in applicability to only those health programs funded through the AHCA. The OTAC met 22 times with its first meeting held on August 27, 2007, and its last meeting held on April 14, 2015.³¹

Most actions of the OTAC revolved around approving guidelines for organ transplantations and reviewing and approving hospital transplant program applications for recommendation to the AHCA, which have been adopted into rule and into the Medicaid State Plan.³² The AHCA indicates that the duties and responsibilities of the OTAC have become redundant because of the oversight of the federal CMS, the Organ Procurement and Transplantation Network, the federal Health Resources and Services Administration, the United Network for Organ Sharing, Organ Procurement Organizations, the Foundation for the Accreditation of Cellular Therapy, and the Joint Commission.³³ The non-statutory function of the OTAC (recommending approval of transplant programs to the Secretary of Health Care Administration for Medicaid-designation) could be undertaken by staff of the AHCA.³⁴

Section 8 of the bill repeals s. 765.53, F.S., to dissolve the Organ Transplant Advisory Council by eliminating its statutory authority. **Section 2** of the bill amends s. 409.815, F.S., to delete a reference to the Organ Transplant Advisory Council which would be dissolved under such repeal.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

³¹ Agency for Health Care Administration, Organ Transplant Advisory Council Meeting Information, available at https://ahca.myflorida.com/medicaid/organ_transplant/meetings.shtml (last viewed Mar. 19, 2021).

³² *Supra* note 1.

³³ *Id.*

³⁴ *Id.*

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The AHCA reports that the bill will not have a fiscal impact on the Medicaid program, nor have any impact on recipients or providers.³⁵

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 402.81, 409.815, 409.908, 409.91195, and 409.913.

This bill repeals the following sections of the Florida Statutes: 409.91213 and 765.53.

This bill reenacts section 409.912 of the Florida Statutes.

³⁵ *Id.*

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 24, 2021:

The CS reinstates the current requirement in s. 409.908(2)(b), F.S., for the AHCA to submit an annual report related to nursing home direct and indirect care costs to the Legislature.

The CS also reinstates the current requirement in s. 409.913(d), F.S., that a determination of medical necessity must be made by a licensed physician, but also creates an exception for behavior analysis services by authorizing a doctoral-level, board-certified behavior analyst to make a determination of medical necessity, in addition to a licensed physician. The CS also reinstates and revises the current requirement for a determination of medical necessity to be based upon information available at the time the goods and services are “requested,” rather than when they are “provided.”

B. Amendments:

None.



577006

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
03/24/2021	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Between lines 70 and 71
insert:

Section 3. Subsection (13) is added to section 409.904,
Florida Statutes, to read:

409.904 Optional payments for eligible persons.—The agency
may make payments for medical assistance and related services on
behalf of the following persons who are determined to be
eligible subject to the income, assets, and categorical



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eligibility tests set forth in federal and state law. Payment on
behalf of these Medicaid eligible persons is subject to the
availability of moneys and any limitations established by the
General Appropriations Act or chapter 216.

(13) An adult described in 42 U.S.C. s.
1396a(a)(10)(A)(i)(VIII).

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

And the title is amended as follows:

Between lines 7 and 8

insert:

amending s. 409.904, F.S.; extending Medicaid
eligibility to specified adults;



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/24/2021	.	
	.	
	.	
	.	

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

Senate Amendment (with directory and title amendments)

Delete lines 101 - 741
and insert:

(14) A provider of prescribed drugs shall be 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



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~~charge billed by the provider the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee. The Medicaid maximum allowable fee for ingredient cost must be based on the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.~~

(a) Medicaid providers must dispense generic drugs if available at lower cost and the agency has not determined that the branded product is more cost-effective, unless the prescriber has requested and received approval to require the branded product.

~~(b) The agency shall implement a variable dispensing fee for prescribed medicines while ensuring continued access for Medicaid recipients. The variable dispensing fee may be based upon, but not limited to, either or both the volume of prescriptions dispensed by a specific pharmacy provider, the volume of prescriptions dispensed to an individual recipient, and dispensing of preferred-drug-list products.~~

~~(c) The agency may increase the pharmacy dispensing fee authorized by statute and in the General Appropriations Act by \$0.50 for the dispensing of a Medicaid preferred-drug-list product and reduce the pharmacy dispensing fee by \$0.50 for the dispensing of a Medicaid product that is not included on the preferred drug list.~~

~~(d) The agency may establish a supplemental pharmaceutical dispensing fee to be paid to providers returning unused unit-~~



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dose packaged medications to stock and crediting the Medicaid program for the ingredient cost of those medications if the ingredient costs to be credited exceed the value of the supplemental dispensing fee.

~~(c)~~ ~~(e)~~ The agency may limit reimbursement for prescribed medicine in order to comply with any limitations or directions provided in the General Appropriations Act, which may include implementing a prospective or concurrent utilization review program.

Section 4. Subsections (9) and (11) of section 409.91195, Florida Statutes, are amended, and subsection (4) of that section is reenacted for the purpose of incorporating the amendment made by this act to section 409.912, Florida Statutes, in a reference thereto, to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.—There is created a Medicaid Pharmaceutical and Therapeutics Committee within the agency for the purpose of developing a Medicaid preferred drug list.

(4) Upon recommendation of the committee, the agency shall adopt a preferred drug list as described in s. 409.912(5). To the extent feasible, the committee shall review all drug classes included on the preferred drug list every 12 months, and may recommend additions to and deletions from the preferred drug list, such that the preferred drug list provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

~~(9) Upon timely notice, the agency shall ensure that any therapeutic class of drugs which includes a drug that has been removed from distribution to the public by its manufacturer or~~



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~~the United States Food and Drug Administration or has been required to carry a black box warning label by the United States Food and Drug Administration because of safety concerns is reviewed by the committee at the next regularly scheduled meeting. After such review, the committee must recommend whether to retain the therapeutic class of drugs or subcategories of drugs within a therapeutic class on the preferred drug list and whether to institute prior authorization requirements necessary to ensure patient safety.~~

~~(10)(11)~~ Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Agency for Health Care Administration ~~Department of Children and Families.~~

Section 5. Paragraphs (a) and (c) of subsection (5) of section 409.912, Florida Statutes, are 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,



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99 including competitive bidding pursuant to s. 287.057, designed
100 to facilitate the cost-effective purchase of a case-managed
101 continuum of care. The agency shall also require providers to
102 minimize the exposure of recipients to the need for acute
103 inpatient, custodial, and other institutional care and the
104 inappropriate or unnecessary use of high-cost services. The
105 agency shall contract with a vendor to monitor and evaluate the
106 clinical practice patterns of providers in order to identify
107 trends that are outside the normal practice patterns of a
108 provider's professional peers or the national guidelines of a
109 provider's professional association. The vendor must be able to
110 provide information and counseling to a provider whose practice
111 patterns are outside the norms, in consultation with the agency,
112 to improve patient care and reduce inappropriate utilization.
113 The agency may mandate prior authorization, drug therapy
114 management, or disease management participation for certain
115 populations of Medicaid beneficiaries, certain drug classes, or
116 particular drugs to prevent fraud, abuse, overuse, and possible
117 dangerous drug interactions. The Pharmaceutical and Therapeutics
118 Committee shall make recommendations to the agency on drugs for
119 which prior authorization is required. The agency shall inform
120 the Pharmaceutical and Therapeutics Committee of its decisions
121 regarding drugs subject to prior authorization. The agency is
122 authorized to limit the entities it contracts with or enrolls as
123 Medicaid providers by developing a provider network through
124 provider credentialing. The agency may competitively bid single-
125 source-provider contracts if procurement of goods or services
126 results in demonstrated cost savings to the state without
127 limiting access to care. The agency may limit its network based



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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, 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



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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 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 ~~consultation~~ by telephone or other telecommunication device within 24 hours after receipt of a request for prior authorization ~~consultation~~; 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



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186 plus a professional dispensing fee, or the usual and customary
187 charge billed by the provider ~~Reimbursement to pharmacies for~~
188 ~~Medicaid prescribed drugs shall be set at the lowest of: the~~
189 ~~average wholesale price (AWP) minus 16.4 percent, the wholesaler~~
190 ~~acquisition cost (WAC) plus 1.5 percent, the federal upper limit~~
191 ~~(FUL), the state maximum allowable cost (SMAC), or the usual and~~
192 ~~customary (UAC) charge billed by the provider.~~

193 3. The agency shall develop and implement a process for
194 managing the drug therapies of Medicaid recipients who are using
195 significant numbers of prescribed drugs each month. The
196 management process may include, but is not limited to,
197 comprehensive, physician-directed medical-record reviews, claims
198 analyses, and case evaluations to determine the medical
199 necessity and appropriateness of a patient's treatment plan and
200 drug therapies. The agency may contract with a private
201 organization to provide drug-program-management services. The
202 Medicaid drug benefit management program shall include
203 initiatives to manage drug therapies for HIV/AIDS patients,
204 patients using 20 or more unique prescriptions in a 180-day
205 period, and the top 1,000 patients in annual spending. The
206 agency shall enroll any Medicaid recipient in the drug benefit
207 management program if he or she meets the specifications of this
208 provision and is not enrolled in a Medicaid health maintenance
209 organization.

210 4. The agency may limit the size of its pharmacy network
211 based on need, competitive bidding, price negotiations,
212 credentialing, or similar criteria. The agency shall give
213 special consideration to rural areas in determining the size and
214 location of pharmacies included in the Medicaid pharmacy



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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 Medicaid-participating 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 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 shall 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



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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 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 guaranteed 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 shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a~~



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~~procurement, as necessary, in order to implement this program.
The procurements must include agreements with a pharmacy or
pharmacies located in the state to provide mail order delivery
services at no cost to the recipients who elect to receive home
delivery of pharmacy products. The procurement must focus on
serving recipients with chronic diseases for which pharmacy
expenditures represent a significant portion of Medicaid
pharmacy expenditures or which impact a significant portion of
the Medicaid population. The agency may seek and implement any
federal waivers necessary to implement this subparagraph.~~

~~9. The agency shall limit to one dose per month any drug
prescribed to treat erectile dysfunction.~~

~~10.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
elements:

(I) Provide for the development and adoption of best
practice guidelines for behavioral health-related drugs such as
antipsychotics, antidepressants, and medications for treating



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

~~9.11.~~ The agency shall implement a Medicaid prescription



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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 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



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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.

~~10.12.~~ 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.

~~11.13.~~ 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.

~~12.14.~~ The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize 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 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



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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.

~~13.15.~~ 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.

~~14.16.~~ 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 shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the



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agency with additional written medical or clinical documentation that the product is medically necessary because:

a. 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; or

c. Based on historic 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.

~~15.17.~~ 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 implementation and operation of the program. The return and reuse program 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 if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be



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reused.

~~(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed drug expenditures.~~

Section 6. Section 409.91213, Florida Statutes, is repealed.

Section 7. Paragraph (d) of subsection (1) of section 409.913, Florida Statutes, is amended to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Each January 15, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs shall submit a report to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions in overpayment amounts negotiated in settlement agreements or by other means; the amount of final agency determinations of overpayments; the amount deducted from federal claiming as a



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result of overpayments; the amount of overpayments recovered each year; the amount of cost of investigation recovered each year; the average length of time to collect from the time the case was opened until the overpayment is paid in full; the amount determined as uncollectible and the portion of the uncollectible amount subsequently reclaimed from the Federal Government; the number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and abuse; and all costs associated with discovering and prosecuting cases of Medicaid overpayments and making recoveries in such cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from enrolling in or reenrolling in the Medicaid program as a result of documented Medicaid fraud and abuse and must include policy recommendations necessary to prevent or recover overpayments and changes necessary to prevent and detect Medicaid fraud. All policy recommendations in the report must include a detailed fiscal analysis, including, but not limited to, implementation costs, estimated savings to the Medicaid program, and the return on investment. The agency must submit the policy recommendations and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. The agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs each must include detailed unit-specific performance standards, benchmarks, and metrics in the report, including projected cost savings to the state Medicaid program during the following fiscal year.

(1) For the purposes of this section, the term:



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(d) "Medical necessity" or "medically necessary" means any goods or services necessary to palliate the effects of a terminal condition, or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards of medical practice. For purposes of determining Medicaid reimbursement, the agency is the final arbiter of medical necessity. Determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency, except for behavior analysis services, which may be determined by a licensed physician or a doctoral-level board-certified behavior analyst. Determinations ~~and~~ must be based upon information available at the time the goods or services are requested ~~provided~~.

=====
D I R E C T O R Y C L A U S E A M E N D M E N T
=====
And the directory clause is amended as follows:

Delete lines 71 - 72

and insert:

Section 3. Subsection (14) of section 409.908, Florida Statutes, is amended to read:

=====
T I T L E A M E N D M E N T
=====
And the title is amended as follows:

Delete lines 8 - 38

and insert:

amending s. 409.908, F.S.; revising the method for determining prescribed drug provider reimbursements;



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deleting a requirement for the agency to implement certain fees for prescribed medicines; deleting authorization for the agency to increase certain dispensing fees by certain amounts; reenacting and amending s. 409.91195, F.S., relating to the Medicaid Pharmaceutical and Therapeutics Committee; deleting a requirement for the agency to ensure that the committee reviews certain drugs under certain circumstances; designating the agency, rather than the Department of Children and Families, as the administrator for certain hearings; amending s. 409.912, F.S.; requiring the agency to establish certain procedures related to prior authorization requests rather than prior consultation requests; revising the method for determining prescribed drug provider reimbursements; deleting a requirement for the agency to expand home delivery of pharmacy products; deleting a dosage limitation on certain drugs; deleting a requirement for the agency to submit certain quarterly reports to the Governor and the Legislature; repealing s. 409.91213, F.S., relating to quarterly progress reports and annual reports; amending s. 409.913, F.S.; revising the definitions of the terms "medical necessity" and "medically necessary" to provide an exception for behavior analysis services determinations; requiring that determinations be based on information available at the time goods or services are requested, rather than at the time such goods or services are provided;



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563

repealing s. 765.53, F.S., relating to the

By Senator Bean

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1 A bill to be entitled
 2 An act relating to Medicaid; amending s. 402.81, F.S.;
 3 deleting a requirement for the Agency for Health Care
 4 Administration to submit an annual report to the
 5 Legislature on the operation of the pharmaceutical
 6 expense assistance program; amending s. 409.815, F.S.;
 7 conforming a provision to changes made by the act;
 8 amending s. 409.908, F.S.; deleting a requirement for
 9 the agency to submit an annual report to the
 10 Legislature on certain direct and indirect care costs;
 11 revising the method for determining prescribed drug
 12 provider reimbursements; deleting a requirement for
 13 the agency to implement certain fees for prescribed
 14 medicines; deleting authorization for the agency to
 15 increase certain dispensing fees by certain amounts;
 16 reenacting and amending s. 409.91195, F.S., relating
 17 to the Medicaid Pharmaceutical and Therapeutics
 18 Committee; deleting a requirement for the agency to
 19 ensure that the committee reviews certain drugs under
 20 certain circumstances; designating the agency, rather
 21 than the Department of Children and Families, as the
 22 administrator for certain hearings; amending s.
 23 409.912, F.S.; requiring the agency to establish
 24 certain procedures related to prior authorization
 25 requests rather than prior consultation requests;
 26 revising the method for determining prescribed drug
 27 provider reimbursements; deleting a requirement for
 28 the agency to expand home delivery of pharmacy
 29 products; deleting a dosage limitation on certain

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

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30 drugs; deleting a requirement for the agency to submit
 31 certain quarterly reports to the Governor and the
 32 Legislature; repealing s. 409.91213, F.S., relating to
 33 quarterly progress reports and annual reports;
 34 amending s. 409.913, F.S.; revising the definitions of
 35 the terms "medical necessity" and "medically
 36 necessary" to delete a requirement that determinations
 37 of medical necessity be made by certain licensed
 38 physicians; repealing s. 765.53, F.S., relating to the
 39 Organ Transplant Advisory Council; providing an
 40 effective date.

41
 42 Be It Enacted by the Legislature of the State of Florida:

43
 44
 45 Section 1. Subsection (4) of section 402.81, Florida
 46 Statutes, is amended to read:

47 402.81 Pharmaceutical expense assistance.—

48 (4) ADMINISTRATION.—The agency shall administer the
 49 pharmaceutical expense assistance program ~~shall be administered~~
 50 ~~by the agency,~~ in collaboration with the Department of Elderly
 51 Affairs and the Department of Children and Families. ~~By January~~
 52 ~~1 of each year, the agency shall report to the Legislature on~~
 53 ~~the operation of the program. The report shall include~~
 54 ~~information on the number of individuals served, use rates, and~~
 55 ~~expenditures under the program.~~

56 Section 2. Paragraph (e) of subsection (2) of section
 57 409.815, Florida Statutes, is amended to read:

58 409.815 Health benefits coverage; limitations.—

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(2) BENCHMARK BENEFITS.—In order for health benefits coverage to qualify for premium assistance payments for an eligible child under ss. 409.810-409.821, the health benefits coverage, except for coverage under Medicaid and Medikids, must include the following minimum benefits, as medically necessary.

(e) *Organ transplant services.*—Covered services include pretransplant, transplant, and postdischarge services and treatment of complications after transplantation for transplants deemed necessary and appropriate within the guidelines set by the ~~Organ Transplant Advisory Council~~ under s. 765.53 or the Bone Marrow Transplant Advisory Panel under s. 627.4236.

Section 3. Paragraph (b) of subsection (2) and subsection (14) of section 409.908, Florida Statutes, are amended to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected

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retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(2)

(b) Subject to any limitations or directions in the General Appropriations Act, the agency shall establish and implement a state Title XIX Long-Term Care Reimbursement Plan for nursing home care in order to provide care and services in conformance with the applicable state and federal laws, rules, regulations, and quality and safety standards and to ensure that individuals eligible for medical assistance have reasonable geographic access to such care.

1. The agency shall amend the long-term care reimbursement plan and cost reporting system to create direct care and indirect care subcomponents of the patient care component of the per diem rate. These two subcomponents together shall equal the patient care component of the per diem rate. Separate prices shall be calculated for each patient care subcomponent, initially based on the September 2016 rate setting cost reports

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and subsequently based on the most recently audited cost report used during a rebasing year. The direct care subcomponent of the per diem rate for any providers still being reimbursed on a cost basis shall be limited by the cost-based class ceiling, and the indirect care subcomponent may be limited by the lower of the cost-based class ceiling, the target rate class ceiling, or the individual provider target. The ceilings and targets apply only to providers being reimbursed on a cost-based system. Effective October 1, 2018, a prospective payment methodology shall be implemented for rate setting purposes with the following parameters:

- a. Peer Groups, including:
 - (I) North-SMMC Regions 1-9, less Palm Beach and Okeechobee Counties; and
 - (II) South-SMMC Regions 10-11, plus Palm Beach and Okeechobee Counties.
- b. Percentage of Median Costs based on the cost reports used for September 2016 rate setting:
 - (I) Direct Care Costs.....100 percent.
 - (II) Indirect Care Costs.....92 percent.
 - (III) Operating Costs.....86 percent.
- c. Floors:
 - (I) Direct Care Component.....95 percent.
 - (II) Indirect Care Component.....92.5 percent.
 - (III) Operating Component.....None.
- d. Pass-through Payments.....Real Estate and
.....Personal Property
.....Taxes and Property Insurance.
- e. Quality Incentive Program Payment Pool.....6.5 percent of

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September

.....2016 non-property related
.....payments of included facilities.

- f. Quality Score Threshold to Quality for Quality Incentive Payment.....20th percentile of included facilities.
- g. Fair Rental Value System Payment Parameters:
 - (I) Building Value per Square Foot based on 2018 RS Means.
 - (II) Land Valuation.....10 percent of Gross Building value.
 - (III) Facility Square Footage.....Actual Square Footage.
 - (IV) Moveable Equipment Allowance.....\$8,000 per bed.
 - (V) Obsolescence Factor.....1.5 percent.
 - (VI) Fair Rental Rate of Return.....8 percent.
 - (VII) Minimum Occupancy.....90 percent.
 - (VIII) Maximum Facility Age.....40 years.
 - (IX) Minimum Square Footage per Bed.....350.
 - (X) Maximum Square Footage for Bed.....500.
 - (XI) Minimum Cost of a renovation/replacements.\$500 per bed.
- h. Ventilator Supplemental payment of \$200 per Medicaid day of 40,000 ventilator Medicaid days per fiscal year.

2. The direct care subcomponent shall include salaries and benefits of direct care staff providing nursing services including registered nurses, licensed practical nurses, and certified nursing assistants who deliver care directly to residents in the nursing home facility, allowable therapy costs, and dietary costs. This excludes nursing administration, staff development, the staffing coordinator, and the administrative portion of the minimum data set and care plan coordinators. The direct care subcomponent also includes medically necessary dental care, vision care, hearing care, and podiatric care.

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3. All other patient care costs shall be included in the indirect care cost subcomponent of the patient care per diem rate, including complex medical equipment, medical supplies, and other allowable ancillary costs. Costs may not be allocated directly or indirectly to the direct care subcomponent from a home office or management company.

~~4. On July 1 of each year, the agency shall report to the Legislature direct and indirect care costs, including average direct and indirect care costs per resident per facility and direct care and indirect care salaries and benefits per category of staff member per facility.~~

5. Every fourth year, the agency shall rebase nursing home prospective payment rates to reflect changes in cost based on the most recently audited cost report for each participating provider.

~~5.6.~~ A direct care supplemental payment may be made to providers whose direct care hours per patient day are above the 80th percentile and who provide Medicaid services to a larger percentage of Medicaid patients than the state average.

~~6.7.~~ For the period beginning July 1, 2020, the agency shall establish a unit cost increase as an equal percentage for each nursing home.

~~7.8.~~ For the period beginning on October 1, 2018, and ending on September 30, 2021, the agency shall reimburse providers the greater of their September 2016 cost-based rate plus the July 1, 2020, unit cost increase or their prospective payment rate plus the July 1, 2020, unit cost increase. Effective October 1, 2021, the agency shall reimburse providers the greater of 95 percent of their cost-based rate plus the July

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1, 2020, unit cost increase or their rebased prospective payment rate plus the July 1, 2020, unit cost increase, using the most recently audited cost report for each facility. This subparagraph shall expire September 30, 2023.

~~8.9.~~ Pediatric, Florida Department of Veterans Affairs, and government-owned facilities are exempt from the pricing model established in this subsection and shall remain on a cost-based prospective payment system. Effective October 1, 2018, the agency shall set rates for all facilities remaining on a cost-based prospective payment system using each facility's most recently audited cost report, eliminating retroactive settlements.

It is the intent of the Legislature that the reimbursement plan achieve the goal of providing access to health care for nursing home residents who require large amounts of care while encouraging diversion services as an alternative to nursing home care for residents who can be served within the community. The agency shall base the establishment of any maximum rate of payment, whether overall or component, on the available moneys as provided for in the General Appropriations Act. The agency may base the maximum rate of payment on the results of scientifically valid analysis and conclusions derived from objective statistical data pertinent to the particular maximum rate of payment.

(14) A provider of prescribed drugs shall be 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

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~~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 the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee. The Medicaid maximum allowable fee for ingredient cost must be based on the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.~~

(a) Medicaid providers must dispense generic drugs if available at lower cost and the agency has not determined that the branded product is more cost-effective, unless the prescriber has requested and received approval to require the branded product.

~~(b) The agency shall implement a variable dispensing fee for prescribed medicines while ensuring continued access for Medicaid recipients. The variable dispensing fee may be based upon, but not limited to, either or both the volume of prescriptions dispensed by a specific pharmacy provider, the volume of prescriptions dispensed to an individual recipient, and dispensing of preferred drug list products.~~

~~(c) The agency may increase the pharmacy dispensing fee authorized by statute and in the General Appropriations Act by \$0.50 for the dispensing of a Medicaid preferred drug list product and reduce the pharmacy dispensing fee by \$0.50 for the dispensing of a Medicaid product that is not included on the~~

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~~preferred drug list.~~

~~(d)~~ The agency may establish a supplemental pharmaceutical dispensing fee to be paid to providers returning unused unit-dose packaged medications to stock and crediting the Medicaid program for the ingredient cost of those medications if the ingredient costs to be credited exceed the value of the supplemental dispensing fee.

~~(c)~~ ~~(e)~~ The agency may limit reimbursement for prescribed medicine in order to comply with any limitations or directions provided in the General Appropriations Act, which may include implementing a prospective or concurrent utilization review program.

Section 4. Subsections (9) and (11) of section 409.91195, Florida Statutes, are amended, and subsection (4) of that section is reenacted for the purpose of incorporating the amendment made by this act to section 409.912, Florida Statutes, in a reference thereto, to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.—There is created a Medicaid Pharmaceutical and Therapeutics Committee within the agency for the purpose of developing a Medicaid preferred drug list.

(4) Upon recommendation of the committee, the agency shall adopt a preferred drug list as described in s. 409.912(5). To the extent feasible, the committee shall review all drug classes included on the preferred drug list every 12 months, and may recommend additions to and deletions from the preferred drug list, such that the preferred drug list provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

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~~(9) Upon timely notice, the agency shall ensure that any therapeutic class of drugs which includes a drug that has been removed from distribution to the public by its manufacturer or the United States Food and Drug Administration or has been required to carry a black box warning label by the United States Food and Drug Administration because of safety concerns is reviewed by the committee at the next regularly scheduled meeting. After such review, the committee must recommend whether to retain the therapeutic class of drugs or subcategories of drugs within a therapeutic class on the preferred drug list and whether to institute prior authorization requirements necessary to ensure patient safety.~~

~~(10)(11)~~ Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Agency for Health Care Administration Department of Children and Families.

Section 5. Paragraphs (a) and (c) of subsection (5) of section 409.912, Florida Statutes, are 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

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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 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 single-

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source-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, 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

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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 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 ~~consultation~~ by telephone or other telecommunication device within 24 hours after receipt of a request for prior authorization ~~consultation~~; 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

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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 ~~Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) 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, 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 shall 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,

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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 Medicaid-participating 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 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 shall require that if a generic-drug

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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 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 guaranteed 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

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to implement this initiative.

~~8.a. The agency shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a procurement, as necessary, in order to implement this program. The procurements must include agreements with a pharmacy or pharmacies located in the state to provide mail order delivery services at no cost to the recipients who elect to receive home delivery of pharmacy products. The procurement must focus on serving recipients with chronic diseases for which pharmacy expenditures represent a significant portion of Medicaid pharmacy expenditures or which impact a significant portion of the Medicaid population. The agency may seek and implement any federal waivers necessary to implement this subparagraph.~~

~~9. The agency shall limit to one dose per month any drug prescribed to treat erectile dysfunction.~~

~~10.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 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 quality-based medication component for severely mentally ill

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individuals and emotionally disturbed children who are high users of care.

~~9.11-~~ 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 and peer-to-peer consultation.

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581 (III) Assess Medicaid recipients who are outliers in their
 582 use of a single or multiple prescription drugs with regard to
 583 the numbers and types of drugs taken, drug dosages, combination
 584 drug therapies, and other indicators of improper use of
 585 prescription drugs.

586 (IV) Alert prescribers to recipients who fail to refill
 587 prescriptions in a timely fashion, are prescribed multiple drugs
 588 that may be redundant or contraindicated, or may have other
 589 potential medication problems.

590 10.12- The agency may contract for drug rebate
 591 administration, including, but not limited to, calculating
 592 rebate amounts, invoicing manufacturers, negotiating disputes
 593 with manufacturers, and maintaining a database of rebate
 594 collections.

595 11.13- The agency may specify the preferred daily dosing
 596 form or strength for the purpose of promoting best practices
 597 with regard to the prescribing of certain drugs as specified in
 598 the General Appropriations Act and ensuring cost-effective
 599 prescribing practices.

600 12.14- The agency may require prior authorization for
 601 Medicaid-covered prescribed drugs. The agency may prior-
 602 authorize the use of a product:

- 603 a. For an indication not approved in labeling;
- 604 b. To comply with certain clinical guidelines; or
- 605 c. If the product has the potential for overuse, misuse, or
 606 abuse.

607
 608 The agency may require the prescribing professional to provide
 609 information about the rationale and supporting medical evidence

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

618 13.15- The agency, in conjunction with the Pharmaceutical
 619 and Therapeutics Committee, may require age-related prior
 620 authorizations for certain prescribed drugs. The agency may
 621 preauthorize the use of a drug for a recipient who may not meet
 622 the age requirement or may exceed the length of therapy for use
 623 of this product as recommended by the manufacturer and approved
 624 by the Food and Drug Administration. Prior authorization may
 625 require the prescribing professional to provide information
 626 about the rationale and supporting medical evidence for the use
 627 of a drug.

628 14.16- The agency shall implement a step-therapy prior
 629 authorization approval process for medications excluded from the
 630 preferred drug list. Medications listed on the preferred drug
 631 list must be used within the previous 12 months before the
 632 alternative medications that are not listed. The step-therapy
 633 prior authorization may require the prescriber to use the
 634 medications of a similar drug class or for a similar medical
 635 indication unless contraindicated in the Food and Drug
 636 Administration labeling. The trial period between the specified
 637 steps may vary according to the medical indication. The step-
 638 therapy approval process shall be developed in accordance with

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

a. 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; or

c. Based on historic 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.

15.17. 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 implementation and operation of the program. The return and reuse program 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 if the program has reduced the amount of

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Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused.

~~(e) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed drug expenditures.~~

Section 6. Section 409.91213, Florida Statutes, is repealed.

Section 7. Paragraph (d) of subsection (1) of section 409.913, Florida Statutes, is amended to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Each January 15, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs shall submit a report to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions

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697 in overpayment amounts negotiated in settlement agreements or by
 698 other means; the amount of final agency determinations of
 699 overpayments; the amount deducted from federal claiming as a
 700 result of overpayments; the amount of overpayments recovered
 701 each year; the amount of cost of investigation recovered each
 702 year; the average length of time to collect from the time the
 703 case was opened until the overpayment is paid in full; the
 704 amount determined as uncollectible and the portion of the
 705 uncollectible amount subsequently reclaimed from the Federal
 706 Government; the number of providers, by type, that are
 707 terminated from participation in the Medicaid program as a
 708 result of fraud and abuse; and all costs associated with
 709 discovering and prosecuting cases of Medicaid overpayments and
 710 making recoveries in such cases. The report must also document
 711 actions taken to prevent overpayments and the number of
 712 providers prevented from enrolling in or reenrolling in the
 713 Medicaid program as a result of documented Medicaid fraud and
 714 abuse and must include policy recommendations necessary to
 715 prevent or recover overpayments and changes necessary to prevent
 716 and detect Medicaid fraud. All policy recommendations in the
 717 report must include a detailed fiscal analysis, including, but
 718 not limited to, implementation costs, estimated savings to the
 719 Medicaid program, and the return on investment. The agency must
 720 submit the policy recommendations and fiscal analyses in the
 721 report to the appropriate estimating conference, pursuant to s.
 722 216.137, by February 15 of each year. The agency and the
 723 Medicaid Fraud Control Unit of the Department of Legal Affairs
 724 each must include detailed unit-specific performance standards,
 725 benchmarks, and metrics in the report, including projected cost

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726 savings to the state Medicaid program during the following
 727 fiscal year.
 728 (1) For the purposes of this section, the term:
 729 (d) "Medical necessity" or "medically necessary" means any
 730 goods or services necessary to palliate the effects of a
 731 terminal condition, or to prevent, diagnose, correct, cure,
 732 alleviate, or preclude deterioration of a condition that
 733 threatens life, causes pain or suffering, or results in illness
 734 or infirmity, which goods or services are provided in accordance
 735 with generally accepted standards of medical practice. For
 736 purposes of determining Medicaid reimbursement, the agency is
 737 the final arbiter of medical necessity. ~~Determinations of~~
 738 ~~medical necessity must be made by a licensed physician employed~~
 739 ~~by or under contract with the agency and must be based upon~~
 740 ~~information available at the time the goods or services are~~
 741 ~~provided.~~
 742 Section 8. Section 765.53, Florida Statutes, is repealed.
 743 Section 9. This act shall take effect July 1, 2021.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: February 24, 2021

I respectfully request that **Senate Bill #1292**, relating to Medicaid, be placed on the:

- ☐ committee agenda at your earliest possible convenience.
- ☒ next committee agenda.

A handwritten signature in cursive script that reads "Aaron Bean".

Senator Aaron Bean
Florida Senate, District 4



2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION

BILL NUMBER:	SB 1292
BILL TITLE:	Medicaid
BILL SPONSOR:	Senator Bean
EFFECTIVE DATE:	July 1, 2021

COMMITTEES OF REFERENCE

1)
2)
3)
4)
5)

CURRENT COMMITTEE

SIMILAR BILLS

BILL NUMBER:	HB 1057
SPONSOR:	Representative Garrison

PREVIOUS LEGISLATION

BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

IDENTICAL BILLS

BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?

Y __ X _ N _ _

BILL ANALYSIS INFORMATION

DATE OF ANALYSIS:	
LEAD AGENCY ANALYST:	
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Overview:

SB 1292 proposes to eliminate or amend multiple sections of Medicaid related statute to repeal or amend language that is obsolete or out of alignment with federal or state Medicaid policy and operations.

This proposal includes:

Elimination or revision of obsolete statutory language: Multiple sections of current statute include prescription medication and pharmacy services language that is obsolete based on updated federal requirements and changes to the operation of the Medicaid program and the Medicaid State Plan, or that are no longer reflective of how the Medicaid program operates. This includes language related to:

- Drugs prescribed to treat erectile dysfunction
- Expansion of mail order delivery of pharmacy products
- Reimbursement of prescribed drugs based on average wholesale price
- Implementation of a variable dispensing fee
- Increases and decreases in the variable dispensing fee
- Review by the Pharmaceutical and Therapeutics committee of drugs that carry an FDA required black box warning
- Providing prior “authorizations” rather than “consultations” for pharmacy services
- The definition of “medical necessity”
- Remove obsolete Fair Hearing language

Elimination of obsolete reports and councils: Multiple sections of current statute include reporting requirements that are obsolete based on updated federal requirements and changes to the operation of the Medicaid program and the Medicaid State Plan, or that is no longer reflective of how the Medicaid program operates. This includes language related to:

- Quarterly reports related to the Medicaid Reform 1115 waiver,
- Annual report related to Nursing Home Direct and Indirect Care Costs,
- The Fee-For-Service Quarterly Pharmaceutical report, and
- The Pharmaceutical Expense Assistance program annual report.

These reports are obsolete as the Agency is either no longer required to submit the federal report that the State report is tied to, because the majority of Medicaid recipients are enrolled in Medicaid managed care, or because the program being reported is no longer enrolling new recipients.

In addition, current statutory language relating to the Organ Transplant Advisory Council (OTAC) is obsolete. The OTAC was created in 1986 when organ transplantation surgery was not the standard of care that it has become today. As a result, the duties and responsibilities have become redundant with those conducted by other oversight bodies.

The bill would not have a fiscal impact.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act. This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare and Medicaid Services (CMS) and maintain any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Florida Legislature.

A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs. The Medicaid state plan establishes groups of individuals covered under

the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements.

State Medicaid programs may request a formal waiver of the requirements codified in the Social Security Act. Federal waivers give states flexibility not afforded through the Medicaid state plan. Florida has several waivers authorized that facilitate implementation of certain statutory requirements.

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the Agency under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has three components: the integrated Managed Medical Assistance (MMA) program and Long-Term Care (LTC) component and the Dental component. Florida's SMMC program benefits are authorized through federal waivers and are specifically required by the Florida Legislature in sections 409.973 and 409.98, F.S. The SMMC benefits are a robust health care package covering both acute and long-term care services. The SMMC program was passed into law in 2011 and implemented in 2013 and 2014.

Obsolete Statutory Provisions:

Restricted Coverage for Drugs to Treat Erectile Dysfunction: Currently, section 409.912 (5) (a), F.S., states that the Agency shall limit any drug prescribed to treat erectile dysfunction to one dose per month. This language pre-dates a federal prohibition barring state Medicaid programs from covering these drugs.

In 2005, Section 1903(i) of the Social Security Act was amended to prohibit Medicaid federal financial participation for drugs used for the treatment of sexual or erectile dysfunction, effective January 1, 2006. Federal CMS sent a letter to states that included information regarding the federal regulations eliminating Medicaid coverage of drugs used to treat sexual or erectile dysfunction unless such drugs are used to treat conditions other than sexual or erectile dysfunction and these uses have been approved by the Food and Drug Administration.

Home Delivery of Pharmaceuticals: Currently, section 409.912 (5) (a), F.S., requires the Agency to "expand" home delivery of pharmaceuticals. This language has been in place since 2011. This predates the implementation of the SMMC program and the current Medicaid pharmacy services rule. The current SMMC contract and the Medicaid rule both allow for broad use of mail order pharmacy, as long as certain conditions are met.

Drug Pricing Formula: Currently, sections 409.908 (14) and 409.912 (5) (a), F.S., state that a provider of prescribed drugs shall be reimbursed the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee and then it describes the Medicaid maximum allowable fee.

On February 1, 2016, CMS published the Covered Outpatient Drug final rule, CMS-2345-FC. The rule had an effective date of April 1, 2017. This rule required states to submit a State Plan Amendment by June 30, 2017, to update their reimbursement methodologies for covered outpatient drugs in the Medicaid program. The requirements of this rule included a revised requirement from 42 CFR §447.512(b) for states to reimburse at an aggregate upper limit based on actual acquisition cost plus a professional dispensing fee established by the state Medicaid agency.

While states retained the flexibility to establish reimbursement methodologies consistent with the requirements of this final rule, the reimbursement methodology outlined in current Florida Statute did not align with the new federal requirements as specified in CMS-2345-FC. As a result, the Agency was required to amend our reimbursement methodology for covered outpatient drugs causing the current statutory language to become obsolete. The Agency's proposed change to statutory language would align statute with current federal Medicaid policy.

As a result of the federal requirements, the Agency currently reimburses an amount not to exceed the lesser of: a) the actual acquisition cost (based on the CMS National Average Drug Acquisition Cost) plus a professional dispensing fee (PDF), b) the wholesale acquisition cost plus a PDF, c) the state

maximum allowable cost plus a PDF, or d) the usual and customary charge billed by the provider as authorized by CMS-2345-FC, final rule. This reimbursement methodology is promulgated into rule 59G-4.251, Florida Administrative Code.

Implementation of a Variable Dispensing Fee and Increases and Decreases to Variable Dispensing Fee: Currently, section 409.908 (14)(b), F.S., states that the Agency shall implement a variable dispensing fee for prescribed drugs. and section 409.908 (14) (C), F.S., states that the Agency may increase the dispensing fee by \$0.50 for the dispensing of a drug on the Medicaid preferred drug list and reduce the dispensing fee by \$0.50 for drugs not on the preferred drug list.

Effective April 1, 2017, federal CMS implemented the use of the term “professional dispensing fee” and mandated certain criteria be met in setting the dispensing fee. To comply with this rule, the Agency had to update the Medicaid State Plan with a new professional dispensing fee that does not conform to the variable dispensing fee language in Florida Statutes.

FDA Black Box Warning: Currently, section 409.91195 (9), F.S., states that the Agency shall ensure that any drug that has been removed from distribution to the public or that has been required to carry a black box warning label is reviewed by the Pharmaceutical and Therapeutics (P&T) committee for recommendation on whether or not to retain the drug on the Medicaid preferred drug list and if a prior authorization process should be implemented.

The P&T Committee was established to provide recommendations to the Agency regarding the development of the Medicaid preferred drug list (PDL) and to provide recommendations regarding additions and deletions from the PDL. The P&T Committee may also make recommendations regarding prior authorizations for prescribed drugs covered by Medicaid. However, while the P&T committee submits recommendations to the Agency, the Agency is the ultimate authority in making determinations regarding the PDL and prior authorization requirements. The Agency exercises this authority in the current process for removal of drugs removed from distribution for safety reasons by the FDA.

Currently, if drugs are removed from distribution for safety reasons, the drugs are coded in the pharmacy system in such a way that claims received for reimbursement of those drugs deny. When FDA mandates a black box warning, the Agency updates the clinical criteria for those drugs. The Agency does not wait until the P & T committee reviews the drugs before taking these actions.

Since the P & T committee is required by the Sunshine laws to meet in the public, all meetings require formal notice at least 7 days in advance. In practice, this means that 10 or more days could go by before the Agency could act on FDA warnings.

“Consultation” for Prescription Drugs: Currently, section 409.912 (5) (a), F.S., requires the Agency to establish procedures to ensure that there is a response to a request for “prior consultation” by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation for Medicaid coverage of contraceptive drugs.

A consultation as it relates to prescription medications is a review of medications with a registered pharmacist (R.D.) or doctor of pharmacy (Pharm.D.). By reviewing medical history, the medications that have been prescribed, over-the-counter medications, and/or herbal or vitamin products being consumed, the pharmacist can provide a wealth of information; they can explain how the medications work and why they are being taken, the best ways to take the medication, the possible side effects to watch for, potential conflicts with other medications or other diseases, and sometimes ways to use medications more economically.

Neither the Agency nor the Medicaid health plans provide consultations, as that responsibility lies with the pharmacist. The Agency and the health plans provide authorizations for prescription medications.

Definition of Medical Necessity: Currently, section 409.913 (1) (d), F.S., defines “medical necessity” or “medically necessary” and states that determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency.

While the Agency utilizes physicians for nearly all determination, for certain specialized services, like applied behavioral analysis services, a Board-Certified Behavioral Analyst -PhD is used instead, as their expertise is more appropriate. Due to the state law requirement, however, a physician must then sign off on the decision, adding an unnecessary layer of review.

Current federal regulations allow a more expansive array of health care professionals than physicians to authorize services for Medicaid recipients.

Removing Obsolete Fair Hearing Language: Currently, section 409.91195 (11), F.S., states that Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Department of Children and Families. However, the administration of Medicaid service-related fair hearings was moved from the Department of Children and Families to the Agency as a result of language included in HB 5101 that was passed during the 2016 legislative session.

Obsolete Reports and Councils:

Medicaid Reform 1115 Waiver Report: Currently, section 409.91213, F.S. requires the Agency to submit to the Legislature a quarterly progress report that was submitted to the federal CMS for the Medicaid Reform 1115 waiver which is tied to the original 2006 Medicaid Reform waiver authority. The Medicaid Reform pilot program ended in 2014 with the full implementation of the Statewide Medicaid Managed Care Program.

Nursing Home Direct and Indirect Care Costs Report: Currently, section 409.908 (2) (b), F.S., requires the Agency to submit an annual report to the Legislature each July 1st detailing nursing home direct and indirect care costs. This reporting requirements has been in place since 2010 and predates mandated minimum staffing requirements, the legislatively mandated transition to the Statewide Medicaid Managed Care program, and the implementation of the prospective payment system for nursing home reimbursement.

Fee-for-Service Quarterly Pharmaceutical report: Currently, section 409.912 (5) (c), F.S., requires the Agency to submit quarterly reports to the Legislature on the implementation of a Medicaid prescribed-drug spending-control program for the fee-for-service (FFS) delivery system. This reporting requirement has been in place since 2010 and pre-dates the implementation of the Statewide Medicaid Managed Care Program therefore, the cost controls described are no longer applicable to most Medicaid recipients in Florida.

Pharmaceutical Expense Assistance Annual Report: Currently section 402.81 (4), F.S. requires the Agency to submit an annual report to the Legislature on the operation of the Pharmaceutical Expense Assistance program. The Pharmaceutical Expense Assistance program was established under Section 20 of HB 5007 during the 2006 legislative session. The program was set up to pay Medicare Part B coinsurance and deductibles for Medicare eligible recipients enrolled in the Medically Needy program and was designed specifically address a shortfall in coverage created when Medicare Part D was implemented on January 1, 2006.

The initial program was funded with \$3,709,409 and there were approximately 650 people identified as potentially eligible for the program. Only those unique individuals identified as eligible at the time of the program’s passage are eligible, and, as a result, program size and expenditures have reduced significantly. The data below reflects enrollment and expenditures from FY 2013-14 through FY 2019-20.

Fiscal Year	Max Recipients	Total Expenditures

FY2013-14	42	\$31,455.60
FY2014-15	41	\$27,848.06
FY2015-16	38	\$13,930.71
FY2016-17	24	\$2,279.47
FY2017-18	19	\$7,094.99
FY2018-19	22	\$11,687.96
FY2019-20	14	\$5,612.59

Organ Transplant Advisory Council: Currently, Section 765.53, F.S., mandates the maintenance of the Organ Transplant Advisory Council (OTAC). The OTAC consists of twelve active transplant physician/surgeons and was created to recommend to the Agency indications for adult and pediatric organ transplants and to formulate guidelines and standards for organ transplant and for the development of end stage organ disease and tissue/organ transplant programs. The council was created in 1986 and predates current oversight by the federal Centers for Medicare and Medicaid Services as well as multiple other organizations that establish the standard of care for transplants that are in place today.

2. EFFECT OF THE BILL:

Section 1: Pharmaceutical Expense Assistance Annual Report

SB 1292 amends ss. 402.81 (4), F.S., to eliminate the requirement that the Agency submit an annual report each January 1st on the operation of the pharmaceutical expense assistance program.

The Pharmaceutical Expense Assistance program pays for pharmacy expenses for approximately 20 individuals who were covered prior to 2006. The Agency is not authorized to enroll any new individuals in the program, and the program has therefore decreased in size to expend only \$4,457 during federal fiscal year 2019-20. Therefore, this report is unnecessary.

This change would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 2: Organ Transplant Advisory Council

The bill amends s. 409.815 (2) (e), F.S.; conforming a provision to changes made by the act in Section 8 related to the Organ Transplant Advisory Council.

This change would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 3: Nursing Home Direct and Indirect Care Costs Report; Drug Pricing Formula; Implementation of a Variable Dispensing Fee; Increases and Decreases to Variable Dispensing Fee

The bill amends ss. 409.908 (2) (b), F.S., to eliminate an obsolete requirement that the Agency submit an annual report each July 1st detailing nursing home direct and indirect care costs. The initial intent of the nursing home direct and indirect care costs report was to provide comparative information for the patient care component split as reported in the nursing home cost reports (direct care and indirect care). However, since the implementation of specific, statutorily mandated, nursing facility staffing ratios, the information provided by the report is of limited value, and the direct care and indirect care split is now well established making this reporting requirement obsolete.

The bill amends ss. 409.908 (14), F.S., to make multiple changes including modifying language related to Medicaid reimbursement of prescribed drugs based on average wholesale price, eliminating obsolete language related to the implementation of a variable dispensing fee for prescribed drugs, and eliminating obsolete language related to increasing or decreasing the variable dispensing fee for prescribed drugs based on whether the drug was on the Agency's preferred drug list or not.

In regard to reimbursement of prescribed drugs based on average wholesale price, the Medicaid prescribed drug pricing methodology is subject to changes that may precede statute updates. These changes could be the result of new federal requirements or changes in industry practices that require the Agency to update the prescribed drug pricing methodology prior to statutory changes being made.

In addition, based on a federal rule changed, the Medicaid State Plan was amended to change its outpatient drug reimbursement methodology making the current statutory language related to dispensing fees obsolete.

These changes would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 4: FDA Black Box Warning; Removing Obsolete Fair Hearing Language

The bill amends ss. 409.91195 (9), F.S., to remove language requiring the Agency to have any therapeutic class of drugs which includes a drug that has been removed from distribution to the public by its manufacturer or the United States Food and Drug Administration or has been required to carry a black box warning label by the United States Food and Drug Administration because of safety concerns reviewed by the Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting.

If drugs that are covered by Florida Medicaid are removed from distribution for safety reasons or FDA mandates a black box warning, the Agency should have the flexibility to act immediately upon being informed of such directives whenever patient safety is involved. The Agency is not required to wait for the quarterly P&T committee meetings, discussions, and recommendations.

The proposed bill amends ss. 409.91195 (11), F.S., to reflect that the Agency is responsible for Medicaid service-related Fair Hearings rather than the Department of Children and Families. Section 4 of HB 5101, Health Care Services, from the 2016 session moved the authority for hearings related to services provided in the Medicaid program from the purview of the Department of Children and Families to the Agency for Health Care Administration so this change aligns this section of statute with the changes made by HB 5101.

These changes would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 5: "Consultation" for Prescription Drugs; Fee-for-Services Quarterly Pharmaceutical report; Drug Pricing Formula; Home Delivery of Pharmaceuticals; Restricted Coverage for Drugs to Treat Erectile Dysfunction

The bill amends ss. 409.912 (5) (a), F.S., to change the word "consultation" to "authorization" as it relates to Medicaid coverage of contraceptive drugs as the Agency does not provide pharmacy consultations. The Agency's counsel agreed that this should be interpreted as prior authorizations, not consultations.

The bill amends ss. 409.912 (5), F.S., to eliminate the requirement that the Agency submit quarterly reports to the Legislature on the implementation of a Medicaid prescribed-drug spending-control program. The Quarterly Pharmaceutical report only applies to fee-for-service (FFS) Medicaid, which excludes the vast majority of Medicaid recipients. The FFS population are not enrolled in health plans because of very specific health needs, the presence of other insurance, or living in a facility that provides their prescription drugs; this skews the results of the report so they are not generally applicable to the Medicaid population. Since the cost controls described in this section of the statutes are no longer applicable to most Medicaid recipients in Florida, and since the reporting criteria no longer accurately reflect the policy and cost trends for much of the remaining FFS population, this report should be discontinued.

The bill amends ss. 409.912 (5), F.S., to make multiple changes including modifying language related to Medicaid reimbursement of prescribed drugs based on average wholesale price, eliminating obsolete language requiring expansion of home delivery of pharmacy products, and eliminating obsolete language related to coverage of drugs used to treat erectile dysfunction.

The language requiring expansion of home delivery of pharmacy products is no longer needed because Florida Medicaid fee-for-service and managed care plans allow for mail order delivery of drugs.

The section limiting the doses of sexual or erectile dysfunction drugs is obsolete, as Florida Medicaid does not cover drugs used to treat sexual or erectile dysfunction based on an amendment to Section 1903(i) of the Social Security Act that prohibited coverage of drugs used to treat sexual or erectile dysfunction unless such drugs were approved by FDA to treat a different condition.

These changes would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 6: Medicaid Reform 1115 Waiver Report

The bill repeals ss. 409.91213 requiring the Agency to submit to the Legislature a quarterly progress report previously submitted to CMS for the Medicaid Reform 1115 waiver, which is tied to the 2006 Medicaid Reform original waiver authority.

The content and frequency of reporting on the 1115 Managed Medical Assistance waiver are dictated by CMS and have changed periodically, making them out of synch with statutory requirements. All reports regarding the waiver are posted on the Agency's web page to ensure transparency about the waiver. As a result, this statutory requirement is obsolete.

This change would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 7: Definition of Medical Necessity

The bill amends ss 409.913 (1) (d), F.S., to amend the definition of "medical necessity" or "medically necessary" currently in statute that states that determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency and must be based upon information available at the time the goods or services are provided.

Federal regulations allow a more expansive array of health care professionals than physicians to authorize services for Medicaid recipients. There are health care professionals who have more expertise in the services being authorized than a physician, but under current Florida law, a physician must always sign off on any denial of service. While the Agency utilizes physicians for nearly all determination, for certain specialized services, like applied behavioral analysis services, a Board-Certified Behavioral Analyst -PhD is used instead, as their expertise is more appropriate. Due to the state law requirement, however, a physician must then sign off on the decision, adding an unnecessary layer of review. This change would allow these limited reviews for specialized services to be completed without a secondary review by a physician. This change will bring Florida law into line with federal regulations.

This change would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 8: Organ Transplant Advisory Council

The bill repeals ss. 765.53, eliminating the Organ Transplant Advisory Council (Council).

The Council consists of twelve active transplant physician/surgeons. The functions of the Council are to recommend to the Agency indications for adult and pediatric organ transplants and to formulate guidelines and standards for organ transplant and for the development of end stage organ disease and tissue/organ transplant programs. The Agency has added other functions by requesting the Council to recommend approval of transplant programs to the Secretary for Medicaid-designation; this has been promulgated into rule and into the Medicaid State Plan.

The OTAC was created in 1986 when organ transplantation surgery was not the standard of care that it has become today. As a result, the duties and responsibilities have become redundant because of the oversight of the Centers for Medicare and Medicaid Services, the Organ Procurement and Transplantation Network, Health Resources and Services Administration, United Network for Organ Sharing, Organ Procurement Organizations, Foundation for the Accreditation of Cellular Therapy, and Joint Commission. The non-statutory function of the Council, designating Medicaid transplant facilities, could be undertaken by Agency staff.

This change would not have a fiscal impact on the Medicaid program and would not impact recipients or providers.

Section 9: Effective Date

The bill will be effective July 1, 2021.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y ___ N X _

If yes, explain:	
Is the change consistent with the agency's core mission?	Y <u>X</u> N ___
Rule(s) impacted (provide references to F.A.C., etc.):	

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	
Opponents and summary of position:	

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ___ N X _

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQUIRED BY THIS BILL? Y X N ___

Board:	Organ Transplant Advisory Council
Board Purpose:	The functions of the Council are to recommend to the Agency indications for adult and pediatric organ transplants and to formulate guidelines and standards for organ transplant and for the development of end stage organ disease and tissue/organ transplant programs. The Agency has added other functions by requesting the Council to recommend approval of transplant programs to the Secretary for Medicaid-designation; this has been promulgated into rule and into the Medicaid State Plan.
Who Appointments:	Secretary of Health Care Administration
Appointee Term:	Two years

Changes:	Eliminate council
Bill Section Number(s):	<u>Section 12</u>

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y ___ N ___X___

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees? If yes, explain.	
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y ___ N ___X___

Revenues:	
Expenditures:	
Does the legislation contain a State Government appropriation?	
If yes, was this appropriated last year?	

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y ___N ___X___

Revenues:	
Expenditures:	
Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y ___ N ___X___

If yes, explain impact.	
Bill Section Number:	

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y ___ N ___X___

If yes, describe the anticipated impact to the agency including any fiscal impact.	

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y ___ N _X _

If yes, describe the anticipated impact including any fiscal impact.	

ADDITIONAL COMMENTS

LEGAL – GENERAL COUNSEL’S OFFICE REVIEW

Issues/concerns/comments:	

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 1976

INTRODUCER: Senator Brodeur

SUBJECT: Freestanding Emergency Departments

DATE: March 23, 2021

REVISED: _____

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. Looke	Brown	HP	Favorable
2. _____	_____	AHS	_____
3. _____	_____	AP	_____

I. Summary:

SB 1976 amends multiple sections of law related to freestanding emergency departments (FED) to draw a stronger distinction between FEDs and urgent care centers (UCC). The bill modifies the definition of a UCC to no longer include FEDs and adds a separate definition of a “freestanding emergency department” as a facility that:

- Provides emergency services and care;
- Is owned and operated by a licensed hospital and operates under the hospital’s license; and
- Is located on separate premises from the hospital.

The bill prohibits FEDs from holding themselves out to the public as UCCs. The bill requires FEDs to have signage in and around their premises stating that the FED is a hospital emergency department, that the FED is not a UCC,¹ and that hospital emergency department rates apply within the FED. The signs must also specify the facility’s average facility fee, if any. The bill also requires any advertisements for the FED to specify that the FED is an emergency department and not a UCC.

The bill requires the Agency for Health Care Administration (AHCA) to post on its website information that provides a description of the differences between FEDs and UCCs. The bill also amends the Insurance Code to require health insurers to post on their websites, and update at least annually, a comparison of average in-network and out-of-network UCC and FED charges for the 30 most common UCC services, at least two examples of the impact on insured and insurer paid amounts of the inappropriate utilization of emergency departments for nonemergent services, and an interactive tool to locate local in-network and out-of-network UCCs.

¹ Unless the FED shares a location and public entrance with a UCC.

The bill repeals legislative intent language regarding emergency services and care; repeals obsolete language prohibiting the AHCA from authorizing FEDs prior to July 1, 2006; and makes other conforming changes.

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

II. Present Situation:

Off-Site Emergency Departments

Any Florida-licensed hospital that has a dedicated emergency department may provide emergency services in a location off of the hospital's main premises. The off-site emergency department must be under the same direction, offer the same services, and comply with the same regulatory requirements as the emergency department located on the hospital's main premises. There are no additional rules or standards specific for emergency departments located off the premises of the licensed hospital.

Hospitals desiring to offer off-site emergency departments must meet the physical plant review requirements of s. 395.0163, F.S. The AHCA must review the facility's plans and specifications before any construction can begin. Reviews are also conducted during the construction phase, and final physical plant approval is granted when the facility is determined to meet all applicable hospital building codes.²

As of February 24, 2021, there were 86 off-site emergency departments operated by 58 hospitals.³

Emergency Department Utilization and Charges

Although the total number of patients treated in an emergency department (ED)⁴ has increased since 2008, the number of patients treated who were considered low-acuity⁵ has dropped nearly 60 percent. In 2008, the number of patients treated in an ED who reported with a low-acuity problem was nearly 33 percent of all patients seen. By 2018, those numbers had dropped to approximately 12 percent.⁶

Despite the fact that the percentage of patients using EDs for low-acuity problems and is trending downward, the overall volume of patients is still high. In 2018, EDs saw an approximate total of 9 million patients. At 12 percent, this indicates that just over 1 million patients used EDs for nonemergent medical issues. Patients using EDs for such problems could see significant

² Emergency Services, AHCA, *available at* https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Hospitals/EmergencyServices.shtml, (last visited Mar. 19, 2021).

³ Agency for Health Care Administration, *House Bill 1157 Fiscal Analysis* (Feb. 23, 2021) (on file with the Senate Committee on Health Policy.)

⁴ In all EDs, not just in off-site emergency departments.

⁵ Requiring only straightforward or low complexity medical decision making and usually presenting with problems that are minor or are of low to moderate severity. See Emergency Department Utilization Report 2018, AHCA, p. 22, *available at* <https://fhfstore.blob.core.windows.net/documents/researchers/documents/ED%20Report%202018%20Final.pdf> (last visited Mar. 19, 2021).

⁶ *Id.* at pp. 8 and 9.

charges billed. For example, also in 2018, treatment for an upper respiratory infection averaged a \$2,772 charge; treatment for abdominal pain averaged a \$10,506 charge; and treatment for a urinary tract infection averaged a \$7,598 charge.⁷

Urgent Care Centers

There is no specific licensure program for UCCs. A UCC may be operated by a hospital, one or more clinicians, or by other persons or entities. Hospitals report off-site emergency departments, outpatient surgical locations, and other wholly-owned off-site outpatient locations through the hospital licensure process. The hospital's other outpatient locations are identified by name and address only, not services. Clinicians, other persons, and entities operating a UCC may be licensed as a health care clinic under ch. 400, Part X, F.S., or meet an exemption to the health care clinic licensure requirements.⁸

As of March 19, 2021, there were 212 UCCs in Florida.⁹ In 2018, the average charge for a patient seen in a UCC was \$193.¹⁰

Hospital-based Urgent Care Centers

Hospital-based UCCs are walk-in clinics owned and operated by a hospital and offer ambulatory care services outside of the traditional emergency room setting. Unlike emergency departments, UCCs typically operate during designated business hours and do not offer ambulance delivery services to the general public. However, based on their proximity to the hospital, hospital-based UCCs have the capacity to afford integrated hospital services to patients under their direct care. The basic services include, but are not limited to:

- Ambulatory care (outpatient medical care, including, but not limited to, diagnosis, observation, treatment, consultation, intervention, and rehabilitation services).
- Prescriptions for medications.
- Arrangements for additional or long-term health care services.
- Integrated hospital services.

While the AHCA does not license hospital-based UCCs separately, they must comply with the ambulatory care requirements found in hospital licensure regulations. Hospital-based UCCs are required to publish a schedule of charges for medical services offered to patients. Posted schedules must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule must be at least 15 square feet in size, displayed in a conspicuous location within the reception area of the UCC, and must include the 50 services most frequently provided by the clinic.¹¹

⁷ Id. at p. 10.

⁸ Id.

⁹ See Florida Health Finder report, available at <https://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx>, (last visited Mar. 19, 2021).

¹⁰ See <https://www.unitedhealthgroup.com/content/dam/UHG/PDF/2019/UHG-Avoidable-ED-Visits.pdf> (last visited Mar. 19, 2021).

¹¹ AHCA Consumer Awareness Series, *Emergency and Urgent Care*, available at <https://fhfstore.blob.core.windows.net/documents/reports-guides/documents/English%20-%20Urgent%20Care%20Guide.pdf>, (last visited Mar. 19, 2021).

Physician-based Urgent Care Centers

Physician-based UCCs are owned and operated by a physician or group of physicians and offer ambulatory medical treatment for non-life-threatening conditions on a walk-in basis. A typical physician-based UCC is a freestanding office operating during designated business hours, usually staffed by at least one physician, several medical assistants, nurses, and other health care professionals. These facilities are usually not equipped to offer integrated hospital services to individuals and will normally refer patients to either a primary care physician or specialist for advanced testing and/or treatment. The basic services include, but are not limited to:

- Ambulatory care (diagnosis and treatment of non-life-threatening conditions, such as minor cuts or burns, the flu, or sinus infections).
- Prescriptions for medications.
- Arrangements for advanced or long-term health care services.

While the AHCA does license and regulate health care clinics, there are currently no separate licensure requirements for UCCs. However, a physician-based UCC may hold and maintain a health care clinic license, depending on the nature of its operation. Like all UCCs, physician-based UCCs are subject to the same charge schedule publishing requirements outlined above.¹²

Health Care Clinic-based Urgent Care Center

Much like physician-based urgent care facilities, health care clinic-based UCCs typically offer ambulatory medical treatment for members of the community on a walk-in basis. These facilities usually provide medical care services to individuals at little to no cost and could potentially be a viable option for members of the community that are either uninsured or cannot afford treatment.

Additionally, while the AHCA does license and regulate health care clinics, there are currently no separate licensure requirements for UCCs. However, a health care clinic-based UCC must maintain an active health care clinic license.¹³

III. Effect of Proposed Changes:

SB 1976 amends multiple sections of law related to FEDs and UCCs.

Section 1 amends s. 395.002, F.S., to define for “freestanding emergency department” as a facility that:

- Provides emergency services and care;
- Is owned and operated by a licensed hospital and operates under the hospital’s license; and
- Is located on separate premises from the hospital.

The bill also strikes language including off-site emergency departments in the definition of a UCC.

Section 2 amends s. 395.003, F.S., to repeal obsolete language prohibiting the AHCA from approving any FEDs prior to July 1, 2006.

¹² Id.

¹³ Id.

Section 3 amends s. 395.104, F.S., to:

- Prohibit FEDs from holding themselves out to the public as UCCs.
- Require FEDs to identify themselves as hospital emergency departments using, at a minimum, prominent, lighted signage with the word “EMERGENCY” and the name of the hospital.
- Require FEDs to post conspicuous signs at locations readily accessible and visible to patients outside entrances and in waiting areas stating: “THIS IS A HOSPITAL EMERGENCY DEPARTMENT” and, unless the FED shares a location and a public entrance with a UCC, stating “THIS IS NOT AN URGENT CARE CENTER. HOSPITAL EMERGENCY DEPARTMENT RATES ARE BILLED FOR OUR SERVICES.” The signs must also specify the facility’s average facility fee, if any, and notify the public that care at the facility may be out-of-network. The signs must be at least two square feet and the text must be no smaller than 36 point font.
- Require any FED advertisements to include the statement “This emergency department is not an urgent care center. It is part of (insert hospital name) and its services and care are billed at hospital emergency department rates.” Additionally, any FED billboard advertising which measures at least 200 square feet must include the following statement at least 15 inches high “(INSERT NAME OF HOSPITAL) EMERGENCY DEPARTMENT. THIS IS NOT AN URGENT CARE CENTER.”
- Require the AHCA to post on its website, and update annually, information that provides a description of the difference between FEDs and UCCs, including:
 - At least two examples illustrating the impact on insured and insurer paid amounts of inappropriate utilization of nonemergent services and care in a hospital emergency department setting compared to utilization of nonemergent services and care in an urgent care center;
 - An interactive tool to locate local urgent care centers; and
 - What to do in the event of a true emergency.
- Require each hospital to post a link to the information on the AHCA website on its own website.

Section 4 amends s. 627.6405, F.S., to eliminate legislative intent language regarding the inappropriate use of EDs and to require health insurers to post on their websites, and update at least annually, a comparison of average in-network and out-of-network UCC and FED charges for the 30 most common UCC services, at least two examples of the impact on insured and insurer paid amounts of the inappropriate utilization of emergency departments for nonemergent services, and an interactive tool to locate local in-network and out-of-network UCCs.

Sections 5 through 12 amend ss. 385.211, 390.011, 394.4787, 395.701, 400.9935, 409.905, 409.975, 468.505, 627.64194, and 765.101, F.S., to make conforming changes.

Section 15 provides an effective date of July 1, 2021.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

SB 1976 may have an indeterminate negative fiscal impact on hospitals with FEDs due to the increased requirements of signage. The bill may have an indeterminate positive fiscal impact on patients who pay for health care out of pocket and if they decide to seek treatment for low-acuity health issues at UCCs rather than FEDs. The bill may have an indeterminate positive fiscal impact on health insurers if insureds choose to use lower-cost UCCs rather than FEDs for low-acuity health issues.

C. Government Sector Impact:

The AHCA indicates that the bill's requirement for an interactive tool to be placed on the agency's website will require approximately \$15,000 to cover contracted services, but this amount can be absorbed within existing agency resources.¹⁴

VI. Technical Deficiencies:

None.

¹⁴ Supra n. 3.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.002, 395.003, 395.1041, 627.6405, 385.211, 390.011, 394.4787, 395.701, 400.9935, 409.905, 409.975, 468.505, 627.64194, and 765.101.

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 Brodeur

9-01437-21

20211976__

1 A bill to be entitled
 2 An act relating to freestanding emergency departments;
 3 amending s. 395.002, F.S.; defining and revising
 4 terms; amending s. 395.003, F.S.; deleting an obsolete
 5 provision relating to a prohibition on new emergency
 6 departments located off the premises of licensed
 7 hospitals; amending s. 395.1041, F.S.; prohibiting a
 8 freestanding emergency department from holding itself
 9 out to the public as an urgent care center; requiring
 10 a freestanding emergency department to clearly
 11 identify itself as a hospital emergency department
 12 using certain signage; requiring a freestanding
 13 emergency department to post signs in certain
 14 locations which contain specified statements;
 15 providing requirements for such signs; providing
 16 requirements for the advertisement of freestanding
 17 emergency departments; requiring the Agency for Health
 18 Care Administration to post information on its website
 19 describing the differences between a freestanding
 20 emergency department and an urgent care center;
 21 requiring the agency to update such information on its
 22 website at least annually; requiring hospitals to post
 23 a link to such information on their websites; amending
 24 s. 627.6405, F.S.; deleting legislative findings and
 25 intent; requiring health insurers to post certain
 26 information regarding appropriate use of emergency
 27 care services on their websites and update such
 28 information at least annually; revising the definition
 29 of the term "emergency care"; amending ss. 385.211,

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

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30 390.011, 394.4787, 395.701, 400.9935, 409.905,
 31 409.975, 468.505, 627.64194, and 765.101, F.S.;
 32 conforming cross-references; providing an effective
 33 date.

34
 35 Be It Enacted by the Legislature of the State of Florida:

36
 37 Section 1. Present subsections (10) through (32) of section
 38 395.002, Florida Statutes, are redesignated as subsections (11)
 39 through (33), respectively, a new subsection (10) is added to
 40 that section, and present subsections (10), (27), and (29) are
 41 amended, to read:

42 395.002 Definitions.—As used in this chapter:

43 (10) "Freestanding emergency department" means a facility
 44 that:

45 (a) Provides emergency services and care;

46 (b) Is owned and operated by a licensed hospital and
 47 operates under the license of the hospital; and

48 (c) Is located on separate premises from the hospital.

49 (11)-(10) "General hospital" means any facility which meets
 50 the provisions of subsection (13) ~~(12)~~ and which regularly makes
 51 its facilities and services available to the general population.

52 (28)-(27) "Specialty hospital" means any facility which
 53 meets the provisions of subsection (13) ~~(12)~~, and which
 54 regularly makes available either:

55 (a) The range of medical services offered by general
 56 hospitals, but restricted to a defined age or gender group of
 57 the population;

58 (b) A restricted range of services appropriate to the

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

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diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or

(c) Intensive residential treatment programs for children and adolescents as defined in subsection (16) ~~(15)~~.

~~(30)-(29)~~ "Urgent care center" means a facility or clinic that provides immediate but not emergent ambulatory medical care to patients. ~~The term includes an offsite emergency department of a hospital that is presented to the general public in any manner as a department where immediate and not only emergent medical care is provided.~~ The term also includes:

(a) An offsite facility of a facility licensed under this chapter, or a joint venture between a facility licensed under this chapter and a provider licensed under chapter 458 or chapter 459, that does not require a patient to make an appointment and is presented to the general public in any manner as a facility where immediate but not emergent medical care is provided.

(b) A clinic organization that is licensed under part X of chapter 400, maintains three or more locations using the same or a similar name, does not require a patient to make an appointment, and holds itself out to the general public in any manner as a facility or clinic where immediate but not emergent medical care is provided.

Section 2. Paragraph (c) of subsection (1) of section 395.003, Florida Statutes, is amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1)

~~(c) Until July 1, 2006, additional emergency departments located off the premises of licensed hospitals may not be~~

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~~authorized by the agency.~~

Section 3. Paragraph (m) is added to subsection (3) of section 395.1041, Florida Statutes, to read:

395.1041 Access to emergency services and care.—

(3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF FACILITY OR HEALTH CARE PERSONNEL.—

(m)1. A freestanding emergency department may not hold itself out to the public as an urgent care center and must clearly identify itself as a hospital emergency department using, at a minimum, prominent lighted external signage that includes the word "EMERGENCY" in conjunction with the name of the hospital.

2. A freestanding emergency department shall conspicuously post signs at locations that are readily accessible to and visible by patients outside the entrance to the facility and in patient waiting areas which state the following: "THIS IS A HOSPITAL EMERGENCY DEPARTMENT." Unless the freestanding emergency department shares a location and a public entrance with an urgent care center, the signs must also state the following: "THIS IS NOT AN URGENT CARE CENTER. HOSPITAL EMERGENCY DEPARTMENT RATES ARE BILLED FOR OUR SERVICES." The signs must also specify the facility's average facility fee, if any, and notify the public that the facility or a physician providing medical care at the facility may be an out-of-network provider. The signs must be at least 2 square feet in size and the text must be in at least 36-point type.

3. Except as provided in this paragraph, any advertisement for a freestanding emergency department must include the following statement: "This emergency department is not an urgent

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117 care center. It is part of (insert hospital name) and its
 118 services and care are billed at hospital emergency department
 119 rates." Any billboard advertising a freestanding emergency
 120 department which measures at least 200 square feet must include
 121 the following statement in clearly legible contrasting color
 122 text at least 15 inches high: "(INSERT NAME OF HOSPITAL)
 123 EMERGENCY DEPARTMENT. THIS IS NOT AN URGENT CARE CENTER."

124 4.a. The agency shall post on its website information that
 125 provides a description of the differences between a freestanding
 126 emergency department and an urgent care center. Such description
 127 must include:

128 (I) At least two examples illustrating the impact on
 129 insured and insurer paid amounts of inappropriate utilization of
 130 nonemergent services and care in a hospital emergency department
 131 setting compared to utilization of nonemergent services and care
 132 in an urgent care center;

133 (II) An interactive tool to locate local urgent care
 134 centers; and

135 (III) What to do in the event of a true emergency.

136 b. The agency shall update the information required in sub-
 137 paragraph a. at least annually. Each hospital shall post a
 138 link to such information in a prominent location on its website.

139 Section 4. Section 627.6405, Florida Statutes, is amended
 140 to read:

141 627.6405 Decreasing inappropriate utilization of emergency
 142 care.—

143 ~~(1) The Legislature finds and declares it to be of vital~~
 144 ~~importance that emergency services and care be provided by~~
 145 ~~hospitals and physicians to every person in need of such care,~~

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146 ~~but with the double-digit increases in health insurance~~
 147 ~~premiums, health care providers and insurers should encourage~~
 148 ~~patients and the insured to assume responsibility for their~~
 149 ~~treatment, including emergency care. The Legislature finds that~~
 150 ~~inappropriate utilization of emergency department services~~
 151 ~~increases the overall cost of providing health care and these~~
 152 ~~costs are ultimately borne by the hospital, the insured~~
 153 ~~patients, and, many times, by the taxpayers of this state.~~
 154 ~~Finally, the Legislature declares that the providers and~~
 155 ~~insurers must share the responsibility of providing alternative~~
 156 ~~treatment options to urgent care patients outside of the~~
 157 ~~emergency department. Therefore, it is the intent of the~~
 158 ~~Legislature to place the obligation for educating consumers and~~
 159 ~~creating mechanisms for delivery of care that will decrease the~~
 160 ~~overutilization of emergency service on health insurers and~~
 161 ~~providers.~~

162 ~~(2)~~ A health insurer ~~insurers~~ shall post ~~provide~~ on its
 163 website ~~their websites~~ information regarding appropriate
 164 utilization of emergency care services which shall include, but
 165 need not be limited to:

166 (a) A list of alternative urgent care contracted
 167 providers;

168 (b) The types of services offered by these providers;

169 (c) A comparison of statewide average in-network and out-
 170 of-network urgent care center and freestanding emergency
 171 department charges for the 30 most common urgent care center
 172 services;

173 (d) At least two examples illustrating the impact on
 174 insured and insurer paid amounts of inappropriate utilization of

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nonemergent services and care in a hospital emergency department setting compared to utilization of nonemergent services and care in an urgent care center;

(e) An interactive tool to locate local in-network and out-of-network urgent care centers; and

(f) What to do in the event of a true emergency.

Health insurers shall update the information required in this subsection on its website at least annually.

(2)(3) Health insurers shall develop community emergency department diversion programs. Such programs may include, at the discretion of the insurer, but not be limited to, enlisting providers to be on call to insurers after hours, coordinating care through local community resources, and providing incentives to providers for case management.

(3)(4) As a disincentive for insureds to inappropriately use emergency department services for nonemergency care, health insurers may require higher copayments for urgent care or primary care provided in an emergency department and higher copayments for use of out-of-network emergency departments. Higher copayments may not be charged for the utilization of the emergency department for emergency care. For the purposes of this section, the term "emergency care" has the same meaning as the term "emergency services and care" as defined provided in s. 395.002(9) s. 395.002 and includes shall include services provided to rule out an emergency medical condition.

Section 5. Subsection (2) of section 385.211, Florida Statutes, is amended to read:

385.211 Refractory and intractable epilepsy treatment and

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research at recognized medical centers.—

(2) Notwithstanding chapter 893, medical centers recognized pursuant to s. 381.925, or an academic medical research institution legally affiliated with a licensed children's specialty hospital as defined in s. 395.002(28) s. 395.002(27), that contracts with the Department of Health, may conduct research on cannabidiol and low-THC cannabis. This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 6. Subsection (7) of section 390.011, Florida Statutes, is amended to read:

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

(7) "Hospital" means a facility as defined in s. 395.002(13) s. 395.002(12) and licensed under chapter 395 and part II of chapter 408.

Section 7. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and 394.4789.—As used in this section and ss. 394.4786, 394.4788, and 394.4789:

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to s. 395.002(28) s. 395.002(27) and part II of chapter 408 as a specialty psychiatric hospital.

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Section 8. Paragraph (c) of subsection (1) of section 395.701, Florida Statutes, is amended to read:

395.701 Annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance; administrative fines for failure to pay assessments when due; exemption.—

(1) For the purposes of this section, the term:

(c) "Hospital" means a health care institution as defined in s. 395.002(13) ~~s. 395.002(12)~~, but does not include any hospital operated by a state agency.

Section 9. Paragraph (i) of subsection (1) of section 400.9935, Florida Statutes, is amended to read:

400.9935 Clinic responsibilities.—

(1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:

(i) Ensure that the clinic publishes a schedule of charges for the medical services offered to patients. The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule may group services by price levels, listing services in each price level. The schedule must be posted in a conspicuous place in the reception area of any clinic that is considered an urgent care center as defined in s. 395.002(30)(b) ~~s. 395.002(29)(b)~~ and must include, but is not limited to, the 50 services most frequently provided by the clinic. The posting may be a sign that must be at least 15 square feet in size or through an electronic messaging board that is at least 3 square

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feet in size. The failure of a clinic, including a clinic that is considered an urgent care center, to publish and post a schedule of charges as required by this section shall result in a fine of not more than \$1,000, per day, until the schedule is published and posted.

Section 10. Subsection (8) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(8) NURSING FACILITY SERVICES.—The agency shall pay for 24-hour-a-day nursing and rehabilitative services for a recipient in a nursing facility licensed under part II of chapter 400 or in a rural hospital, as defined in s. 395.602, or in a Medicare certified skilled nursing facility operated by a hospital, as defined by s. 395.002(11) ~~s. 395.002(10)~~, that is licensed under part I of chapter 395, and in accordance with ~~provisions set~~

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291 ~~forth in~~ s. 409.908(2)(a), which services are ordered by and
 292 provided under the direction of a licensed physician. However,
 293 if a nursing facility has been destroyed or otherwise made
 294 uninhabitable by natural disaster or other emergency and another
 295 nursing facility is not available, the agency must pay for
 296 similar services temporarily in a hospital licensed under part I
 297 of chapter 395 provided federal funding is approved and
 298 available. The agency shall pay only for bed-hold days if the
 299 facility has an occupancy rate of 95 percent or greater. The
 300 agency is authorized to seek any federal waivers to implement
 301 this policy.

302 Section 11. Paragraph (b) of subsection (1) of section
 303 409.975, Florida Statutes, is amended to read:

304 409.975 Managed care plan accountability.—In addition to
 305 the requirements of s. 409.967, plans and providers
 306 participating in the managed medical assistance program shall
 307 comply with the requirements of this section.

308 (1) PROVIDER NETWORKS.—Managed care plans must develop and
 309 maintain provider networks that meet the medical needs of their
 310 enrollees in accordance with standards established pursuant to
 311 s. 409.967(2)(c). Except as provided in this section, managed
 312 care plans may limit the providers in their networks based on
 313 credentials, quality indicators, and price.

314 (b) Certain providers are statewide resources and essential
 315 providers for all managed care plans in all regions. All managed
 316 care plans must include these essential providers in their
 317 networks. Statewide essential providers include:

- 318 1. Faculty plans of Florida medical schools.
- 319 2. Regional perinatal intensive care centers as defined in

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320 s. 383.16(2).

321 3. Hospitals licensed as specialty children's hospitals as
 322 defined in s. 395.002(28) ~~s. 395.002(27)~~.

323 4. Accredited and integrated systems serving medically
 324 complex children which comprise separately licensed, but
 325 commonly owned, health care providers delivering at least the
 326 following services: medical group home, in-home and outpatient
 327 nursing care and therapies, pharmacy services, durable medical
 328 equipment, and Prescribed Pediatric Extended Care.

329
 330 Managed care plans that have not contracted with all statewide
 331 essential providers in all regions as of the first date of
 332 recipient enrollment must continue to negotiate in good faith.
 333 Payments to physicians on the faculty of nonparticipating
 334 Florida medical schools shall be made at the applicable Medicaid
 335 rate. Payments for services rendered by regional perinatal
 336 intensive care centers shall be made at the applicable Medicaid
 337 rate as of the first day of the contract between the agency and
 338 the plan. Except for payments for emergency services, payments
 339 to nonparticipating specialty children's hospitals shall equal
 340 the highest rate established by contract between that provider
 341 and any other Medicaid managed care plan.

342 Section 12. Paragraph (1) of subsection (1) of section
 343 468.505, Florida Statutes, is amended to read:

344 468.505 Exemptions; exceptions.—

345 (1) Nothing in this part may be construed as prohibiting or
 346 restricting the practice, services, or activities of:

- 347 (1) A person employed by a nursing facility exempt from
- 348 licensing under s. 395.002(13) ~~s. 395.002(12)~~, or a person

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exempt from licensing under s. 464.022.

Section 13. Paragraph (b) of subsection (1) of section 627.64194, Florida Statutes, is amended to read:

627.64194 Coverage requirements for services provided by nonparticipating providers; payment collection limitations.—

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

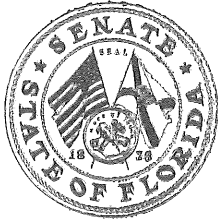
(b) "Facility" means a licensed facility as defined in s. 395.002(17) ~~s. 395.002(16)~~ and an urgent care center as defined in s. 395.002.

Section 14. Subsection (2) of section 765.101, Florida Statutes, is amended to read:

765.101 Definitions.—As used in this chapter:

(2) "Attending physician" means the physician who has primary responsibility for the treatment and care of the patient while the patient receives such treatment or care in a hospital as defined in s. 395.002(13) ~~s. 395.002(12)~~.

Section 15. This act shall take effect July 1, 2021.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR JASON BRODEUR

9th District

COMMITTEES:

Environment and Natural Resources, *Chair*
Health Policy, *Vice Chair*
Appropriations Subcommittee on Agriculture,
Environment, and General Government
Appropriations Subcommittee on Health and
Human Services
Children, Families, and Elder Affairs
Community Affairs

SELECT COMMITTEE:

Select Committee on Pandemic
Preparedness and Response

JOINT COMMITTEE:

Joint Administrative Procedures Committee

March 5, 2021

Honorable Manny Diaz, Jr.
306 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Diaz,

I am writing to request that SB 1976, Freestanding Emergency Departments, be placed on the agenda to be heard in the Health Policy Committee.

I appreciate your consideration in this matter.

Sincerely,

A handwritten signature in black ink that reads "Jason Brodeur". The signature is fluid and cursive.

Jason Brodeur

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

REPLY TO:

□ 311 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5009

Senate's Website: www.flsenate.gov

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore



2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION

BILL NUMBER:	HB 1157
BILL TITLE:	Freestanding Emergency Departments
BILL SPONSOR:	Representative Koster
EFFECTIVE DATE:	July 1, 2021

COMMITTEES OF REFERENCE

1)
2)
3)
4)
5)

CURRENT COMMITTEE

SIMILAR BILLS

BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION

BILL NUMBER:	
SPONSOR:	
YEAR:	

IDENTICAL BILLS

BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?

Y ___ N _X_

LAST ACTION:	

BILL ANALYSIS INFORMATION

DATE OF ANALYSIS:	February 23, 2021
LEAD AGENCY ANALYST:	Teresa Wooten
ADDITIONAL ANALYST(S):	Angel Stock, Terrence Frech, Nikole Helvey, Jack Plagge
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

This bill makes a distinction difference freestanding emergency departments, currently referred to as an off-site emergency department, and an urgent care center, and requires signage and advertising for freestanding emergency departments include information such as the fee for services. As part of the signage requirements, a freestanding emergency department would be required to specify that this is not an urgent care center and include the average facility fee for services. Clarification is needed to ensure that posting the facility fee does not conflict with federal Emergency Medical Treatment & Labor Act (EMTALA) requirements that historically prohibit hospitals from discussing costs prior to patient treatment for emergency care.

The bill requires the Agency for Health Care Administration (Agency) to post an interactive tool to locate local urgent care centers on its website. The Agency does not currently maintain a list of urgent care centers, and providers currently licensed by the Agency are not required to identify as urgent care centers.

The bill also requires health insurers post a list of in-network and out-of-network urgent care centers. The bill also requires health plans to provide a comparison of statewide average in-network and out-of-network urgent care center and freestanding emergency department charges for the 30 most common urgent care center services.

The bill has a fiscal impact to state government as the Agency's Florida Center for Health Information & Transparency would require approximately \$15,000 to cover contracted services to create the interactive tool on www.floridahealthfinder.gov. This amount could be absorbed within existing Agency resources.

The bill would be effective on July 1, 2021.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

As of February 24, 2021, there are 86 off-site emergency departments operated by 58 hospitals. The off-site emergency departments licensed by the Agency continue to operate, although some have been converted to hospitals by adding inpatient services. A list of hospitals and emergency department locations with effective dates is available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/OSSED_List.pdf.

Hospitals operating off-site emergency departments must offer the same emergency services at their off-site location as at their primary location and must comply with s. 395.1041, F.S., (Access to Emergency Services and Care) and Rule 59A-3.255, F.A.C., (Emergency Care). The physical plant must meet Florida Hospital Building Code in order to be licensed. There are no regulations specific for the operation of off-site emergency departments. Signage requirements for the general hospital are also applicable to the off-site location. Emergency services are a function of a hospital, and there is no licensure available to non-hospital entities to operate an emergency department.

There is not a specific licensure program for urgent care centers. An urgent care center may be operated by a hospital, one or more clinicians, or by other persons or entities. Hospitals report off-site emergency departments, outpatient surgical locations, and other wholly-owned off-site outpatient locations through the hospital licensure process. The hospital's other outpatient locations are identified by name and address only, not services. Clinicians, other persons, and entities operating an urgent care center may be licensed as a health care clinic under chapter 400, Part X, F.S., or meet an exemption to the health care clinic licensure requirements.

The Agency receives patient billing complaints concerning pricing and available services. If the facility is part of a hospital's license, the allegations are reviewed using the transparency requirements in s. 395.301, F.S.

The Agency also publishes consumer guides explaining the difference between an urgent care center and an emergency department. The consumer guides are available at www.floridahealthfinder.gov.

2. EFFECT OF THE BILL:

Upon implementation of this bill, the Agency would refer to emergency departments located off-premises of hospitals as freestanding emergency departments. The terminology would need to be updated in all Agency systems and publications.

The Agency would enforce the signage requirements at the facility, and Agency surveyors would have to adjust their checklist accordingly. Section 395.1041, F.S., would require prominently lighted external signage that includes the word "EMERGENCY," in conjunction with the name of the hospital. The term "prominent" is not defined in terms of a specified size, and "lighted" could include lights behind translucent letters or illuminated by flood/spotlights. The bill also requires signage include "THIS IS A HOSPITAL..." in at least 36-point type but does not identify a specific font. The Life Safety Code and Florida Building Code require a specific height of characters and width of "principle strokes." These levels of

specificity could be addressed in the statute, or may be considered during future building code revisions by the Building Commission.

The bill also requires the signs to specify the facility's average "facility fee" which is not defined. Hospitals are required to follow federal EMTALA regulations: *"Hospitals may not attempt to coerce individuals into making judgments against their interest by informing them that they will have to pay for their care if they remain but that their care will be free or at a lower cost if they transfer to another hospital."* The federal regulations have historically been interpreted to consider discussion of the price of emergency services in a hospital a violation of EMTALA as it may discourage a person from seeking an emergency service if they feel they will be unable to pay. However, the Centers for Medicare and Medicaid Services (CMS) has recently promulgated several rules forwarding price transparency in hospitals. It is possible that CMS would not see the uniform posting of pricing information as an EMTALA violation if posting is required by state law (since the intent would not be to coerce a person from seeking care for which they may be unable to pay).

The bill requires the Agency to post "an interactive tool to locate local urgent care centers" on its website and will require a list of urgent care centers be maintained. The Agency's *FloridaHealthFinder.gov* website could be utilized to post such a tool. However, the Agency does not currently maintain a list of urgent care centers, and providers are not required to identify as an urgent care center. By modifying the Agency's licensure system, the Agency could identify hospital-based centers and health care clinics proclaiming to be urgent care centers. The definition of an urgent care center in s. 395.002(20)(b), F.S., was amended in 2012 (2012-160, Laws of Florida) to include a clinic organization licensed as a health care clinic operating at three or more locations. Health care clinic licensure, initiated in 2003, identifies services offered by clinics as urgent care that are not part of an organization of three or more clinics. Those clinics exempt from the definition of urgent care centers are not required to post a schedule of charges pursuant to s. 400.9935(1)(i), F.S. Some clinics may identify themselves as urgent care centers that would not meet the statutory definition. It may be beneficial to consumers to allow health care clinics that hold themselves out as urgent care centers to be listed on Florida Health Finders even if they do not operate at least three locations.

Urgent care centers that are not regulated by the Agency such as a physician's practices are not required to identify to the Agency that they are urgent care centers. The Department of Health could collect the information from physicians and physician practices that are not licensed by the Agency; and the Agency would need to establish a data sharing agreement and methodology to receive the information from the Department to be included in the interactive tool.

The bill requires the Agency to publish at least two examples illustrating the impact on insured and insurer paid amounts resulting from inappropriate utilization of emergency departments for non-emergency services compared to the same services when provided in an urgent care center. The Agency may be able to utilize data in the state's designated multi-payer claims database to calculate the average cost related to specific diagnoses and/or services for each setting.

The bill requires health insurers to post a list of in-network and out-of-network urgent care centers, . Regarding health maintenance organizations (HMOs), many of these requirements are already in place and shared on health plan websites and in member materials; so, these resources would only need to be revised and updated. Members often overlook the difference in copayments and deductibles when utilizing an urgent care center versus the emergency room (ER), but all the information would have been included in their member handbook and should be readily available on the HMO's website.

The bill requires health plans to provide "a comparison of statewide average in-network and out-of-network urgent care center and freestanding emergency department charges for the 30 most common urgent care center services." However, the bill does not establish which are the 30 most common services. This is important as these services can vary by plan and by individual clinic location.

The bill has a fiscal impact to state government. The Agency's Florida Center for Health Information & Transparency would require approximately \$15,000 in the first year to cover contracted services to create the interactive tool on www.floridahealthfinder.gov. This amount could be absorbed within existing Agency resources.

The bill would be effective on July 1, 2021.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y ___ N X___

If yes, explain:	
Is the change consistent with the agency's core mission?	Y <u>X</u> N ___
Rule(s) impacted (provide references to F.A.C., etc.):	While the bill does not specifically direct the Agency to develop rules, the Agency will need to revise existing rules (59A-3, 59A-33 and 59A-35, F.A.C.) in order to

	be able to collect information related to urgent care centers. Existing rule authority exists that would allow the agency to develop rules if needed.

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ___ N X

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQUIRED BY THIS BILL? Y ___ N X

Board:	
Board Purpose:	
Who Appointments:	
Appointee Term:	
Changes:	
Bill Section Number(s):	

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y ___ N X

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees? If yes, explain.	
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y X N

Revenues:	None
Expenditures:	\$15,000
Does the legislation contain a State Government appropriation?	No

If yes, was this appropriated last year?	

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y ___ N X

Revenues:	
Expenditures:	
Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y ___ N X

If yes, explain impact.	
Bill Section Number:	

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y X ___ N

If yes, describe the anticipated impact to the agency including any fiscal impact.	The existing licensure system would need to be updated to be able to collect information specific to urgent care centers although these revisions could be made with existing resources. This change can be addressed with existing resources.

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y ___ N X

If yes, describe the anticipated impact including any fiscal impact.	

ADDITIONAL COMMENTS

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

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 1366

INTRODUCER: Senator Brodeur

SUBJECT: Licensure Examinations for Dental Practitioners

DATE: March 23, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto Van-Winkle	Brown	HP	Favorable
2.	_____	_____	JU	_____
3.	_____	_____	RC	_____

I. Summary:

SB 1366 authorizes the Board of Dentistry (BOD), within the Department of Health (DOH), to accept passing examination scores for the dental and dental hygiene clinical licensure examinations developed and administered by the Western Regional Examining Board (WREB) for licensure as a dentist or dental hygienist as an additional clinical licensure examination. The bill also:

- Amends legislative intent;
- Requires the BOD to maintain representation on the American Board of Dental Examiners, Inc.(ADEX) and the WREB's boards of directors, examination development committees, and any additional committees the BOD requires to ensure examination standards are maintained;
- Authorizes clinical licensure examinations for dentists and dental hygienists to utilize mannequins¹ during the examinations upon BOD approval; and
- Makes additional conforming changes.

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

II. Present Situation:

The Practice of Dentistry

The BOD regulates dental practice in Florida, including dentists, dental hygienists, and dental assistants under the Dental Practice Act.² A dentist is licensed to examine, diagnose, treat, and

¹ The word "mannequin" is used in ss. 466.006 and 466.007, F.S., but the word "manikin" is used throughout all the materials researched, including the American Dental Association and the various dental and dental hygiene testing agencies, so they will be used interchangeably in this analysis.

² Section 466.004, F.S.

care for conditions within the human oral cavity and its adjacent tissues and structures.³ A dental hygienist provides education, preventive, and delegated therapeutic dental services.⁴

Florida currently uses the American Dental Licensing Examination (ADLEX) and the American Dental Hygiene Licensing Examination (ADHLEX) for its clinical examinations. Both are produced by the American Board of Dental Examiners, Inc. (ADEX),⁵ as the legislatively mandated state clinical licensure examinations for dentists and dental hygienists.⁶ Both clinical examinations are administered by two national testing agencies:

- Commission for Dental Competency Assessments (CDCA).
- Council of Interstate Testing Agencies (CITA).

According to the American Dental Association (ADA) and the ADEX, there are currently five national clinical testing agencies:^{7,8}

- Commission for Dental Competency Assessments (CDCA);
- Council of Interstate Testing Agencies (CITA);
- Central Regional Dental Testing Services, Inc. (CRDTS);
- Southern Regional Testing Agency, Inc. (SRTA); and
- Western Regional Examining Board (WREB).

Only three jurisdictions currently administer their own clinical examinations:

- California;
- Delaware; and
- The U.S. Virgin Islands.⁹

Dentists

The requirements for dental licensure in Florida are found in s. 466.006, F.S. An applicant must apply to the DOH to take and pass the following examinations:

- The ADLEX;¹⁰ and
- An exam on Florida laws and rules relating to dentistry.

³ Section 466.003(3), F.S.

⁴ Section 466.003(4) and (5), F.S.

⁵ The American Board of Dental Examiners, Inc. (ADEX) develops both dental and dental hygiene clinical examinations. The first ADLEX exam was produced by the ADEX and administered in 2005; and is now simply called the “ADEX Dental Exam” or the “ADEX Dental Hygiene Exam.” The ADEX does not administer examinations. For clarity purposes, this analysis will continue to refer to American Dental Licensing Examination as the “ADLEX,” the American Dental Hygiene Licensing Examination as the “ADHLEX,” and reserve the abbreviation “ADEX” for the American Board of Dental Examiners, Inc.

⁶ See ss. 466.006(4)(b) and 466.007(4)(b), F.S.

⁷ American Dental Association, *Licensure Pathways*, available at <https://www.ada.org/en/education-careers/licensure/licensure-students/licensure-pathways> (last visited Mar. 18, 2021).

⁸ The American Board of Dental Examiners, Inc., ADEX. *What ADEX Does* available at <https://adexexams.org/about-adex/> (last visited Mar. 19, 2021).

⁹ American Dental Association, *Understanding Licensure*, available at <http://www.ada.org/en/~media/ADA/Education%20and%20Careers/Files/understanding-licensure> (last visited Mar. 21, 2021).

¹⁰ Section 466.006, F.S.

To take the ADLEX clinical examination, a dental applicant must be at least 18 years of age and must be:

- A graduate from a dental school accredited by the ADA Commission on Dental Accreditation (CODA) or any other dental accrediting entity recognized by the U.S. Department of Education (DOE); or
- A dental student in the final year of a program at an ADA-CODA-accredited dental school who has completed all the coursework necessary to prepare the student to perform the clinical and diagnostic procedures required to pass the examinations. A passing score on the examination is valid for 365 days; and
- Have passed Parts I and II of the National Board Dental Examination (NBDE), administered by the Joint Commission on National Dental Examinations (JCNDE).¹¹

Current law requires the ADLEX clinical dental examination to include the following:

- Comprehensive diagnostic skills examination including an examination, clinical diagnosis and treatment planning;
- Two restorations on a live patient or patients;¹²
- Demonstration of periodontal skills on a live patient;
- Demonstration of prosthetics and restorative skills in complete and partial dentures and crowns and bridges and the utilization of practical methods of evaluation;
- Demonstration of restorative skills on a manikin including procedures performed in preparation for a cast restoration;
- Demonstration of endodontic skills; and
- Diagnostic skills examination demonstrating ability to diagnose conditions within the human oral cavity and its adjacent tissues and structures from photographs, slides, radiographs, or models.¹³

A dental school graduate from a school not accredited by the ADA CODA, a United States DOE-recognized dental accrediting entity, or approved by the BOD, and desiring to take the ADLEX, is not entitled to do so unless the applicant:

- Demonstrates completion of a program defined by BOD rule at an accredited American dental school and receives either a D.D.S. or D.M.D. from the school; or
- Submits proof of successful completion of at least two consecutive years at a full-time supplemental general dentistry program accredited by the ADA CODA.

¹¹ American Dental Association, Joint Commission on National Dental Examinations, *About the JCNDE*, available at <https://www.ada.org/en/jcnde/about-us> (last visited Mar. 19, 2021) The Joint Commission on National Dental Examinations (JCNDE) is the agency responsible for the development and administration of the National Board Dental Examinations (NBDE). This 16-member Commission includes representatives from dental schools, dental practice, state dental examining boards, dental hygiene, dental students, and the public.

¹² See Fla. Admin. Code R. 64B5-2.013 (2021), which specified the class of restorations required for the clinical examination. It was repealed by the BOD in May 2012, after the clinical examination was transitioned to the ADLEX, because the ADEX had specified the class of restorations required to be performed in the ADLEX.

¹³ Section 466.006(5)(a), F.S.

Dental Hygienists

The requirements for licensure as a dental hygienist are found in s. 466.007, F.S. An applicant must apply to the DOH to take the ADHLEX and is entitled to licensure if he or she is 18 years of age or older and has:¹⁴

- Graduated from a dental hygiene college or school that is:
 - Board approved;
 - Accredited by the ADA CODA;
 - Accredited by any other dental accrediting entity recognized by the United States DOE;
- Passed the Florida Laws and Rules examination; and
- Passed the ADHLEX examination.

A dentist who is a graduate of an accredited dental college or school or a graduate of an unaccredited dental college or school, may also take the ADHLEX and obtain licensure as a dental hygienist if he or she meets certain additional criteria.¹⁵

Dental and Dental Hygiene Examinations

The Legislature has authorized the BOD to use the ADLEX and the ADHLEX developed by ADEX in lieu of an independent state-developed practical or clinical examination for both dentists and dental hygienists.¹⁶ Dental licensure is a process every dentist must go through, and, in the United States, licensure requirements vary from state to state. State legislatures and dental boards establish the licensure requirements, including which licensure examinations its prospective licensees must take and pass as evidence of clinical competence for a dental license.

The American Dental Licensing Examination (ADLEX)

The ADLEX clinical examination administered by CDCA and the CITA is accepted in 48 states plus Puerto Rico, Jamaica, and the United States Virgin Islands.¹⁷ The ADLEX clinical examination is given in two formats:

- The traditional format;^{18,19} and
- The Patient-Centered Curriculum Integrated Format (PC CIF).^{20,21}

¹⁴ Section 466.007, F.S.

¹⁵ See s. 466.007 (2)(b)1. and (3), F.S.

¹⁶ See ss. 466.006(4)(b) and 466.007(4)(b), F.S.

¹⁷ The Commission on Dental Competency Assessments, 2021 ADEX Acceptance Maps, *Dental*, available at <https://www.cdcaexams.org/ADEX-acceptance-map/> (last visited Mar. 18, 2021). Only New York and Delaware do not accept the ADEX dental examination.

¹⁸ The Commission on Dental Competency Assessments, *Dental (ADEX)*, available at <https://www.cdcaexams.org/dental-exams/> (last visited Mar. 18, 2021).

¹⁹ American Dental Association, *Licensure Pathways*, available at <https://www.ada.org/en/education-careers/licensure/licensure-dental-students/licensure-pathways> (last visited Mar. 18, 2021).

²⁰ See note 18.

²¹ American Board of Dental Examiners, Inc., ADEX Patient Centered Curriculum Integrated Format (PC CIF), *ADEX* available at <https://ADEXexams.org/wp-content/uploads/2016/06/ADEX-Patient-Centered-Curriculum-Integrated-Format-PC-CIF-2.pdf> (last visited Mar. 19, 2021). The PC CIF format focuses on patient care needs, rather than the candidate's examination. The examination itself is identical to the ADEX Licensing Examination for initial licensure in dentistry.

The traditional format uses a clinical manikin and patient-based examinations administered in a single sitting at the end of a dental student's senior year by a testing agency or individual state. It is for those students who have elected not to take the PC CIF or for those who have already graduated from dental school.²²

The PC CIF is an alternative to the traditional format. The PC CIF option is offered by the CRDTS, CITA, CDCA, and SRTA, but not the WREB. The PC CIF allows dental students to be examined in sections, during the fourth year of dental school. With the PC CIF, the manikin-based clinical examinations are administered late in the junior year or early in the senior year, and the clinical patient-based examinations are administered during the senior year. Only students or graduates of schools accredited by the ADA CODA or the Commission on Dental Accreditation of Canada may take the ADLEX PC CIF clinical examination.²³

All other candidates (including international graduates) must apply through a state's dental board in the state or jurisdiction where they wish to practice for permission to take an examination for licensure only in that state or jurisdiction.

The ADLEX examination series includes computer simulations and clinical examinations performed on patients and manikins and is an Objective Structured Clinical Examination (OSCE).²⁴ There are five skill-specific components including a high-fidelity computerized OSCE testing a candidate's ability to apply knowledge to the care of patients. The five areas are:

- Diagnostic Skill Examination;
- Restorative – Anterior and Posterior;
- Prosthodontics;²⁵
- Endodontics;²⁶ and
- Periodontal Scaling.

The cost of taking the full dental ADLEX examination is \$2,295 plus ancillary fees.²⁷

²² *Id.*

²³ Section 466.006(2)(b), F.S.

²⁴ National Institute of Health, US National Library of Medicine, Oman Med J. 2011 Jul; 26(4): 219–222, *Objective Structured Clinical Examination: The Assessment of Choice*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3191703/> (last visited Mar. 18, 2021). The Objective Structured Clinical Examination is a versatile multipurpose evaluative tool that can be utilized to assess health care professionals in a clinical setting. It assesses competency, based on objective testing through direct observation. It is precise, objective, and reproducible allowing uniform testing of students for a wide range of clinical skills. Unlike the traditional clinical exam, the OSCE could evaluate areas most critical to performance of health care professionals such as communication skills and ability to handle unpredictable patient behavior.

²⁵ Prosthodontics is the branch of dentistry concerned with the design, manufacture, and fitting of artificial replacements for teeth and other parts of the mouth.

²⁶ Endodontics is the branch of dentistry concerning dental pulp and tissues surrounding the roots of a tooth. Endodontic treatment, or root canal treatment, treats the soft pulp tissue inside the tooth.

²⁷ See note 18.

The Western Regional Examining Board Examination (WREB) – Dental

The WREB dental examination is fully accepted in 21 states²⁸ with 16 other states accepting successful results only in support of initial licensure.²⁹ The WREB does not require membership as a pre-requisite for utilization of its dental and dental hygiene examinations. The WREB does not require the passage of Part I and Part II of the national dental boards prior to taking the WREB clinical examination and does not administer state-specific jurisprudence examinations.³⁰

The 2021 WREB dental examination consists of the following sections:³¹

- Operative;
- Endodontics; and
- Comprehensive Treatment Planning (CTP).

The WREB offers optional sections in prosthodontic and periodontal, if required by the state in which a candidate is applying for initial licensure.

The operative section is performed on either a live patient or a simulation performed on a manikin. The candidate may complete up to two procedures to demonstrate competence on the Operative section.

Patient Operative:

- A Class II restoration – Composite or Amalgam; and
- If required:
 - Direct Class II Composite or Amalgam restoration; or
 - Direct Class III Composite restoration.

Simulation Operative: A Class II and Class III preparation and restoration procedure must be completed.³²

The endodontics section is completed on simulated teeth for both the patient-based and manikin formats. Candidates are required to place and maintain the manikin in correct patient treatment position and remain articulated in correct vertical dimension. Candidates have three hours to complete their treatment and postoperative radiographs. Candidates are required to perform the following endodontic procedures:

- Anterior – Graded on access and condensation; and
- Posterior – Graded on access only.

²⁸ Western Regional Examining Board, About Us, *States Accepting WREB*, available at <https://wreb.org/about-us/> (last visited Mar. 18, 2021). Alaska, Arizona, Arkansas, California, Idaho, Illinois, Iowa, Kansas, Minnesota, Missouri, Montana, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, Texas, Utah, Washington, West Virginia and Wyoming. States that do not accept the WREB in come form are Delaware, Florida, Georgia, Maryland, North Carolina, New Jersey, New Hampshire, New York, South Carolina, and Vermont, plus DC and Puerto Rico.

²⁹ Id. Those state are Alabama, Colorado, Connecticut, Indiana, Kentucky, Maine, Massachusetts, Michigan, Nebraska, Ohio, Pennsylvania, Rhode Island, South Dakota, Tennessee, Virginia, and Wisconsin.

³⁰ Department of Health, *Senate Bill 1366 Fiscal Analysis* (Feb. 23, 2021) (on file with the Senate Committee on Health Policy).

³¹ Western Regional Examining Board, Dental Candidates, Policies and Procedures, 2021 Policies and Procedures, *2021 WREB Exam Procedures*, available at https://wreb.org/Candidates/Dental/2021_Dental_PDFs/2021_WREB_Exam_Procedures.pdf (last visited Mar. 19, 2021).

³² *Id.*

The comprehensive treatment planning (CTP) section of the WREB exam, for patient-based or manikin formats, is a computer-based written examination administered by Prometric Testing Centers. The exam consists of three patient cases of varying complexity, one of which is a pediatric patient. For each case, candidates assess patient history, photographs, radiographs, and clinical information. Candidates are required to create and submit a treatment plan and then answer questions or perform tasks related to each case. Candidates have three hours to complete the CTP exam.³³

Prosthodontics, another optional section, consists of the simulated preparation of two abutments, which are connecting pieces that join the prosthesis to the implants:

- One to support a posterior three-unit fixed partial denture prosthesis; and
- One of an anterior tooth for a full-coverage ceramic crown.

The prosthodontic preparations are completed in a single day and candidates are allotted three and one-half hours to complete the prosthodontic preparations.

The periodontal section, also optional, consists of Initial Phase Treatment (IPT), Scaling/Root Preparation, on a live patient or on a manikin. Candidates provide a patient for the IPT section and will perform scaling and root-planning on one or two quadrants of the patient's mouth. Only one quadrant is required, but two may be necessary if required criteria are not met. If additional teeth are needed to obtain the required calculus and/or pocket depths, two quadrants may be used.

Periodontics simulation is offered where the patient-based PTI section is not available and for candidates intending to be licensed in states not requiring completion of a periodontal procedure on a patient. The candidate will perform a thorough scaling and root-planning of all teeth in the assigned quadrant of a simulated dental arch.

The cost of taking the full WREB examination is \$2,550 plus ancillary fees.³⁴

Dental Hygiene Examinations

The American Dental Licensing Examination (ADHLEX)

The ADHLEX examination is used in Florida and administered by the CDCA and the CITA. The ADHLEX is designed for students about to complete dental hygiene training and graduate dental hygienists. Forty-seven states accept the ADHLEX examination; only Delaware, Georgia, and Nebraska do not.³⁵

The ADHLEX examination is based on specific performance criteria used to measure clinical competence. There are two skill-specific clinical and simulated clinical OSCE:

- The Computer Simulated Clinical Examination (CSCE-OSCE); and

³³ See note 31.

³⁴ Id.

³⁵ The Commission on Dental Competency Assessments, 2021 ADEX Acceptance Maps, *Dental Hygiene*, available at <https://www.cdcaexams.org/ADEX-acceptance-map/> (last visited Mar. 18, 2021).

- The Patient Treatment Clinical Examination (PTCE).³⁶

The CSCE-OSCE exam is designed to assess various levels of diagnosis and treatment planning knowledge, skills, and abilities. Clinically-based questions are utilized through computer-enhanced photographs, radiographs, optical images of study and working models, laboratory data, and other clinical digitized reproductions.³⁷

The PTCE evaluates candidates on their clinical and judgment skills. Clinical skills include:³⁸

- Detection and removal of calculus;
- Accurate periodontal pocket depth measurements;
- Tissue management; and
- Final case presentation.

Judgment skills include:

- Presenting an eligible patient;
- Diagnostic-quality radiographs meeting all examination criteria; and
- An acceptable case selection of teeth that meets all calculus requirements.

The non-patient version of this ADHLEX examination is called the Manikin Treatment Clinical Examination (MTCE).³⁹

The cost of taking the full ADHLEX exam, both patient and manikin based, is \$995.⁴⁰

The Western Regional Examining Board Examination – Dental Hygiene

The WREB dental hygiene examination is designed for students about to complete dental hygiene training and graduate dental hygienists. The WREB dental hygiene examination is fully accepted in 22 states.

The dental hygiene WREB exam is given in three formats:

- The Patient-based format;⁴¹

³⁶ The Commission on Dental Competency Assessments, *Dental Hygiene (ADEX)*, available at <https://www.cdcaexams.org/dental-hygiene-ADEX-exam/> (last visited Mar. 18, 2021).

³⁷ *Id.*

³⁸ See note 36.

³⁹ The Commission on Dental Competency Assessments, *Dental Hygiene (ADEX)*, available at <https://www.cdcaexams.org/dental-hygiene-ADEX-exam/> (last visited Mar. 18, 2021).

⁴⁰ *Id.*

⁴¹ Western Regional Examination Board, *2021 Dental Hygiene Manikin Clinical Examination Candidate Guide* available at https://wreb.org/Candidates/Hygiene/hygienePDFs/2021_DH_Forms/2021_WREB_HYG_Manikin_Candidate_Guide_v012_72021.pdf (last visited Mar. 19, 2021). The examination is two hours and consists of two sections: Assessment and Detection and Removable Calculus. The Assessment and Detection section is administered first. Each section is administered separately and must be completed within the allotted time. The Assessment and Detection section consists of Extra-oral and intra-oral test items in addition to accurately evaluating and recording the following oral conditions: Furcation classification; Periodontal probing depths; Gingival recession; and Sub-gingival calculus.

- The Manikin format;⁴² and
- The OSCE format.⁴³

The 2021 WREB dental hygiene examination consists of the following sections:

- *Local Anesthesia* is a two-part exam written and clinical. Passage of the written local anesthesia exam is required prior to attempting any of the clinical examinations.⁴⁴
 - *The written examination* is a multiple-choice exam administered by Prometric Testing Centers. In order to attempt the clinical exam, a candidate must successfully complete the written exam within the specified testing timeframe or both their clinical exam attempt and registration fees will be forfeit.
 - *The clinical examination* requires the administration of two nerve block injections⁴⁵. The patient-based format may include the administration of local anesthetics if certain criteria are met.⁴⁶
- *Dental Hygiene Patient-based and Manikin-Based Clinical Examination*: The dental hygiene patient-based or manikin-based clinical examination consists of an evaluation of a candidate's ability to utilize professional judgment and clinical competency in providing oral health care to a live patient, including:⁴⁷
 - Extra-oral and intra-oral evaluation;
 - Calculus detection and removal;
 - Tissue management – probing and recession;
 - Periodontal assessment;⁴⁸ and
 - Professional judgment.
- *Restoration Examination*: The dental hygiene restorative clinical examination consists of the placement, carving, and finishing of:
 - One amalgam;
 - One composite restoration; and
 - Preparation of:
 - One mesiocclusal (MO); and
 - One distocclusal (DO) maxillary and mandibular acidental molar preparation.

⁴² Western Regional Examination Board, *2021 Dental Hygiene Patient-based Clinical Examination Candidate Guide*, available at https://wreb.org/Candidates/Hygiene/hygienePDFs/2021_DH_Forms/2021_WREB_HYG_PT-based_Candidate_Guide_v12162020.pdf (last visited Mar. 19, 2021)

⁴³ Western Regional Examination Board, *2021 Dental Hygiene Objective Structured Clinical Examination (OSCE) Candidate Guide*, p. 5, available at https://wreb.org/Candidates/Hygiene/hygienePDFs/2021_DH_Forms/2021_WREB_HYG_OSCE_Candidate_Guide_v12142020.pdf (last visited Mar. 19, 2021). The WREB dental hygiene OSCE is a two hour multiple-choice written examination that assesses the multi-faceted components of dental hygiene care. This is a comprehensive overview of dental hygiene knowledge that a clinician should possess to safely treat a Patient in a clinical setting. Multiple choice items are discipline based.

⁴⁴ Western Regional Examining Board, *2021 Local Anesthesia Examination Candidate Guide*, available at https://wreb.org/Candidates/Hygiene/hygienePDFs/2021_DH_Forms/2021_WREB_ANE_Candidate_Guide_v12172020.pdf (last visited Mar. 19, 2021).

⁴⁵ *Id.* The two required nerve blocks are the inferior alveolar (IA) and a posterior superior alveolar (PSA).

⁴⁶ See note 44.

⁴⁷ *Id.*

⁴⁸ See note 44. Periodontal assessment includes assessment and recording of: periodontal pocket depth; gingival recession; type and Severity of radiographic bone loss; and classification of furcation involvement.

The WREB fees for taking the dental hygiene examinations are as follows:⁴⁹

- Local anesthesia, written: \$125
- Local anesthesia, clinical: \$270
- Dental hygiene patient-based or manikin-based clinical: \$1,175
- Dental hygiene OSCE: \$450
- Restorative: \$460

Florida Board of Dentistry

The Florida BOD considered and discussed the addition of the WREB examination, as provided in SB 1366, on February 19, 2021. The BOD unanimously voted against the WREB.⁵⁰

SB 1366 is almost identical to SB 1032 (2020). The BOD, on January 20, 2020, called a board meeting to specifically discuss and consider the bill and its effect of adding the WREB clinical examination as a licensure examination for both dentists and dental hygienists. Board members and members of the public, including a BOD clinical examiner of 13 years, and the Florida Dental Association, expressed the following concerns with adopting the WREB:

- There were scoring discrepancies with the WREB examinations, especially the dental exam, resulting in nine states no longer accepting the WREB examination;
- Only one state, Alaska, accepted only the WREB;
- Two portions of the WREB examinations were optional in areas that were required in Florida, which could result in:
 - Issues involving standards of care; and
 - A requirement to check all applicants' actual examinations to ensure all requirements had been met by each applicant;
- The WREB examinations seemed to be less rigorous with less requirements, creating possible public safety issues;
- The WREB creates additional burdens on the BOD without much benefit to the citizens of Florida;
- The WREB examinations were not an improvement on the ADLEX or the ADHLEX; and
- The WREB examinations were weaker examinations and accepting the WREB examinations Florida would be lowering the state's standards.

No one present at either meeting testified in favor of adopting the WREB examinations. The BOD unanimously voted to oppose SB 1032 (2020).⁵¹

III. Effect of Proposed Changes:

The bill:

⁴⁹ Western Regional Examination Board, *Dental Hygiene, Local Anesthesia, and Restorative Exam Fees*, available at <https://wreb.org/hygiene-candidates/2018-hygiene-exam-fees/> (last visited Mar. 21, 2021).

⁵⁰ See Board of Dentistry, General Business Meeting Minutes, Feb. 19, 2021, 7:30 a.m. EST (on file with the Senate Committee on Health Policy) audio available at <https://floridasdentistry.gov/meeting-information/past-meetings/> starting at 6:26:11 through 29:18 (last listened Mar. 21, 2021).

⁵¹ See Board of Dentistry, General Business Meeting Minutes, Jan. 24, 2020, 9:00 a.m. EST (on file with the Senate Committee on Health Policy) audio available at <https://floridasdentistry.gov/meeting-information/past-meetings/page/4/> (last listened Mar. 21, 2021).

- Amends the legislative intent in s. 466.006(1)(a) and (6)(a), F.S., to:
 - Provide that the Legislature intends for the state to use the dental clinical examination developed and administered by the WREB, in addition to the ADEX, to test applicants for licensure;
 - Find that the WREB examination meets accepted testing standards to adequately and reliably measure an applicant's ability to practice dentistry;
 - Find that there is an important state interest to improve access to dental care for underserved residents and to further economic development;
 - Find that allowing practicing dentists in other states or territories, who apply to practice in Florida based on out-of-state WREB examination scores, is substantially related to achieving these important state interests; and
 - Find that out-of-state applicants, receiving Florida dental licenses based on out-of-state WREB scores, and planning to relocate to Florida, must be required to actually engage in the full-time dental practice in Florida within one year of receiving licensure to meet those state goals; and that if they do not, access to dental care for the public will not increase.
- Amends s. 466.006(4)(b) F.S., to:
 - Add the WREB clinical dental examination as an additional legislatively approved clinical examination provided the BOD has attained, or maintains, representation on:
 - The board of directors of the WREB;
 - The WREB examination development committee; and
 - Any other committees of the WREB that the BOD deems appropriate;
 - Require the BOD to recognize as valid, for purposed of licensure, passing scores on the WREB practical examination taken in another jurisdiction after October 1, 2011;⁵² However, if more than 365 days have passed since the passing score was achieved, the applicant must demonstrate additional standards including demonstrating five consecutive years of full-time dental practice;⁵³
- Amends s. 466.006(5), F.S., to authorize the use of mannequins for the two required restorations and one required periodontal portion of the clinical examinations as approved by the BOD;
- Amends s. 466.007(4)(b) F.S., to:
 - Add the WREB clinical dental hygiene examination as an additional legislatively approved dental hygiene clinical examination provided the BOD has attained, or maintains, representation on:
 - The board of directors of the WREB;
 - The WREB dental hygiene examination review board; and
 - Any other dental hygiene committees of the WREB that the BOD deems appropriate;
 - Authorize the use of mannequins in the ADHLEX and the WREB dental hygiene clinical examinations as approved by the BOD;
- Amends s. 466.007(5)(a), F.S., to require that a passing score on the WREB dental hygiene examination that is administered out-of-state is considered the same as a passing score for the ADHLEX or the WREB dental hygiene examination administered in state.

⁵² Section 466.006(4)(b)1., F.S. This section may not be applied retroactively.

⁵³ Section 466.006(4)(b)2(e)(II), F.S. Full time practice is defined as a minimum of 1,200 hours per year for each year in the consecutive five-year period.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DOH might experience non-recurring costs for:

- Rulemaking;
- Increase in workload and costs associated with updating the Licensing and Enforcement Information Database System (LEIDS) to record examination results received from the WREB dental examination; and
- A new web service to support receiving examination results from the WREB on candidates applying for licensure in Florida.

Current resources and budget authority are adequate to absorb these costs.⁵⁴

⁵⁴ See note 17.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Lines 53-55 contain text from current law indicating that the DOH will “purchase” from “ADEX and WREB” clinical examinations. The DOH does not purchase examinations from any testing agency. The applicants for licensure sign up with either the CDCA or the CITA to take the ADLEX or the ADHLEX. The agency then sends the scores to the BOD via DOH.

The proposed language in s. 466.006(1)(b), F.S., contains outdated language requiring the applicant to submit two recent photographs to the DOH. Historically, photographs were required when the DOH developed and administered examinations and photographs were used for identification purposes. These are no longer collected at the time of application.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 466.006 and 466.007.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

By Senator Brodeur

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A bill to be entitled

An act relating to licensure examinations for dental practitioners; amending s. 466.006, F.S.; authorizing passage of a dental examination produced by the Western Regional Examining Board (WREB) to satisfy licensure examination requirements for applicants to practice dentistry in this state; requiring the Board of Dentistry to have representation on WREB's board of directors and certain committees for a specified purpose; revising provisions related to licensure examination requirements; conforming provisions to changes made by the act; making technical changes; amending s. 466.007, F.S.; authorizing passage of a dental hygiene examination produced by WREB to satisfy licensure examination requirements for applicants to practice as dental hygienists in this state; requiring the board to have representation on WREB's board of directors and certain committees; revising provisions related to licensure examination requirements; conforming provisions to changes made by the act; making technical changes; providing an effective date.

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

Section 1. Subsections (1) and (4), paragraph (a) of subsection (5), and paragraph (a) of subsection (6) of section 466.006, Florida Statutes, are amended to read:

466.006 Examination of dentists.—

(1)(a) It is the intent of the Legislature to reduce the

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costs associated with an independent, state-developed practical or clinical examination to measure an applicant's ability to practice the profession of dentistry and to use the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc., (ADEX) and the dental examination developed by the Western Regional Examining Board (WREB), in lieu of an independent, state-developed practical or clinical examination. The Legislature finds that the American Dental Licensing Examination and WREB's dental examination, in both their ~~its~~ structure and function, consistently meet ~~meets~~ generally accepted testing standards and have ~~has~~ been found, as they are ~~it is~~ currently organized and operated ~~operating~~, to adequately and reliably measure an applicant's ability to practice the profession of dentistry.

(b) Any person desiring to be licensed as a dentist shall apply to the department to take one of the licensure examinations identified in paragraph (a) and shall verify the information required on the application by oath. The application must ~~shall~~ include two recent photographs. The board shall ~~There shall be an application fee~~ set a nonrefundable application fee, which may by the board ~~to~~ exceed \$100 which shall be ~~nonrefundable~~. The board also ~~There shall set also be an~~ examination fee ~~set by the board~~, which may ~~shall~~ not exceed \$425 plus the actual per applicant cost to the department for the purchase of some or all of the examinations ~~examination~~ from ADEX and WREB, or their respective successor entities ~~the American Board of Dental Examiners or its successor entity~~, if any, provided the board finds the successor entities' ~~entity's~~ clinical examinations comply ~~examination complies~~ with the

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provisions of this section. The examination fee may be refunded
~~refundable~~ if the applicant is found ineligible to take an
~~examination the examinations.~~

(4) Notwithstanding any other provision ~~of law~~ in chapter
 456 pertaining to the clinical dental licensure examination or
 national examinations, to be licensed as a dentist in this
 state, an applicant must successfully complete both of the
 following:

(a) A written examination on the laws and rules of the
 state regulating the practice of dentistry.

(b) A practical or clinical examination, which must be the
 American Dental Licensing Examination produced by ADEX ~~the~~
~~American Board of Dental Examiners, Inc.,~~ or its successor
 entity, if any, or the dental examination produced by WREB or
its successor entity, if any, which that is administered in this
 state, provided that the board has attained, and continues to
 maintain thereafter, representation, as applicable, on the ADEX
~~board of directors of the American Board of Dental Examiners,~~
~~the WREB board of directors,~~ the ADEX examination development
~~committee, the WREB examination development committee of the~~
~~American Board of Dental Examiners,~~ and such other committees of
ADEX and WREB as the board identifies by rule as being
appropriate to ensure the American Board of Dental Examiners as
~~the board deems appropriate by rule to assure~~ that the standards
 established herein are maintained organizationally. A passing
 score on the American Dental Licensing Examination or WREB's
dental examination administered in this state is valid for 365
 days after the date the official examination results are
 published.

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1. As an alternative to such practical or clinical
 examination, an applicant may submit scores from ~~the an~~ American
 Dental Licensing Examination or WREB's dental examination that
~~was~~ previously administered in a jurisdiction other than this
 state and that was completed by the applicant after October 1,
 2011, and such examination results must ~~shall~~ be recognized as
 valid for the purpose of licensure in this state. A passing
 score on the American Dental Licensing Examination or WREB's
dental examination that was administered out of state is ~~shall~~
~~be~~ the same as the passing score for the American Dental
 Licensing Examination or WREB's dental examination that was
 administered in this state. Except as provided in subparagraph
2., the examination results are valid for 365 days after the
 date the official examination results are published. The
 applicant must have completed the examination after October 1,
 2011. This subparagraph may not be given retroactive
 application.

2. If more than 365 days have passed since the date of an
 applicant's passing scores from the American Dental Licensing
Examination or WREB's dental examination that was ~~scores from an~~
~~examination~~ previously administered in a jurisdiction other than
 this state under subparagraph 1. ~~is older than 365 days,~~ such
 scores are nevertheless valid for the purpose of licensure in
 this state, ~~but only~~ if the applicant demonstrates that all of
 the following additional standards have been met:

- a. The applicant completed the American Dental Licensing
 Examination or WREB's dental examination after October 1, 2011.
 This sub-subparagraph may not be given retroactive application;
- b. The applicant graduated from a dental school accredited

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by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting organization recognized by the United States Department of Education. Provided, however, if the applicant did not graduate from such a dental school, the applicant may submit proof of having successfully completed a full-time supplemental general dentistry program accredited by the American Dental Association Commission on Dental Accreditation of at least 2 consecutive academic years at such accredited sponsoring institution. Such program must provide didactic and clinical education at the level of a D.D.S. or D.M.D. program accredited by the American Dental Association Commission on Dental Accreditation. For purposes of this sub-subparagraph, a supplemental general dentistry program does not include an advanced education program in a dental specialty;

c. The applicant currently possesses a valid and active dental license in good standing, with no restriction, which has never been revoked, suspended, restricted, or otherwise disciplined, from another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico;

d. The applicant submits proof that he or she has never been reported to the National Practitioner Data Bank, the Healthcare Integrity and Protection Data Bank, or the American Association of Dental Boards Clearinghouse. This sub-subparagraph does not apply if the applicant successfully appealed to have his or her name removed from the data banks of these agencies;

e. (I) (A) The applicant submits proof of having been

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consecutively engaged in the full-time practice of dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico ~~for~~ in the 5 years immediately preceding the date of application for licensure in this state; or

(B) If the applicant has been licensed in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico for less than 5 years, the applicant submits proof of having been engaged in the full-time practice of dentistry since the date of his or her initial licensure.

(II) As used in this sub-sub-subparagraph and subsection (6) section, "full-time practice" is defined as a minimum of 1,200 hours per year for each and every year in the consecutive 5-year period or, when applicable, the period since initial licensure, and must include any combination of the following:

(A) Active clinical practice of dentistry providing direct patient care.

(B) Full-time practice as a faculty member employed by a dental or dental hygiene school approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(C) Full-time practice as a student at a postgraduate dental education program approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(III) The board shall develop rules to determine what type of proof of full-time practice is required and to recoup the cost to the board of verifying full-time practice under this section. Such proof must, at a minimum, be:

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- 175 (A) Admissible as evidence in an administrative proceeding;
 176 (B) Submitted in writing;
 177 (C) Submitted by the applicant under oath with penalties of
 178 perjury attached;
 179 (D) Further documented by an affidavit of someone unrelated
 180 to the applicant who is familiar with the applicant's practice
 181 and testifies with particularity that the applicant has been
 182 engaged in full-time practice; and
 183 (E) Specifically found by the board to be both credible and
 184 admissible.
 185 (IV) An affidavit of only the applicant is not acceptable
 186 proof of full-time practice unless it is further attested to by
 187 someone unrelated to the applicant who has personal knowledge of
 188 the applicant's practice. If the board deems it necessary to
 189 assess credibility or accuracy, the board may require the
 190 applicant or the applicant's witnesses to appear before the
 191 board and give oral testimony under oath;
 192 f. The applicant submits documentation that he or she has
 193 completed, or will complete before he or she is licensed in this
 194 state, continuing education equivalent to this state's
 195 requirements for the last full reporting biennium;
 196 g. The applicant proves that he or she has never been
 197 convicted of, or pled nolo contendere to, regardless of
 198 adjudication, any felony or misdemeanor related to the practice
 199 of a health care profession in any jurisdiction;
 200 h. The applicant has successfully passed a written
 201 examination on the laws and rules of this state regulating the
 202 practice of dentistry and the computer-based diagnostic skills
 203 examination; and

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- 204 i. The applicant submits documentation that he or she has
 205 successfully completed the applicable examination administered
 206 by the Joint Commission on National Dental Examinations or its
 207 successor organization.
 208 (5) (a) The practical examination required under subsection
 209 (4) ~~must shall be the American Dental Licensing Examination~~
 210 ~~developed by the American Board of Dental Examiners, Inc., or~~
 211 ~~its successor entity, if any, provided the board finds that the~~
 212 ~~successor entity's clinical examination complies with the~~
 213 ~~provisions of this section, and shall include, at a minimum:~~
 214 1. A comprehensive diagnostic skills examination covering
 215 the full scope of dentistry and an examination on applied
 216 clinical diagnosis and treatment planning in dentistry for
 217 dental candidates;
 218 2. Two restorations on a live patient or patients, or on a
 219 mannequin as approved by the board. The board by rule shall
 220 determine the class of such restorations;
 221 3. A demonstration of periodontal skills on a live patient,
 222 or on a mannequin as approved by the board;
 223 4. A demonstration of prosthetics and restorative skills in
 224 complete and partial dentures and crowns and bridges and the
 225 utilization of practical methods of evaluation, specifically
 226 including the evaluation by the candidate of completed
 227 laboratory products such as, but not limited to, crowns and
 228 inlays filled to prepared model teeth;
 229 5. A demonstration of restorative skills on a mannequin
 230 which requires the candidate to complete procedures performed in
 231 preparation for a cast restoration;
 232 6. A demonstration of endodontic skills; and

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7. A diagnostic skills examination demonstrating ability to diagnose conditions within the human oral cavity and its adjacent tissues and structures from photographs, slides, radiographs, or models pursuant to rules of the board. If an applicant fails to pass the diagnostic skills examination in three attempts, the applicant ~~is shall~~ not be eligible for reexamination unless she or he completes additional educational requirements established by the board.

The department shall require a mandatory standardization exercise for all examiners prior to each practical or clinical examination and shall retain for employment only those dentists who have substantially adhered to the standard of grading established at such exercise.

(6) (a) ~~It is the finding of~~ The Legislature finds that it is an important state interest to improve access to dental care for underserved residents of this state and to further the economic development goals of this state. Absent a threat to the health, safety, and welfare of the public, the relocation of individuals who are lawfully and currently practicing dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, as applicants to practice dentistry within the geographic boundaries of this state, ~~who are lawfully and currently practicing dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico,~~ based on their scores from the American Dental Licensing Examination or WREB's dental examination administered in a state other than this state, is substantially related to achieving those ~~the~~ important

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~~state interests interest of improving access to dental care for underserved citizens of this state and furthering the economic development goals of the state.~~ Therefore, in order to maintain valid active licensure in this state, all applicants for licensure who are relocating to this state based on scores from the American Dental Licensing Examination or WREB's dental examination administered in a state other than this state shall ~~must actually~~ engage in the full-time practice of dentistry, as defined in sub-sub-subparagraph (4) (b) 2.e. (II), inside the geographic boundaries of this state within 1 year after ~~of~~ receiving such licensure in this state. The Legislature further finds that, if such applicants do not ~~actually~~ engage in the full-time practice of dentistry within the geographic boundaries of this state within 1 year after ~~of~~ receiving such a license in this state, access to dental care for the public will not significantly increase, patients' continuity of care will not be attained, and the economic development goals of the state will not be significantly met.

Section 2. Paragraph (b) of subsection (4) and subsections (5) and (6) of section 466.007, Florida Statutes, are amended to read:

466.007 Examination of dental hygienists.—

(4) Effective July 1, 2012, to be licensed as a dental hygienist in this state, an applicant must successfully complete the following:

(b) A practical or clinical examination, which must ~~approved by the board. The examination shall~~ be the Dental Hygiene Examination produced by the American Board of Dental Examiners, Inc., (ADEX) or its successor entity, if any, or the

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291 dental hygiene examination produced by the Western Regional
 292 Examining Board (WREB) or its successor entity, if any, if the
 293 board finds that the successor entities' entity's clinical
 294 examination meets or exceeds the requirements provisions of this
 295 section. The board shall approve the ADEX Dental Hygiene
 296 Examination and WREB's dental hygiene examination if the board
 297 has attained and continues to maintain representation, as
 298 applicable, on the ADEX House of Representatives, the WREB board
 299 of directors, the ADEX dental hygiene examination development
 300 committee, the WREB dental hygiene examination review board, and
 301 such other ADEX and WREB dental hygiene committees as the board
 302 identifies by rule as being appropriate ~~deems appropriate~~
 303 ~~through rulemaking~~ to ensure that the standards established in
 304 this section are maintained organizationally. The ADEX Dental
 305 Hygiene Examination and WREB's dental hygiene examination, or
 306 the examination produced by their respective successor entities,
 307 ~~if any, its successor entity~~ is a comprehensive examination in
 308 which an applicant must demonstrate skills within the dental
 309 hygiene scope of practice on a live patient, or on a mannequin
 310 as approved by the board, and any other components that the
 311 board deems necessary for the applicant to successfully
 312 demonstrate competency for the purpose of licensure.

313 (5) Effective July 1, 2012, an applicant who has completed
 314 the ADEX Dental Hygiene Examination or WREB's dental hygiene
 315 examination in a jurisdiction other than this state and who has
 316 obtained a passing score may practice dental hygiene in this
 317 state if the applicant:

318 (a) Has successfully completed the National Board Dental
 319 Hygiene Examination at any time before the date of application;

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320 (b) Has been certified by the American Dental Association
 321 Joint Commission on National Dental Examinations at any time
 322 before the date of application, as specified by state law;
 323 (c) Has successfully completed a written examination on the
 324 laws and rules of this state regulating the practice of dental
 325 hygiene;
 326 (d) Has not been disciplined by a board, except for
 327 citation offenses or minor violations; and
 328 (e) Has not been convicted of or pled nolo contendere to,
 329 regardless of adjudication, any felony or misdemeanor related to
 330 the practice of a health care profession.

331 (6) (a) A passing score on the ADEX Dental Hygiene
 332 Examination or WREB's dental hygiene examination that is
 333 administered out of state is ~~must be~~ considered the same as a
 334 passing score for the ADEX Dental Hygiene Examination or WREB's
 335 dental hygiene examination administered in this state.

336 (b) If an applicant fails to pass the ADEX Dental Hygiene
 337 Examination or WREB's dental hygiene examination in three
 338 attempts, the applicant is not eligible to retake the
 339 examination unless the applicant completes additional education
 340 requirements as specified by the board.

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



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: March 16, 2021

I respectfully request that **Senate Bill 1366**, relating to Licensure Examinations for Dental Practitioners, be placed on the:

- ☐ committee agenda at your earliest possible convenience.
- ☒ next committee agenda.

A handwritten signature in black ink that reads "Jason Brodeur".

Senator Jason Brodeur
Florida Senate, District 9



2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Florida Department of Health

<u>BILL INFORMATION</u>	
BILL NUMBER:	<u>1366</u>
BILL TITLE:	<u>Licensure Examinations for Dental Practitioners</u>
BILL SPONSOR:	<u>Brodeur</u>
EFFECTIVE DATE:	<u>7/1/2021</u>

<u>COMMITTEES OF REFERENCE</u>
1) Health Policy
2) Judiciary
3) Rules
4) Click or tap here to enter text.
5) Click or tap here to enter text.

<u>CURRENT COMMITTEE</u>
Health Policy

<u>SIMILAR BILLS</u>	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.

<u>PREVIOUS LEGISLATION</u>	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.
YEAR:	Click or tap here to enter text.
LAST ACTION:	Click or tap here to enter text.

<u>IDENTICAL BILLS</u>	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.

Is this bill part of an agency package?
No

<u>BILL ANALYSIS INFORMATION</u>	
DATE OF ANALYSIS:	2/23/2021
LEAD AGENCY ANALYST:	Jessica Sapp
ADDITIONAL ANALYST(S):	Click or tap here to enter text.
LEGAL ANALYST:	Louise St. Laurent
FISCAL ANALYST:	Jonathan Sackett

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The bill authorizes the Board of Dentistry to accept passing examination scores for the dental and dental hygiene licensure examination developed and administered by the Western Regional Examining Board (WREB) for licensure as a dentist or dental hygienist in Florida.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Currently, section 466.006, Florida Statutes, requires a dental applicant to pass the American Dental Licensing Examination (ADLEX) developed by the American Board of Dental Examiners, Inc. (ADEX) and administered by the Commission on Dental Competency Assessments (CDCA). Section 466.007, F.S., requires a dental hygiene applicant to pass the American Dental Hygiene Licensing Examination (ADHLEX) developed by the American Board of Dental Examiners, Inc. (ADEX) and administered by the Commission on Dental Competency Assessments (CDCA).

Section 466.006(5)(a), Florida Statutes, requires the practical dental examination consist of the following parts:

- Comprehensive diagnostic skills examination covering the full scope of dentistry and an examination on applied clinical diagnosis and treatment planning in dentistry for dental candidates
- Two restorations on a live patient or patients. Note: Rule 64B5-2.013, F.A.C., that specified the class of restorations required was repealed by the Board of Dentistry in May 2012, after the examination was transitioned to ADEX
- Demonstration of periodontal skills on a live patient
- Demonstration of prosthetics and restorative skills in complete and partial dentures and crowns and bridges and the utilization of practical methods of evaluation, specifically including the evaluation by the candidate of completed laboratory products such as, but not limited to, crowns and inlays filled to prepared model teeth
- Demonstration of restorative skills on a mannequin which requires the candidate to complete procedures performed in preparation for a cast restoration
- Demonstration of endodontic skills
- Diagnostic skills examination demonstrating ability to diagnose conditions within the human oral cavity and its adjacent tissues and structures from photographs, slides, radiographs, or models.

The ADEX Dental examination series consists of computer simulations and clinical examinations performed on patients and manikins. There are five skill-specific clinical and simulated clinical examinations:

- Diagnostic Skills Examination Objective Structured Clinical Examination (OSCE) (computer-based)
- Endodontic (manikin)
- Prosthodontic (manikin)
- Restorative (patient-based) (anterior & posterior)
- Periodontal (patient-based) (optional, based on state requirements)

The ADEX dental examination costs \$2,250.00.

The ADEX Dental Hygiene Examination is based on specific performance criteria used to measure clinical competence. There are two skill-specific clinical and simulated clinical examinations:

- The Patient Treatment Clinical Examination (PTCE) evaluates candidates on their clinical and judgment skills. Clinical skills include detection and removal of calculus, accurate periodontal pocket depth measurements, tissue management, and final case presentation. Judgment skills include presenting an eligible patient, diagnostic-quality radiographs that meet all examination criteria, and an acceptable case selection of teeth that meets all calculus requirements

- The Computer Simulated Clinical Examination (CSCE) is designed to assess various levels of diagnosis and treatment planning knowledge, skills, and abilities. Clinically-based questions are utilized through computer-enhanced photographs, radiographs, optical images of study, working models, laboratory data, and other clinical digitized reproductions

The ADEX Dental Hygiene examination costs \$975.00.

In response to the COVID-19 pandemic, on May 28, 2020, the State Surgeon General issued Emergency Order 20-008 suspending the provisions of sections 466.006 and 466.007, Florida Statutes, that would prohibit the use of mannequins or simulated patients in lieu of live patients during the administration of the American Dental Licensing Examination and Dental Hygiene Examination.

The Florida Department of Health contracts with the CDCA to administer the ADEX and ADHEX examinations as well as develop and administer, through computer-based testing, the jurisprudence examinations required in section 466.006(4)(a), Florida Statutes, and section 466.007(4)(a), Florida Statutes, respectively. In Fiscal Year 2019-2020, 869 dentists and 562 hygienists applied to take the ADEX and ADHEX examinations.

Forty states currently accept WREB results for licensure purposes, with Hawaii only accepting the dental hygiene WREB examination.

The WREB Dental examination consists of the following required sections: Operative, Endodontics, and Comprehensive Treatment Planning (CTP). The Periodontal section remains part of the examination and is included in the full examination fee, but the candidate may opt out during registration if the state to which they are applying for initial licensure does not require this procedure. An optional Prosthodontic section will also be offered, if the state to which a candidate is applying for initial licensure requires it. The Prosthodontics and Periodontal procedures are not required sections of the WREB examination, but there is no additional fee to take either section. The Prosthodontics section will be administered on Orientation Day at most examination sites. The Prosthodontics section was developed in 2018 and was not a part of the WREB dental examination prior to that. This has been a requirement for licensure in Florida beginning October 2011.

The CTP examination is a computer simulation examination. A case history (including radiographs, photographs, charting, medical history) of three patients is provided. Using this information, applicants have three hours to develop a treatment plan and answer questions related to each case.

According to the 2021 WREB examination schedule, the dental examination is administered 29 times during the months of February through November in 12 states: Arizona, California, Colorado, Massachusetts, Missouri, Nebraska, Nevada, New York, Oregon, Oklahoma, Texas, and Utah. The dental hygiene examination is administered 76 times during the months of May through December in 14 states: Alaska, Arizona, California, Idaho, Missouri, Montana, Nevada, New Mexico, New York, Oregon, Oklahoma, Texas, Utah, and Washington. The WREB examination is not currently administered in Florida.

The WREB full dental examination fee ranges from \$2,560.00 to \$3,320.00 based on the examination site. The dental hygiene examination fee ranges from \$460.00 to \$1,175.00 based on the examination site. These fees include a complimentary onsite retake (absent of a critical error) in the examination registration fee.

Florida requires the passage of the National Boards Parts 1 and 2 prior to being eligible to sit for the licensure examination. WREB does not require National Boards prior to taking the WREB examination.

WREB does not administer state-specific jurisprudence examinations.

Other states also utilize regional dental and dental hygiene licensure examinations developed and administered by the Council of Interstate Testing Agencies, Inc. (CITA) and the Southern Regional Testing Agency (SRTA).

2. EFFECT OF THE BILL:

The bill amends section 466.006(1)(a), Florida Statutes, to add passage of the dental examination developed and administered by the WREB for applicants applying for licensure in Florida. This will allow potential applicants to take one of the approved licensure examinations, either the ADLEX or the WREB. The language specifies that the Board of Dentistry shall set the examination fee not to exceed \$425 plus the actual cost to the Department for the purchase of some or all of the examinations. The Board of Dentistry does not set the examination fees for national examinations. The examination fee listed of \$425 plus the actual cost for the Department to purchase some or all the examinations is obsolete language.

The proposed language in section 466.006(1)(b), Florida Statutes, contains outdated language requiring the applicant to submit two recent photographs to the Department. Historically, photographs were required when the Department developed and administered examinations and photographs were used for identification purposes. These are no longer collected at time of application.

The bill amends section 466.006(4)(b), Florida Statutes, and section 466.007(4)(b), Florida Statutes, which requires the Board of Dentistry maintain representation on any committees of ADEX and WREB that the Board identifies by rule as being appropriate to ensure that the examination standards are maintained.

WREB does not require membership as a requisite for utilization of their dental and dental hygiene examinations. However, for Florida to have input into the test development and administration process, Florida would be required to join WREB. There is no membership cost to joining WREB.

The bill amends section 466.006(5), Florida Statutes, allowing the use of a mannequin for the restorative and periodontal skills portions on the clinical examination.

The bill provides that the WREB dental examination previously administered in a jurisdiction other than Florida and was completed by the applicant after October 1, 2011, is acceptable for licensure purposes. If more than 365 days have passed since the date of the applicant's passing score from WREB, the applicant will be required to demonstrate five years of having been consecutively engaged in the full-time practice of dentistry in another state or territory. Full time practice is defined as a minimum of 1,200 hours per year for each year in the consecutive 5-year period.

The bill amends section 466.007(4)(b), Florida Statutes, to add passage of the dental hygiene examination developed and administered by the WREB for applicants applying for licensure in Florida. This will allow potential applicants to take one of the approved licensure examinations, either the ADHEX or the WREB dental hygiene examination. This section is also amended to allow for the use of a mannequin on the clinical examination.

The bill amends section 466.007(6)(a), Florida Statutes, to require that a passing score on the ADHEX or WREB dental hygiene examination that is administered out of this state is considered the same as a passing score for the ADHEX or WREB dental hygiene examination administered in this state.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y ☒ N ☐

If yes, explain:	The Board of Dentistry may identify rules to ensure examination standards.
Is the change consistent with the agency's core mission?	Y ☒ N ☐

Rule(s) impacted (provide references to F.A.C., etc.):	64B5-2.014, F.A.C. 64B5-2.0144, F.A.C. 64B5-2.013, F.A.C. 64B5-2.0135, F.A.C. 64B5-2.0146, F.A.C. 64B5-2.0150, F.A.C. 64B5-2.0151, F.A.C. 64B5-2.0152, F.A.C.

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL?Y ☐ N ☒

If yes, provide a description:	N/A
Date Due:	N/A
Bill Section Number(s):	N/A

6. ARE THERE ANY NEW GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSIONS, ETC. REQUIRED BY THIS BILL?Y ☐ N ☒

Board:	N/A
Board Purpose:	N/A
Who Appoints:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS**1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT?**Y ☐ N ☒

Revenues:	N/A
Expenditures:	N/A
Does the legislation increase local taxes or fees? If yes, explain.	N/A

If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT?Y ☒ N ☐

Revenues:	None
Expenditures:	DOH/MQA will incur non-recurring cost for rulemaking, which current budget authority is adequate to absorb. DOH/MQA will experience a non-recurring increase in workload and costs associated with updating the Licensing and Enforcement Information Database System (LEIDS) to record examination results received from the Western Regional Examining Board (WREB) Dental Examination. Additionally, a new web service will be required to support receiving examination results from the WREB on candidates applying for licensure in Florida. Current resources and budget authority are adequate to absorb.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR?Y ☐ N ☒

Revenues:	Unknown
Expenditures:	Unknown
Other:	N/A

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES?Y ☐ N ☒

If yes, explain impact.	N/A
Bill Section Number:	N/A

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y ☒ N ☐

If yes, describe the anticipated impact to the agency including any fiscal impact.	DOH/MQA will experience a non-recurring increase in workload and costs associated with updating the Licensing and Enforcement Information Database System (LEIDS) to record examination results received from the Western Regional Examining Board (WREB) Dental Examination. Additionally, a new web service will be required to support receiving examination results from the WREB on candidates applying for licensure in Florida.

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y ☐ N ☒

If yes, describe the anticipated impact including any fiscal impact.	N/A

ADDITIONAL COMMENTS

None.

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	No legal issues, concerns or comments identified at this time.

**BOARD OF DENTISTRY
GENERAL BUSINESS MEETING MINUTES
TELEPHONE CONFERENCE CALL
February 19, 2021
7:30 A.M. ET
Call In Number: (888) 585-9008
Conference Code: 599-196-982(#)**

Attendees requesting continuing education credit for attending the Board of Dentistry's teleconference call must email MQA.Dentistry@flhealth.gov with your full name, license number and the beginning and end time of your attendance.

I. CALL TO ORDER/ROLL CALL

MEMBERS PRESENT

Nick White, DMD, Chair
Claudio Miro, DDS
T.J. Tejera, DMD, MD
Bradley Cherry, DDS, MD
Christine Bojaxhi, DMD
Thomas McCawley, DDS
Karyn Hill, CRDH, BS
Jose Mellado, DMD
Angela Johnson, RDH
Fabio Andrade, Consumer Member

MEMBER ABSENT

Sara Bernard, BS, JD Consumer Member

STAFF PRESENT

Jessica Sapp, Executive Director
Paulette Schofill, Program Administrator

BOARD COUNSEL

Lawrence Harris
Senior Assistant Attorney General

PROSECUTION SERVICES UNIT

Rose Garrison, Assistant General Counsel
Ashlin Morgan, Qualified Representative
Andrew Pietrylo, Chief Legal Counsel

COURT REPORTER

For the Record
(850) 222-5491

Board chair, Dr. Nick White, opened the meeting by recognizing outgoing board members and thanking them for their service on the Board: Ms. Catherine Cabanzon, Dr. Naved Fatmi, Dr. Matthew Freedman, and Dr. Nick Kavouklis. He also recognized outgoing board counsel, David Flynn, and thanked him for providing counsel to the Board for the last ten years. He also introduced the new board members and new board counsel.

II. DISCIPLINARY PROCEEDINGS

Dr. White asked for motion regarding the Motion to Serve as a Qualified Representative for Ms. Ashlin Morgan.

Motion: by Dr. Tejera to approve
Second: Dr. Miro
Vote: Unanimous

A. Informal Hearings

i. David W. Goldston, DDS, Case No. 2020-01582

(PCP – Miro, Britten, Morgan)

Dr. Miro was recused due to participation on the probable cause panel.

Dr. Goldston was not present. He was not represented by Counsel.

Ms. Morgan summarized the case for the Board. Respondent was charged with the following violation: **Count I:** Section 466.028(1)(aa), Florida Statutes, subjects a licensee to discipline for the violation of a lawful order of the Board previously entered in a disciplinary hearing.

Motion: by Dr. Tejera to find that the Respondent was properly served and has requested an informal hearing.

Second: by Ms. Hill

Vote: Unanimous

Motion: by Dr. Tejera to adopt the findings of fact as set forth in the Administrative Complaint.

Second: by Ms. Hill

Vote: Unanimous

Motion: by Dr. Tejera to adopt the materials and any addendum materials into evidence.

Second: by Ms. Hill

Vote: Unanimous

Motion: by Dr. Tejera to adopt the conclusions of law as set forth in the Administrative Complaint and find that this constitutes a violation of the practice act.

Second: by Ms. Hill

Vote: Unanimous

The Department recommends revocation in this case due to aggravators such as prior discipline and lack of intent towards remediation.

After discussion, the following action was taken:

Motion: by Dr. Tejera for revocation of license

Second: by Mr. Andrade

Vote: Unanimous

Motion: by Tejera to impose costs of \$461.36

Second: Mr. Andrade

Vote: Unanimous

ii. Michael D. Bettner, DDS, Case No. 2019-46067

(PCP – Miro, Perdomo, Morgan)

Dr. Miro was recused due to participation on the probable cause panel.

Dr. Bettner was present and represented by Dwight O. Slater, Esq.

Ms. Morgan summarized the case for the Board. Respondent was charged with the

following violation: **Count I:** 466.028(1)(b), Florida Statutes, by having a license to practice dentistry or dental hygiene revoked, suspended, or otherwise acted against by the licensing authority of another state, territory, or country, shall constitute grounds for disciplinary action by the Board of Dentistry.

Motion: by Dr. Tejera to find that the Respondent was properly served and has requested an informal hearing.

Second: by Ms. Hill

Vote: Unanimous

Motion: by Dr. Tejera to adopt the findings of fact as set forth in the Administrative Complaint.

Second: by Ms. Hill

Vote: Unanimous

Motion: by Dr. Tejera to adopt the materials and any addendum materials into evidence.

Second: by Ms. Hill

Vote: Unanimous

Motion: by Dr. Tejera to adopt the conclusions of law as set forth in the Administrative Complaint and find that this constitutes a violation of the practice act.

Second: by Dr. McCawley

Vote: Unanimous

After discussion, the following action was taken:

Motion: by Dr. Tejera to impose the following penalties:

- Successful completion of a three-semester hour course in Ethics to be completed at or through (online) any accredited college or university within twelve (12) months of the filing of the Final Order
- Successful completion of the Laws and Rules exam within six (6) months of the filing of the Final Order
- Fine of \$1,000.00 to be paid within six (6) months of the filing of the Final order
- Costs of \$140.28 to be paid within six (6) months of the filing of the Final Order

Second: by Dr. Cherry

Vote: Unanimous

B. Settlement Agreements

i. Brigitte Martin, DDS, Case No. 2019-39257

(PCP – Miro, Perdomo, Morgan)

Dr. Miro was recused due to participation on the probable cause panel.

Dr. Martin was present and was represented by David Zika, Esq.

Dr. Martin's counsel was not present on the call. Mr. Harris gave her the option of proceeding with her case or giving her a chance to contact her attorney. Dr. Martin indicated she was fine with proceeding without him.

Ms. Garrison presented the case to the Board. Respondent was charged with the following violation: **Count I:** Section 466.028 (1)(x), Florida Statutes by fabricating and seating a crown with a large overhang on tooth 15 and for failing to diagnose the overhang of the crown on tooth 15.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Letter of Concern
- Fine of \$5,000 to be paid within twelve (12) months of the filing of the Final Order
- Costs of \$2,971.47 to be paid within twelve (12) months of the filing of the Final Order
- Successful completion of a 3-6 hour course in Crown and Bridge to be completed in person at or through a Florida accredited college of dentistry within twelve (12) months of the filing of the Final Order
- Respondent shall refund to the patient the amount of "out of pocket" fees and costs in the amount of \$397.50 within twelve (12) months of the entry of the Final Order
- Successful completion of the Laws and Rules exam within twelve (12) months of the filing of the Final Order

After discussion, the following action was taken:

Motion: by Dr. Tejera to accept the settlement agreement

Second: by Dr. McCawley

Vote: Unanimous

- ii. Charlotte Y. Gerry, DMD, Case No. 2015-23828
(PCP – Thomas, Morgan, Fatmi)

Dr. Gerry was present and was represented by George Brew, Esq.

Mr. Dunn presented the case to the Board. Respondent was charged with the following violation(s): **Count I:** Section 466.028(1)(m), Florida Statutes, for failing to keep written dental records and medical history records justifying the course of treatment by failing to keep a written record of patient's medical history by failing to keep a written record of dental charting or identification of existing decay, missing, and/or filled teeth, and other oral conditions throughout the mouth: by failing to keep a written record in justification of the performance of tooth stripping on or about November 4, 2013, November 18, 2013, February 4, 2014, and/or April 10, 2014; by failing to keep a written record on the delivery, fit, and/or seating of the permanent crown on tooth 19; by failing to keep a written record of the following appointment dates: December 1, 2013, January 10, 2014, April 18, 2014, June 10, 2014, July 18, 2014, and/or September 9, 2014. **Count II:** Section 466.028(1)(x), Florida Statutes for failing to meet the minimum standards of performance in Diagnosis and Treatment by failing to develop an appropriate option to treat patient's dental condition when she diagnosed patient as a candidate for SMS treatment; by failing to obtain sufficient information on patient's dental condition before implementing a treatment plan; by failing to recognize when to cease performing the irreversible treatment of tooth stripping. **Count III:** Section 466.028(1)(z), Florida Statutes, by delegating professional responsibilities, including the adjustment and/or treatment of patient's orthodontic braces, to persons who were not qualified by training, experience, or licensure to perform them.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance

- Reprimand
- Respondent acknowledges that the Florida Board of Dentistry disciplinary terms as outlined in Final Order DOH-20-1324-FOF-MQA for cases 2014-167075, 2015-10268, and 2016-22431, and agrees to implementing those terms concurrently as a resolution of cases 2015-10804 and 2015-23828. Respondent agrees that any violation of Final order DOH-20-1324-FOF-MQA will also constitute a violation of the Final Order adopting and incorporating this Agreement.
- Successful completion of the Laws and Rules exam within twelve (12) months of the filing of the Final Order

After discussion, the following action was taken:

Motion: by Dr. Cherry to reject the settlement agreement.

Second: by Mr. Andrade

Vote: Unanimous

Dr. Tejera proposed a counter settlement agreement that includes all terms of the current settlement agreement with the addition of a permanent practice restriction on placement of implants and orthodontics.

Second: Dr. Miro

Vote: Carried 7/3. Dr. Cherry, Ms. Hill, and Dr. McCawley opposed.

iii. Charlotte Y. Gerry, DMD, Case No. 2015-10804
(PCP – Thomas, Morgan, Fatmi)

Dr. Gerry was present and was represented by George Brew, Esq.

Mr. Dunn presented the case to the Board. Respondent was charged with the following violation(s): **Count I:** Section 466.028(1)(m), Florida Statutes, for failing to keep written dental records and medical history records justifying the course of treatment by failing to keep a written record of patient's medical history by failing to keep an accurate written record of the type and number of implants placed on or about March 31, 2014, and/or on or about April 14, 2014; by failing to keep an accurate written record of the treatment provided on or about April 14, 2014, specifically that radiographs were taken when they were not. **Count II:** Section 466.028(1)(x), Florida Statutes for failing to meet the minimum standards of performance in diagnosis and treatment by failing to develop an appropriate option to treat patient's dental condition by failing to develop an appropriate option for patient's dental condition when offered to place standard-sized implants; by failing to obtain sufficient information on patient's medical history before placing implants; by failing to take a post-operative radiograph following implant surgery; by failing to perform an adequate assessment of patient's post-operative complication. **Count III:** Section 466.028(1)(mm), Florida Statutes, by failing to adhere to the notification requirements when she terminated or relocated her Lake City dental practice.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Reprimand
- Respondent acknowledges that the Florida Board of Dentistry disciplinary terms as outlined in Final Order DOH-20-1324-FOF-MQA for cases 2014-167075, 2015-10268, and 2016-22431, and agrees to implementing those terms concurrently as a

resolution of cases 2015-10804 and 2015-23828. Respondent agrees that any violation of Final order DOH-20-1324-FOF-MQA will also constitute a violation of the Final Order adopting and incorporating this Agreement.

- Successful completion of the Laws and Rules exam within twelve (12) months of the filing of the Final Order

After discussion, the following action was taken:

Motion: by Dr. Cherry to reject the settlement agreement.

Second: by Mr. Andrade

Vote: Unanimous

Dr. Tejera proposed a counter settlement agreement that includes all terms of the current settlement agreement with the addition of a permanent practice restriction on placement of implants and orthodontics.

Second: Dr. Miro

Vote: Carried 7/3. Dr. Cherry, Ms. Hill, and Dr. McCawley opposed.

The Respondent has fourteen (14) days to consider the offer.

iv. Fady A. Zaki, DDS, Case No. 2019-30154
(PCP – Miro, Perdomo, Morgan)

Dr. Miro was recused due to participation on the probable cause panel.

Dr. Zaki was present and was represented by Nichole Koford, Esq.

Ms. Garrison presented the case to the Board. Respondent was charged with the following violation(s): **Count I:** Section 466.028(1)(x), Florida Statutes by failing to meet the minimum standards of performance in diagnosis and treatment for failing to diagnose that the crown on tooth 13 was overcontoured and/or had one or more open margin, failing to correct or refer for correcting the crown on tooth 13, failing to diagnose that the crown on tooth 15 was overcontoured and/or has one or more open margin, for failing to correct or refer for correcting the crown on tooth 15. **Count II:** Section 466.028(1)(m), Florida Statutes for failing to keep written dental records and medical history records justifying the course of treatment by failing to document the open margins and/or overcontouring of the crown at tooth 13, by failing to document the open margins and/or overcontouring of the crown at tooth 15.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Letter of Concern
- Fine of \$7,000 to be paid within twelve (12) months of the filing of the Final Order
- Costs of \$2,418.58 to be paid within twelve (12) months of the filing of the Final Order
- Successful completion of a 3-6 hour course in Crown and Bridge, a 3-6 hour course in Diagnosis and Treatment, and a 3-6 hour course in Endodontics to be completed in person at or through a Florida accredited college of dentistry within twelve (12) months of the filing of the Final Order
- Successful completion of the Laws and Rules exam within twelve (12) months of the

filing of the Final Order

After discussion, the following action was taken:

Motion: by Ms. Hill to accept the settlement agreement

Second: by Mr. Andrade

Vote: Unanimous

- v. Denise M. Shuman, DH, Case No. 2017-08706
(PCP – Miro, Morgan, Cabanzon)

Dr. Miro was recused due to participation on the probable cause panel.

Ms. Shuman was present and was represented by Vanessa Albaum, Esq.

Ms. Garrison presented the case to the Board. Respondent was charged with the following violation: **Count I:** Section 466.028(1)(mm), Florida Statutes by violating Section 456.072(1)(x) for failure to report that she entered a plea of nolo contendere to a crime to the Board of Dentistry in writing within 30 days of entering the plea on or about February 12, 2018.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Reprimand
- The Board shall place the Respondent's license on probation for a period of three (3) years beginning on the date of the filing of the Final Order. During the probation, Respondent shall report all criminal arrest in writing to the Board within thirty (30) days of being criminally arrested. This reporting requirement shall be in addition to Respondent's statutory duty to report all criminal pleas or convictions
- Fine of \$3,000.00 to be paid within twenty-four (24) months of the filing of the Final Order
- Costs of \$2,133.11 to be paid within twenty-four (24) months of the filing of the Final Order
- Successful completion of the Laws and Rules exam within twelve (12) months of the filing of the Final Order

After discussion, the following action was taken:

Motion: by Ms. Hill to accept the settlement agreement.

Second: by Dr. Tejera

Vote: Unanimous

C. Determination of Waiver

- i. Felipe R. Martin, DDS, Case No. 2020-09163
(PCP – Miro, Britten, Morgan)

Dr. Miro was recused due to participation on the probable cause panel.

Dr. Martin was not present. He was not represented by counsel.

Ms. Summers presented the case to the Board. Respondent is charged with the following

violation: Section 456.072(1)(q), Florida Statutes by failing to submit to a mental and physical examination pursuant to section 466.028(1)(s), Florida Statutes.

Motion: by Dr. White to find the Administrative Complaint was properly served on Respondent and that Respondent failed to timely respond to the Administrative Complaint and has waived the right to request a hearing.

Second: by Ms. Hill

Vote: Unanimous

Motion: by Dr. Tejera to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Second: by Mr. Andrade

Vote: Unanimous

Motion: by Dr. Tejera to find the Respondent in violation of the Florida Statutes as charged in the Administrative Complaint.

Second: by Mr. Andrade

Vote: Unanimous

After discussion, the following action was taken:

Motion: by Dr. Tejera to impose the following penalties:

- Suspension of license until completion of a PRN evaluation and appearance before the board to demonstrate the ability to practice with reasonable skill and safety.
- Reserve jurisdiction to impose other conditions

Second: by Dr. Mellado

Vote: Unanimous

Motion: by Dr. White to accept the Motion for costs of \$579.65

Second: Dr. Tejera

Vote: Unanimous

Motion: by Dr. Tejera that the costs of \$579.55 be paid as a condition of reinstatement of the license

Second: Dr. White

Vote: Unanimous

- ii. Walter R. Van Ness, DMD, Case No. 2019-30415
(PCP – Miro, Morgan, Perdomo)

Dr. Miro was recused due to participation on the probable cause panel.

Dr. Van Ness was present and was represented by Ed Bayo, Esq.

Ms. Garrison presented the case to the Board. Respondent is charged with the following violation(s): **Count I:** Section 466.028(1)(x), Florida Statutes for failing to meet the minimum standards of performance in diagnosis and treatment by failing to perform any comprehensive periodontal examination while treating patient between 2014 and patient's last visit in 2018;

and/or by failing to diagnose patient's chronic periodontal disease at any time material to this Complaint. **Count II:** Section 466.028(1)(m), Florida Statutes, for failing to keep written dental records and medical history records justifying the course of treatment by failing document the results of a comprehensive periodontal examination; and/or failing to document diagnosing patient's chronic periodontal disease.

Motion: by Dr. White to find the Administrative Complaint was properly served on Respondent and that Respondent failed to timely respond to the Administrative Complaint and has waived the right to request a hearing.

Second: by Dr. Tejera

Vote: Unanimous

Motion: by Dr. Tejera to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board

Second: by Dr. White

Vote: Unanimous

Motion: by Dr. Tejera to find that the findings of fact support a finding of a violation of 466.028(1)(x), Florida Statutes, as charged in the Administrative Complaint.

Second: by Ms. Hill

Vote: Unanimous

After discussion, the following action was taken:

Motion: by Dr. White to impose the following penalties:

- Fine of \$7500 to be paid within six (6) months of the filing of the Final Order
- Successful completion of a Level II course in Periodontics and Level II course in Diagnosis and Treatment Planning to be completed in person at or through a Florida accredited college of dentistry within twelve (12) months of the filing of the Final Order
- Costs of \$1,505.11 to be paid within six (6) months

Second: by Mr. Andrade

Vote: Unanimous

Motion: by Dr. Dr. White to accept the Motion for Costs of \$1505.11

Second: Mr. Andrade

Vote: Unanimous

D. Voluntary Relinquishment

- i. Regina Cespedes, DR, Case No. 2019-03031
(PCP – Miro, Morgan, Perdomo)

Ms. Cespedes was not present. She was not represented by counsel. She violated Section 466.028(1)(y), Florida Statutes.

After discussion, the following action was taken:

Motion: by Dr. Miro to accept the Voluntary Relinquishment
Second: by Mr. Andrade
Vote: Unanimous

- ii. Blanca N. Bermudez, DR, Case No. 2019-04344
(PCP – Waived)

Ms. Bermudez was not present. She was not represented by counsel. Ms. Bermudez allegedly violated Section 456.072(1)(f), Florida Statutes.
After discussion, the following action was taken:

Motion: by Dr. Miro to accept the Voluntary Relinquishment
Second: by Mr. Andrade
Vote: Unanimous

- iii. Debbie Yaskin, DDS, Case No. 2016-30431
(PCP – Miro, Perdomo, Morgan)

Dr. Yaskin was present. She was not represented by counsel. Dr. Yaskin violated Section 466.028(1)(x), Florida Statutes.

After discussion, the following action was taken:

Motion: by Dr. Miro to accept the Voluntary Relinquishment
Second: by Mr. Andrade
Vote: Unanimous

E. Motion to Assess Costs

- i. Charlotte Y. Gerry, DMD, Case Nos. 2013-11395, 2014-16705, 2015-10268, 2016-22431, 2017-00132
- ii.

Dr. Gerry was present and was represented by George Brew, Esq.

On March 27, 2020, the Department filed a Motion to Assess Costs in the amount of \$79,944.58. The Motion was tabled when the Recommended Order was heard, and the parties have entered into a Settlement Agreement where the Respondent agrees to reimbursement the Department's costs in the amount of \$60,000, payable within one (1) year.

After discussion, the following action was taken:

Motion: by Dr. Tejera to accept the Motion for Costs of \$60,000 to be paid within 1 year.
Second: by Dr. White
Vote: Unanimous

III. PROSECUTION REPORT

A. Rose Garrison, Assistant General Counsel

Ms. Garrison presented the Board with the current status of Board cases.

Motion: by Nick White to continue prosecuting year and older cases

Second: Dr. Tejera

Vote: Unanimous

IV. PETITION TO TERMINATE STAYED SUSPENSION

i. Wade Harrouff, DDS, Case Nos. 2014-04348, 2014-15343

Dr. Harrouff was present and was represented by Ed Bayo, Esq.

On January 13, 2021, Dr. Harrouff submitted a Petition to Terminate Stayed Suspension for Case Nos. 2014-04348 and 2014-15343. The Final Order filed on March 2, 2020 suspended Dr. Harrouff's license to practice dentistry, with said suspension stayed for 3 years to allow him to complete a two (2) year continuum course in general dentistry; a four (4) hour course in risk management; and a three (3) hour course in Ethics. As a result of the current pandemic and closing of various businesses and professional practices, Dr. Harrouff and Nova College of Dentistry were able to complete the full continuum course (74 hours) in an expedited fashion. Dr. Harrouff is requesting the Board terminate the stayed suspension.

A compliance report was received by Board staff on February 18, 2021, indicating that Dr. Harrouff has completed all the requirements of his Final Order.

After discussion, the following action was taken:

Motion: by Dr. Tejera to lift the stayed suspension.

Second: by Dr. Miro

Vote: Unanimous

V. REVIEW OF APPLICATIONS

A. Application for Dental License

i. Tyler Woodling

Dr. Woodling was present. He was not represented by counsel. His appearance was requested due to her previous health history.

After discussion, the following action was taken:

Motion: by Dr. Tejera to approve Dr. Woodling's application for licensure with the condition that he complete a PRN evaluation to determine he is safe to practice.

Second: by Mr. Andrade

Vote: Unanimous

ii. Louisa Correa

Dr. Correa was present and was represented by Ed Bayo, Esq. Her appearance was required due to previous criminal and disciplinary history in other states.

After discussion, the following action was taken:

Motion: by Dr. McCawley to approve her application for licensure

Second: by Mr. Andrade

Vote: 5/5. Dr. Cherry, Dr. Mellado, Dr. Miro, Dr. White and Ms. Johnson opposed.

After further discussion, the following action was taken:

Motion: by Dr. Tejera to approve her application for licensure

Second: Ms. Hill

Vote: 6/4. Motion carried. Dr. Cherry, Dr. Mellado, Dr. Miro, and Ms. Johnson opposed.

iii. Antoine Chiha

Dr. Chiha was present and was represented by Ed Bayo, Esq. His appearance was required due to previous disciplinary history in another state.

After discussion, the following action was taken:

Motion: by Dr. Mellado to accept the application for licensure.

Second: by Dr. McCawley

Vote: Unanimous

VI. PETITION TO INITIATE RULEMAKING

A. Rules 64B5-16.001, 64B5-16.002, 64B5-16.006, F.A.C.

On January 22, 2021, the Florida Dental Hygiene Association submitted a letter formally requesting reconsideration and adoption of the proposed rule granting Florida licensed dentists the freedom to apply their clinical judgment to delegate the use of lasers to dental hygienists in their practices.

Mr. Harris stated that the Board should grant the petition by scheduling a workshop to decide whether to proceed with rulemaking.

Dr. Kusek, President of the Academy of Laser Dentistry spoke in support of the workshop.

Ms. Angie Wallace of the Florida Dental Hygiene Association spoke in support of the workshop.

After discussion, the following action was taken:

Motion: by Dr. Tejera to schedule a future rule workshop

Second: by Dr. McCawley

Vote: Unanimous

VII. REPORTS

A. Board Counsel

i. Rules Report

ii. Rule 64B5-2.0135, F.A.C.

Motion: by Dr. Tejera to reformat the rule language regarding the ADEX 18-month requirement

Second: Dr. White

Vote: Unanimous

Motion: by Dr. Tejera to find no adverse or economic impacts.

Second: by Dr. White

Vote: Unanimous

Motion: by Dr. White to find that a Statement of Estimated Regulatory Cost was not necessary, and the rule will not need legislative ratification.

Second: by Dr. Tejera

Vote: Unanimous

Motion: by Dr. White to find that no part of this rule or a violation of this rule should be designated as a minor violation.

Second: by Dr. Tejera

Vote: Unanimous

Motion: by Dr. White to find that this rule shall not include a sunset provision.

Second: by Dr. Tejera

Vote: Unanimous

iii. Rule 64B5-2.017, F.A.C.

Motion: by Dr. Tejera to approve Mr. Harris' draft response

Second: Dr. White

Vote: Unanimous

iv. Rule 64B5-12.0185, F.A.C.

Motion: by Dr. White to approve Mr. Harris' draft response

Second: Mr. Andrade

Vote: Unanimous

Motion: by Dr. Tejera to find no adverse or economic impacts.

Second: by Dr. White

Vote: Unanimous

Motion: by Dr. White to find that a Statement of Estimated Regulatory Cost was not necessary, and the rule will not need legislative ratification.

Second: by Dr. Tejera

Vote: Unanimous

Motion: by Dr. White to find that no part of this rule or a violation of this rule should be designated as a minor violation.

Florida Board of Dentistry

Meeting Minutes

February 19, 2021

Second: by Dr. Tejera
Vote: Unanimous

Motion: by Dr. White to find that this rule shall not include a sunset provision.
Second: by Dr. Tejera
Vote: Unanimous

v. Rule 64B5-25.007, F.A.C.

Motion: by Dr. Tejera to approve Mr. Harris' draft response and proposed language
Second: Dr. White
Vote: Unanimous

Motion: by Dr. White that there are no adverse or economic impacts
Second: Dr. Tejera
Vote: Unanimous

Motion: by Dr. White to find that a Statement of Estimated Regulatory Cost was not necessary,
and the rule will not need legislative ratification.
Second: by Dr. Tejera
Vote: Unanimous

Motion: by Dr. White to include a Notice of Non-Compliance for a first offense
Second: Dr. Tejera
Vote: Unanimous

Motion: by Dr. White to amend 64B5-13.0045 F.A.C. to add a citation for a violation of Rule
25.007, F.A.C.
Second: by Dr. Tejera
Vote: Unanimous

Motion: by Dr. White to find that this rule shall not include a sunset provision.
Second: by Dr. Tejera
Vote: Unanimous

B. Executive Director

i. Legislation Update

Ms. Sapp provided a summary of the following bills:

SB 604 – An act relating to dental therapy, creating the practice of dental therapy in Florida.

Motion: by Dr. McCawley to oppose SB604
Second: Dr. White
Vote: Unanimous

HB497– An act relating to dentistry and dental hygiene examinations.

Motion: by Dr. White to oppose HB497
Second: Dr. Cherry
Vote: Unanimous

ii. Financial Reports

Ms. Sapp provided the financial reports to the Board for informational purposes.

C. Chair

D. Board Members

i. Ms. Cabanzon

1. CDCA Steering Committee Update

E. Inspection Report

i. Ron Dilworth

Mr. Dilworth provided the Board with an overview of the dental sedation program. The program completed 405 inspections in 2020. So far this year the program has completed 54 inspections.

The Board thanked Mr. Dilworth and the inspectors for their continued diligent work.

VIII. NEW BUSINESS

A. Vice Chair Election

Motion: by Ms. Hill to nominate Fabio Andrade
Second: by Dr. White
Vote: Unanimous

B. Delegation of Authority

Motion: by Dr. Tejera to approve the Delegation of Authority
Second: by Dr. White
Vote: Unanimous

C. 2022 Meeting Dates

After discussion, the following action was taken:

Motion: by Dr. Tejera to approve the following dates:

February 18, 2022

May 20, 2022

August 12, 2022

November 18, 2022

Second: by Mr. Andrade
Vote: Unanimous

D. Licensure Ratification Lists

Florida Board of Dentistry
Meeting Minutes
February 19, 2021

After discussion, the following action was taken:

Motion: by Dr. Tejera to approve the licensure ratification list

Second: by Dr. White

Vote: Unanimous

E. Anesthesia Ratification List

After discussion, the following action was taken:

Motion: by Dr. Tejera to accept the anesthesia ratification list

Second: by Mr. Andrade

Vote: Unanimous

IX. OLD BUSINESS

A. Approval of Board Meeting Minutes – November 13, 2020

After discussion, the following action was taken:

Motion: by Dr. Tejera to approve the meeting minutes

Second: by Mr. Andrade

Vote: Unanimous

X. ADJOURNMENT

There being no further business, the meeting was adjourned at 2:20 p.m.

**BOARD OF DENTISTRY
GENERAL BUSINESS MEETING MINUTES
Call In Number (888) 585-9008, Participant Pass Code: 599-196-982
January 24, 2020
9:00 a.m. EST**

Participants in this public meeting should be aware that these proceedings are being recorded
and that an audio file of the meeting will be posted to the board's website.

I. CALL TO ORDER

MEMBERS PRESENT

Naved Fatmi, DMD, Chair
Nick White, DMD, Vice-Chair
Claudio Miro, DDS
Catherine Cabanzon, RDH, BASDH
Fabio Andrade, Consumer Member

STAFF PRESENT

Jessica Sapp, Program Administrator

BOARD COUNSEL

David Flynn, Esq.
Senior Assistant Attorney General

MEMBERS ABSENT

Matthew Freedman, DMD
T.J. Tejera, DMD, MD
Nick Kavouklis, DMD
Angela Sissine, RDH

II. DISCUSSION

a. SB 1032/HB 1273 – An act relating to dentistry and dental hygiene

Dr. Fatmi asked Ms. Sapp for a brief explanation of the SB1032/HB1273. Ms. Sapp explained that bill authorizes the acceptance of the Western Regional Examining Board (WREB) for licensure in Florida.

Ms. Cabanzon indicated she has done some research into the WREB and found there are some scoring discrepancies with the dental exam. She also researched which states exam WREB and which states accept ADEX. She found there is only 1 state (Alaska) that accepts the WREB but does not accept ADEX. There are 3 states that do not accept the ADEX exam, Georgia, New York and Alaska. She also found the 9 states recently stopped accepting the WREB due to issues with scoring. She does not see any benefit to accepting this exam and did not believe it would change portability.

Dr. Fatmi had concerns with some of the portions of the exam being optional and felt this could cause a conflict with Florida's standard of care. He indicated that he did not see any benefit to accepting this exam.

Dr. Miro had expressed concerns on the requirements and what the benefits would be to accept WREB.

Dr. White expressed concerns with having to check to make sure all required portions had been completed and did not see any benefit. He also added that he was concerned with other states moving away from this exam.

Mr. Andrade expressed his concerns and stated that if it is not an improvement, we should not support.

Dr. Cegielski who is a dentist in Port St. Lucie and who has been an examiner for over 13 years expressed concerns with the exam and feels that the WREB is weaker exam. He also added that Florida would be lowering its standards by accepting this exam and that he does not see any benefit.

Casey Stoutamire speaking on behalf of the Florida Dental Association, shares the concerns of the board.

After discussion, the following action was taken:

Motion: by Ms. Cabanzon that toe Board of Dentistry does not approve adopting this bill

Second: Dr. Fatmi

Vote: Unanimous

III. ADJOURNMENT

There being no further business, the meeting was adjourned.

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

THE FLORIDA SENATE

APPEARANCE RECORD

3/24/21

Meeting Date

SB 1366

Bill Number (if applicable)

Topic

Licensure Exam for Dental Practitioners

Amendment Barcode (if applicable)

Name

Joe Anne Hart

Job Title

Chief Legislative Officer

Address

118 E. Jefferson St.

Phone

850.224.1089

Street

City

Jallahassee, FL 32301

State

Zip

Email

jahart@floridadental.org

Speaking:

☐

For

☒

Against

☐

Information

Waive Speaking:

☐

In Support

☐

Against

(The Chair will read this information into the record.)

Representing

Florida Dental Association

Appearing at request of Chair:

☐

Yes

☒

No

Lobbyist registered with Legislature:

☒

Yes

☐

No

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

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

S-001 (10/14/14)

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

THE FLORIDA SENATE
APPEARANCE RECORD

3/24/21
 Meeting Date

SB 1366
 Bill Number (if applicable)

Topic CLINICAL LICENSURE EXAMINATIONS DENTIST Amendment Barcode (if applicable)

Name DR. BRUCE HORN

Job Title DIRECTOR OF DENTAL EXAMINATIONS

Address 2990 S. SHERIDAN
 Street

Phone 918 492 9890

TULSA & PHOENIX OK/AZ 74130
 City State Zip

Email bdhorn@phs

Speaking: ☒ For ☐ Against ☐ Information

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

Representing WREB DENTAL EXAMINATION

Appearing at request of Chair: ☒ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Finance and Tax, *Vice Chair*
Appropriations Subcommittee on Education
Appropriations Subcommittee on Transportation,
Tourism, and Economic Development
Community Affairs
Health Policy
Military and Veterans Affairs, Space,
and Domestic Security

JOINT COMMITTEE:

Joint Legislative Auditing Committee

SENATOR JANET CRUZ

18th District

March 24, 2021

The Honorable Manny Diaz, Jr.
Chair, Health Policy Committee
530 Knott Building
404 South Monroe Street
Tallahassee, Florida 32399-1100

Dear Chair Diaz,

I respectfully request to be excused from the Health Policy Committee meeting on March 24, 2021. I will monitor the committee virtually to remain informed on the topics that are on the agenda.

Please let me know if you have any questions or concerns regarding this request.

Thank you,

A handwritten signature in blue ink, appearing to read "Janet Cruz". The signature is stylized with a large, sweeping initial "J" and a cursive "Cruz".

Janet Cruz
State Senator, District 18

CC: Allen Brown, Health Policy Committee – Staff Director

REPLY TO:

- 210A S. MacDill Avenue, Tampa, Florida 33609 (813) 348-1017 FAX: (888) 263-3681
- 216 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5018

Senate's Website: www.flsenate.gov

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore

CourtSmart Tag Report

Room: KB 412

Case No.: -

Type:

Caption: Senate Health Policy Committee

Judge:

Started: 3/24/2021 11:35:02 AM

Ends: 3/24/2021 1:13:58 PM

Length: 01:38:57

11:35:00 AM Meeting called to order by Chair Diaz
11:35:04 AM Roll call by CAA Lynn Wells
11:35:12 AM Quorum present
11:35:21 AM Senator Cruz is excused from meeting
11:35:29 AM Comments from Chair Diaz
11:36:03 AM Introduction of Tab 8, SB 1292 by Chair Diaz
11:36:22 AM Explanation of SB 1292, Medicaid by Senator Bean
11:37:03 AM Introduction of Amendment Barcode 577006 by Senator Jones is withdrawn from consideration
11:37:22 AM Introduction of Amendment Barcode 385204 by Chair Diaz
11:37:24 AM Explanation of Amendment by Senator Bean
11:38:01 AM Comments from Chair Diaz
11:38:27 AM Closure waived
11:38:29 AM Amendment adopted
11:38:36 AM Comments from Chair Diaz
11:38:41 AM Question from Senator Albritton
11:39:00 AM Response from Senator Bean
11:39:18 AM Comments from Chair Diaz
11:39:51 AM Senator Farmer in debate
11:42:41 AM Comments from Chair Diaz
11:42:49 AM Senator Bean in closure
11:42:56 AM Roll call by CAA
11:43:12 AM CS/SB 1292 reported favorably
11:43:30 AM Introduction of Tab 3, SB 1786 by Chair Diaz
11:43:46 AM Explanation of SB 1786, Payments for Birth-related Neurological Injuries by Senator Burgess
11:44:59 AM Introduction of Amendment Barcode 719002 by Chair Diaz
11:45:11 AM Explanation of Amendment by Senator Burgess
11:45:33 AM Comments from Chair Diaz
11:45:56 AM Closure waived
11:45:58 AM Amendment adopted
11:46:02 AM Comments from Chair Diaz
11:46:10 AM Question from Senator Farmer
11:46:47 AM Response from Senator Burgess
11:47:11 AM Follow-up question from Senator Farmer
11:47:18 AM Response from Senator Burgess
11:47:54 AM Response from Staff Director Allen Brown
11:48:19 AM Response from Senator Burgess
11:48:29 AM Comments from Chair Diaz
11:48:36 AM Steve Winn, Florida Osteopathic Medical Association waives in support
11:48:53 AM Speaker Stephen Ecenia, Florida Birth-Related Neurological Injury Compensation Association waives in support
11:49:09 AM Comments from Chair Diaz
11:49:13 AM Closure waived
11:49:15 AM Roll call by CAA
11:49:20 AM CS/SB 1786 reported favorably
11:49:32 AM Introduction of Tab 1, Confirmation Hearing by Chair Diaz
11:50:09 AM Swearing in of Simone Marstiller by Chair Diaz
11:50:24 AM Comments from Secretary Simone Marstiller, Secretary Agency for Health Care Administration
11:57:15 AM Comments from Chair Diaz
11:57:45 AM Audrey Brown, Florida Association of Health Plans waives in support
11:58:07 AM Comments from Chair Diaz
11:58:15 AM Closing remarks from Secretary Marstiller
11:58:45 AM Comments from Senator Farmer

12:00:41 PM Senator Bean moves to recommend confirmation of Simone Marstiller as Secretary of the Agency for Health Care Administration
12:00:56 PM Roll call by CAA
12:01:16 PM Confirmation of Simone Marstiller is recommended favorably
12:01:26 PM Comments from Chair Diaz
12:01:58 PM Introduction of Tab 4, SB 1770 by Chair Diaz
12:02:18 PM Explanation of SB 1770, Genetic Counseling by Senator Jones
12:03:14 PM Introduction of Amendment Barcode 229656 by Chair Diaz
12:03:32 PM Explanation of Amendment by Senator Jones
12:03:45 PM Comments from Chair Diaz
12:04:02 PM Closure waived
12:04:05 PM Amendment adopted
12:04:17 PM Speaking Lauren Jackson, Florida Association of Genetic Counselors in support
12:05:14 PM Speaker Debi Cragun, University of South Florida Public Health in support
12:08:00 PM Comments from Chair Diaz
12:08:05 PM Senator Baxley in debate
12:08:53 PM Senator Jones in closure
12:09:00 PM Roll call by CAA
12:09:07 PM CS/SB 1770 reported favorably
12:09:19 PM Introduction of Tab 5, SB 1772 by Chair Diaz
12:09:37 PM Explanation of SB 1772, Fees/Genetic Counselor Licenses by Senator Jones
12:09:54 PM Comments from Chair Diaz
12:09:56 PM Introduction of Amendment Barcode 695202
12:10:01 PM Explanation of Amendment by Senator Jones
12:10:23 PM Comments from Chair Diaz
12:10:35 PM Amendment adopted
12:10:41 PM Speaker Lauren Jackson, Florida Association of Genetic Counselors waives in support
12:10:57 PM Comments from Chair Diaz
12:11:00 PM Closure waived
12:11:03 PM Roll call by CAA
12:11:07 PM CS/SB 1772 reported favorably
12:11:17 PM Introduction of Tab 2, CS/SB 1080 by Chair Diaz
12:11:34 PM Recording Paused
12:11:45 PM Recording Resumed
12:11:52 PM Quorum present
12:12:54 PM Explanation of CS/SB 1080, Tobacco and Nicotine Products by Senator Hutson
12:14:20 PM Introduction of Amendment 363164 (left pending). Substitute Amendment Barcode 413936 is introduced by Chair Diaz
12:14:39 PM Explanation of Amendment 413936 by Senator Hutson
12:15:01 PM Recording Paused
12:15:06 PM Recording Resumed
12:15:15 PM Quorum present
12:16:26 PM Ashley Lyerly, American Lung Association waives in opposition
12:16:35 PM Susan Harbin, American Cancer Society, Cancer Action Network waives in opposition
12:16:48 PM Comments from Chair Diaz
12:16:54 PM Closure waived
12:16:56 PM Amendment adopted
12:17:19 PM Question from Senator Farmer
12:17:32 PM Response from Senator Hutson
12:17:47 PM Follow-up question from Senator Farmer
12:17:55 PM Response from Senator Hutson
12:18:45 PM Follow-up question from Senator Farmer
12:18:51 PM Response from Senator Hutson
12:18:59 PM Response from Senator Hutson
12:19:02 PM Follow-up question from Senator Farmer
12:19:08 PM Response from Senator Hutson
12:19:15 PM Follow-up question from Senator Farmer
12:19:22 PM Response from Senator Hutson
12:19:25 PM Follow-up question from Senator Farmer
12:19:32 PM Response from Senator Hutson
12:20:00 PM Question from Senator Bean
12:20:11 PM Response from Senator Hutson

12:20:32 PM Follow-up question from Senator Bean
12:21:01 PM Response from Senator Hutson
12:21:36 PM Ashley Lyerly, American Lung Association waives in opposition
12:21:43 PM Speaker Susan Harbin, American Cancer Society Cancer Action Network in opposition
12:26:17 PM Comments from Chair Diaz
12:26:26 PM Senator Farmer in debate
12:30:18 PM Senator Hutson in closure
12:31:14 PM Roll call by CAA
12:32:13 PM CS/CS/SB/1080 reported favorably
12:32:37 PM Introduction of Tab 6, SB 1242 by Chair Diaz
12:32:55 PM Explanation of SB 1242, Program of All-Inclusive Care for the Elderly by Senator Book
12:34:09 PM Introduction of Amendment Barcode 284458 by Chair Diaz
12:34:19 PM Explanation of Amendment by Senator Book
12:34:30 PM Comments from Chair Diaz
12:34:57 PM Amendment adopted
12:35:03 PM Comments from Chair Diaz
12:35:15 PM Speaker Matt Hudson, Florida PACE Providers Association
12:35:40 PM Speaker Kelly Mallette, Miami Jewish Health System in support
12:35:56 PM Comments from Chair Diaz
12:36:12 PM Senator Baxley in debate
12:37:00 PM Comments from Chair Diaz
12:37:05 PM Closure waived
12:37:08 PM Roll call by CAA
12:37:10 PM CS/SB 1242 reported favorably
12:37:25 PM Introduction of Tab 7, SB 1268 by Chair Diaz
12:37:33 PM Explanation of SB 1268, Coverage for Hearing Aids for Children by Senator Baxley
12:39:58 PM Comments from Chair Diaz
12:40:10 PM Speaker Mason Rodriguez (child who is deaf) in support
12:42:43 PM Comments from Chair Diaz
12:43:03 PM Speaker Jennifer Manso Farrell in support
12:44:45 PM Speaker Ginger Farrell in support
12:45:56 PM Speaker Angelica Martinez in support
12:46:30 PM Speaker Theresa Bulger waives in support
12:47:33 PM Speaker Edeline Joseph-Theophile, Florida PTA waives in support
12:47:41 PM Speaker Tripp Farrell in support
12:48:58 PM Speaker Daniela Berrios, Speech Language Pathologist in support
12:50:07 PM Speaker Debra Golinski, Sertoma Speech and Hearing Foundation in support
12:50:34 PM Whit Farrell waives in support
12:50:52 PM Comments from Chair Diaz
12:51:01 PM Senator Baxley in closure
12:51:07 PM Roll call by CAA
12:51:39 PM SB 1268 reported favorably
12:51:55 PM Introduction of Tab 9, SB 1976 by Chair Diaz
12:52:15 PM Explanation of SB 1976, Freestanding Emergency Departments by Senator Brodeur
12:52:46 PM Comments from Chair Diaz
12:53:06 PM Closure waived
12:53:10 PM Roll call by CAA
12:53:14 PM SB 1976 reported favorably
12:53:30 PM Introduction of Tab 10, SB 1366 by Chair Diaz
12:53:43 PM Explanation of SB 1366, Licensure Examinations for Dental Practitioners by Senator Brodeur
12:54:08 PM Comments from Chair Diaz
12:54:35 PM Question from Senator Bean
12:54:45 PM Response from Senator Brodeur
12:55:51 PM Response from Chair Diaz
12:56:01 PM Question from Senator Farmer
12:56:10 PM Response from Senator Brodeur
12:56:27 PM Comments from Chair Diaz
12:56:34 PM Speaker Joe Anne Hart, Florida Dental Association in opposition
1:01:09 PM Speaker Dr. Bruce Horn, Director of Dental Examinations in support
1:07:54 PM Comments from Chair Diaz
1:08:08 PM Senator Baxley in debate
1:09:38 PM Senator Farmer in debate

1:11:03 PM Chair Diaz in debate
1:11:11 PM Senator Brodeur in closure
1:11:34 PM Roll call by CAA
1:12:29 PM SB 1366 reported favorably
1:12:50 PM Comments from Chair Diaz regarding motions for missed votes
1:12:57 PM Senator Book would like to shown voting in the affirmative on CS/SB 1292, CS/SB 1786, Confirmation Hearing, CS/SB 1770, and CS/SB 1772. Motion adopted
1:13:09 PM Senator Albritton would like to shown voting in the affirmative on the Confirmation Hearing, CS/SB 1770, and CS/SB 1772. Motion adopted
1:13:20 PM Senator Brodeur would like to be showing voting in the affirmative on the Confirmation Hearing, CS/SB 1770, CS/SB 1772, and CS/CS/SB 1080. Motion adopted
1:13:39 PM Comments from Chair Diaz
1:13:41 PM Senator Garcia moves to adjourn
1:13:48 PM Meeting adjourned