

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Harrell, Chair
Senator Berman, Vice Chair

MEETING DATE: Tuesday, February 18, 2020
TIME: 10:00 a.m.—12:00 noon
PLACE: *Pat Thomas Committee Room, 412 Knott Building*

MEMBERS: Senator Harrell, Chair; Senator Berman, Vice Chair; Senators Baxley, Bean, Book, Cruz, Diaz, Hooper, Mayfield, and Rouson

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	Coronavirus: Potential Impact on Florida by Surgeon General Scott Rivkees and John Sinnott, M.D.		Presented
2	CS/SB 880 Banking and Insurance / Baxley (Similar CS/H 437)	Nurse Registry; Authorizing the use of licensed nurse registries for the placement of attendant care provided for workers' compensation purposes, etc. BI 01/15/2020 Fav/CS HP 02/11/2020 Not Considered HP 02/18/2020 Favorable RC	Favorable Yeas 9 Nays 0
3	SB 584 Harrell (Identical H 471, Compare CS/H 607)	Council on Physician Assistants; Revising requirements relating to the Council on Physician Assistants membership, etc. HP 02/11/2020 Not Considered HP 02/18/2020 Fav/CS AHS AP	Fav/CS Yeas 9 Nays 0
4	SB 626 Pizzo (Identical H 427)	HIV Prevention; Citing this act as the "HIV Prevention Justice Act"; providing that it is a felony for certain persons who have human immunodeficiency virus (HIV) infection to donate human tissue to persons who are not HIV infected, with an exception; expanding the scope of unlawful acts by a person infected with a sexually transmissible disease; providing that certain actions are not sufficient evidence to establish intent on the part of the person who transmits the disease, etc. HP 02/18/2020 Fav/CS ACJ AP	Fav/CS Yeas 9 Nays 0

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

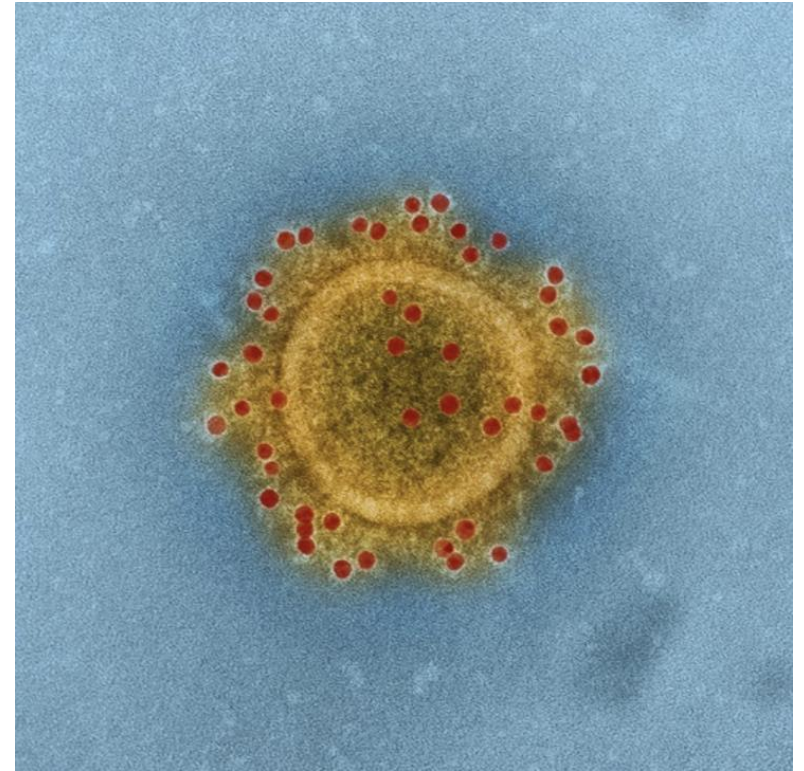
Tuesday, February 18, 2020, 10:00 a.m.—12:00 noon

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
5	SB 780 Gainer (Identical H 409)	Health Care Licensing Requirements; Exempting certain health care practitioners from specified licensing requirements when providing certain services to veterans in this state; requiring such health care practitioners to submit certain information to the Department of Health; requiring the department to notify such health care practitioners of their exemption within a certain timeframe, etc. HP 02/18/2020 Temporarily Postponed AHS AP	Temporarily Postponed
6	SB 714 Hutson (Identical H 389)	Testing for and Treatment of Influenza and Streptococcus; Requiring specified licensed pharmacists to report certain information to the Department of Health; authorizing pharmacists to test for and treat influenza and streptococcus and providing requirements relating thereto; requiring that a pharmacist notify a patient's primary care provider within a specified time period after providing any such testing or treatment, etc. HP 02/18/2020 Fav/CS AHS AP	Fav/CS Yeas 6 Nays 3
7	SB 1470 Book (Compare CS/H 1289)	Informed Consent for Pelvic Examinations; Specifying circumstances under which a health care provider may perform a pelvic examination on an anesthetized or unconscious patient; specifying procedures for obtaining consent for a pelvic examination; prohibiting a student or resident from observing or performing a pelvic examination on a patient without the patient's consent; requiring a health care provider to notify the patient of certain information before the patient is anesthetized and rendered unconscious, etc. HP 02/18/2020 Fav/CS JU RC	Fav/CS Yeas 9 Nays 0

Other Related Meeting Documents

2019 Novel Coronavirus

Prepared for State of Florida Senate
Health Policy Cmte
February 18, 2020



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ได้รับการพ่นยาฆ่าเชื้อแล้ว
DISINFECTED ALEADY
(glutaraldehyde)



ISSUE 1: In the past 3 years US has:

Closed Office of Pandemic Response

↓ CDC outreach from 49 – 10 countries

Ended PREDICT Program

Identified 1,000 new viruses

Trained 5,000 epi responders

ISSUE 2 : Fake News

PRC releases virus to reduce population – tiktok.com

Bill Gates releases virus so he can make vaccine- qanon.com

Coronavirus stolen from Canada Bioweapons Program-
@SolomonYoue twitter

HEALTH

Professor Warns New Coronavirus Has Same Kill Rate as the Spanish Flu

Spanish flu killed 20-50 million people.

MISLEADING

LIVE

theseshrealm

BREAKING NEWS

COCAINE KILLS CORONA VIRUS

12:01

SCIENTISTS IS SHOCKED TO DISCOVER THAT THIS DRUG CAN FIGHT THE VIRUS

New AI Algorithms: predict outbreaks faster



- The BlueDot AI algorithm identified Wuhan outbreak on Dec 31, 2019
- Blue Dot tabulates news, travel data and social media to predict disease outbreaks

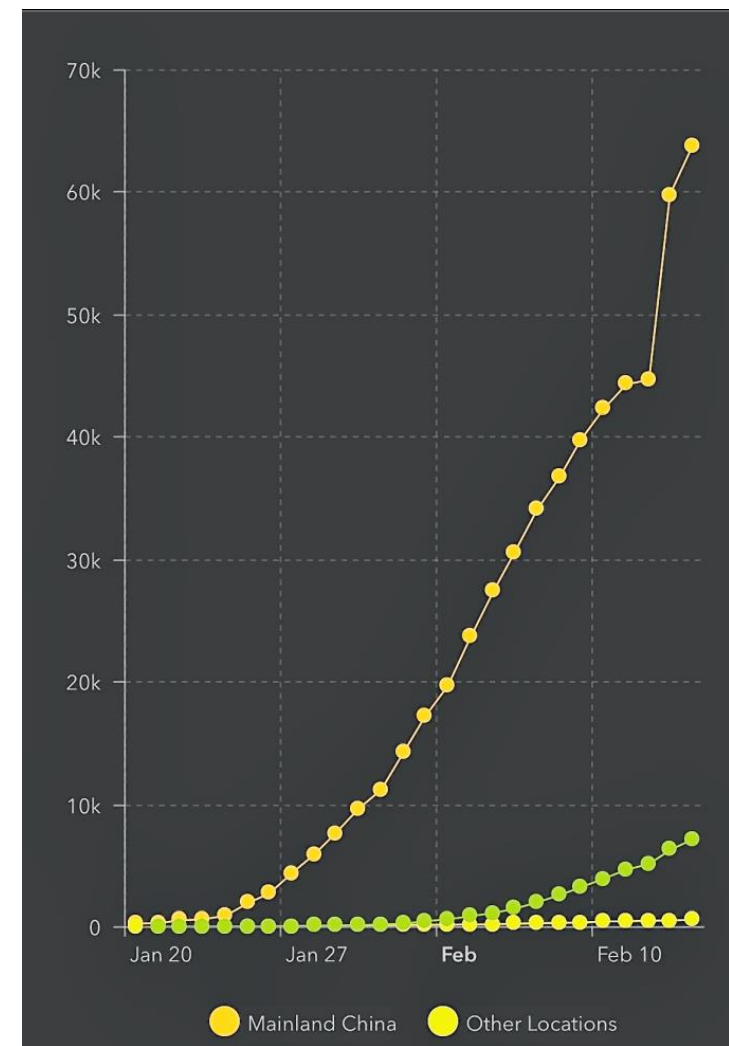
<https://www.wired.com/story/ai-epidemiologist-wuhan-public-health-warnings/>

SITUATION: COVID-19*

Date	Cases
Dec 10	Likely 1 st case
Jan 2	2019-nCoV isolated & linked to wet market
Jan 6	Hubei province declares epidemic
Jan 7	200 cases
Jan 25	2,000 cases
Feb 6	28,353 cases
Feb 14	64,460 cases

*Changes daily

Johns Hopkins CCSE Feb 2, 2020 <https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>



2019-2020 US Flu Season*

October to February

- Influenza >31M
- Doctor visits >15M
- Hospitalized >350,000
- Deaths >25,000

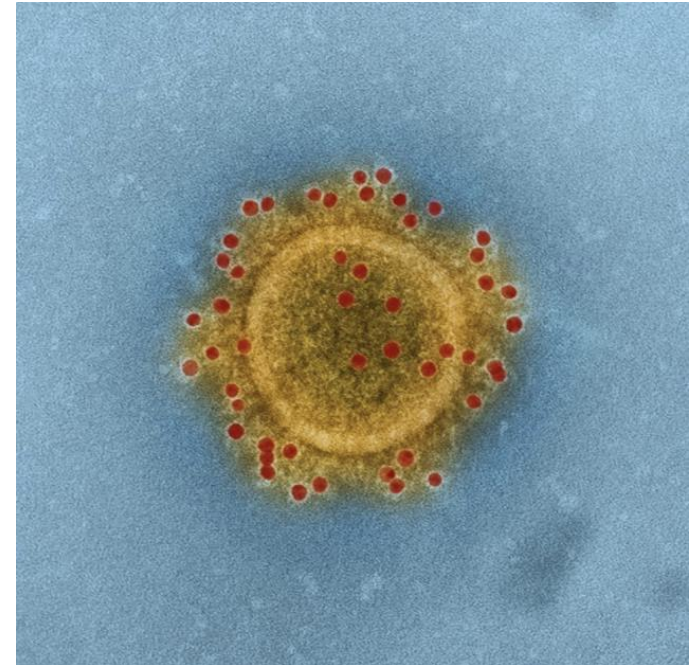
*CDC 2020. These estimates are calculated based on CDC's [weekly influenza surveillance data](#) and are preliminary





“CORONA” VIRUS

- 8 strains
- Rarely MERS CoV or SARS, now COVID-19
- Mostly common cold
- Both upper and lower airway illness



TRANSMISSION

Droplets

Contact

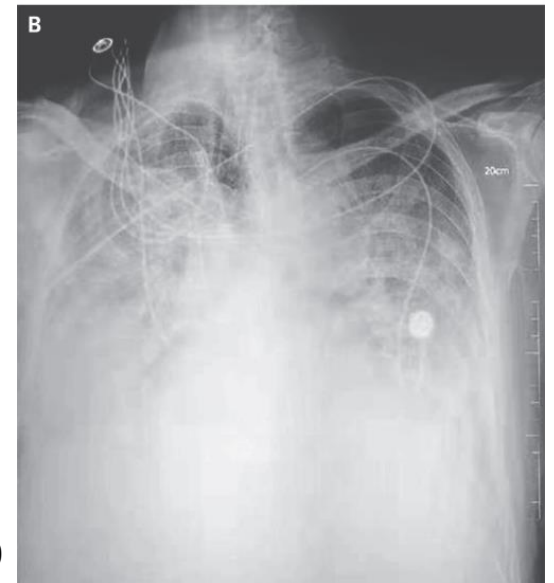
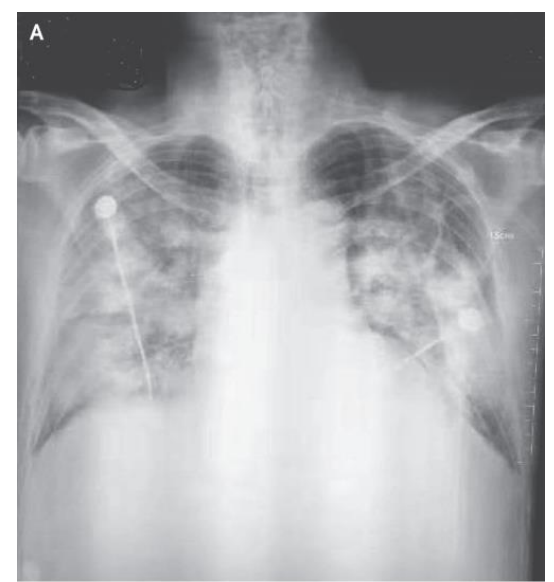
GI



Asymptomatic persons can transmit infection*

SYMPTOMS

- Cough or fever
- Most recover but pneumonia in 2.5%
- In China ~50% with pneumonia die
- Recovery seems complete in survivors



Compared to Influenza

- No muscle aches
- Diarrhea more common (personal communication Han Lin, PhD Lanzhou, China)

EPIDEMIOLOGY

- $R_0 = 2.2$
- Doubling time: 7 days → Epidemic
- Mean age: 59 yo
- Min age: 9-month old
- Deaths: Underlying disease
- >1,700 HCW infected, 6 dead

HOW TO PROTECT YOURSELF

Flu shot

Non-Pharmaceutical Interventions

ACTION	EVIDENCE
Hand wash	Moderate/Strong
Face mask	Moderate
Surface cleaning	Low

WHO 2020



EMERGENCY
EXIT

PULL HANDLE
UNLOCK STRONG
ROTATE OR DOWN
EXIT





COVID-19 suspected? SEE PHYSICIAN

- China in past 14 days AND
- Cough OR fever, short of breath
- Call doctor ahead of time to allow special precautions

FUTURE: UNPREDICTABLE

- More person-to-person spread
- Possible pandemic (epidemic on 2 or more continents) vs. contained
- More cases in US & FL
- CDC Info source
- AVOID FAKE NEWS

What institutions should consider?

Workplace Containment

Recommended

Sick with fever,
cough



Seek medical
attention

Exposed



Quarantine
14 days

Workplace Measures

- Teleworking
- Staggering shifts
- Loosen sick leave
- Decrease travel

School Measures – Variably Effective

- Exclude sick students
- Decrease class mixing
- Closure during epidemic
- Provide hand sanitizer stations

Is the glass half full or half empty?

- 98% of COVID-19 pts fully recover
- Children have lower risk of infection
- Virus does not appear to pass from mother to fetus or cause birth defects

*“Medicine is a science of uncertainty
and an art of probability”*

Sir William Osler

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 880

INTRODUCER: Banking and Insurance Committee and Senator Baxley

SUBJECT: Nurse Registry

DATE: February 10, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Arnold</u>	<u>Knudson</u>	<u>BI</u>	<u>Fav/CS</u>
2.	<u>Rossitto-Van Winkle</u>	<u>Brown</u>	<u>HP</u>	<u>Favorable</u>
3.	_____	_____	<u>RC</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 880 authorizes an employer or workers' compensation insurer to use a licensed nurse registry to place authorized compensable attendant care services for the benefit of an injured worker under the Workers' Compensation Law.

The bill takes effect July 1, 2020.

II. Present Situation:

Workers' Compensation and Attendant Care Benefits

Workers' compensation provides medical benefits and, in cases where the injured worker is unable to work or earn as much as he or she did before the injury, compensation for lost income (also referred to as "wage replacement" or "indemnity" benefits) for compensable workplace injuries arising out of work performed by an employee in the course and scope of employment.¹ Injured workers are entitled to receive all medically necessary remedial treatment, care, and attendance, including medications, medical supplies, durable medical equipment, and prosthetics, for as long as the nature of the injury and process of recovery requires.² Medical services must be

¹ Section 440.09(1), F.S.

² Section 440.13(2)(a), F.S.

provided by a health care provider authorized by the workers' compensation insurance company prior to being provided (except for emergency care).³

There are several types of medical care provided to injured workers both inside and outside of medical facilities, including emergency, interventional, palliative, rehabilitative, and attendant. "Attendant care" means care rendered by trained professional attendants that is beyond the scope of household duties.⁴ Attendant care includes a wide variety of services from skilled nursing care to unskilled tasks, such as bathing, dressing, personal hygiene, and administration of medications. Most attendant care is provided by licensed medical providers; however, family members may provide and receive carrier payment for non-professional attendant care services, excluding normal household duties.⁵

According to a home health care study performed by the Cleveland Clinic, providing in-home attendant care has significant advantages for both the injured worker and the carrier. The injured worker can be more comfortable than in an institution and realize better outcomes, both physically and mentally, concurrent with the carrier achieving significant cost savings.⁶ Under current law, carriers are not specifically prohibited from using a nurse registry or a home health agency to obtain professional and non-professional attendant care for the injured worker.

Placement of Attendant Care Services Through Nurse Registries and Home Health Agencies

A nurse registry is a business that procures, offers, promises, or attempts to procure health care related contracts for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, homemakers, and companions to provide services to patients in their homes and temporary staff to health care facilities or other business entities.⁷ Nurse registries are governed by part II of ch. 408, F.S.,⁸ and associated rules in Florida Administrative Code Rule 59A-35; and the nurse registry rules in Florida Administrative Code Rule 59A-19. A nurse registry must be licensed by the Agency for Health Care Administration (AHCA), pursuant to part III of ch. 400, F.S., to lawfully offer contracts in Florida.⁹

The providers referred by the nurse registry are hired as independent contractors by the patient, health care facility, or another business entity (e.g., a workers' compensation carrier).¹⁰ This is a key defining feature of a nurse registry: It cannot have any employees except for the administrator, alternate administrator, and office staff. All individuals referred by a nurse registry who enter the home of patients to provide direct care must be independent contractors.

³ Section 440.13(3)(a), F.S.

⁴ Section 440.13(1)(b), F.S. Attendant care must be medically necessary and performed at the direction and control of an authorized treating physician pursuant to a written prescription. Section 440.13(2)(b), F.S.

⁵ The valuation of family-member provided attendant care is limited in both duration and cost. Section 440.13(2)(b), F.S.

⁶ A home health care study performed by the Cleveland Clinic found average per patient savings of \$6,433 in the first year after discharge, decrease in readmissions by 18 percent, and decrease in deaths by 20 percent. Roy Xiao et al., *Impact of Home Health Care on Health Care Resource Utilization Following Hospital Discharge: A Cohort Study*, *The American Journal of Medicine*, April 2018, Volume 131, Issue 4, pp. 395-407, e35.

⁷ Section 400.462(21), F.S.

⁸ Section 400.506(2), F.S. A nurse registry is also governed by the provisions in s. 400.506, F.S.

⁹ Section 400.506(1), F.S.

¹⁰ *Supra* note 7.

Home health agencies (HHAs) are organizations that provide health and medical services and medical supplies to an individual in the individual's home or place of residence.¹¹ HHAs are governed by part II of ch. 408, F.S.,¹² associated rules in Florida Administrative Code Rules 59A-35, and 59A-8. Like a nurse registry, an HHA must be licensed by AHCA, pursuant to part III of ch. 400, F.S., to lawfully offer contracts in Florida.¹³

The key difference between HHAs and nurse registries is the nature of the employment relationship with the health care professionals with whom they contract. Health care providers who contract with an HHA are employees of that agency. In contrast, health care providers who contract with nurse registries are independent contractors. Additionally, while a nurse registry and an HHA may provide services that are privately paid for by insurance or other means to patients in their home or place of residence and provide staff to health care facilities, schools, or other business entities, a nurse registry does not qualify for Medicare reimbursements; an HHA qualifies for such reimbursement.¹⁴

Florida's Workers' Compensation Law is silent regarding how attendant care providers are selected to provide authorized compensable care for injured workers. A workers' compensation carrier is neither prohibited nor specifically authorized to use a nurse registry to place attendant care providers for the benefit of an injured worker.

III. Effect of Proposed Changes:

Section 1 amends s. 440.13, F.S., to specifically authorize an employer or workers' compensation insurer to use a licensed nurse registry to place authorized, compensable attendant care services for the benefit of an injured worker under the Workers' Compensation Law.

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.

¹¹ Section 400.462(12), (14), F.S.

¹² Section 400.464(1), F.S. An HHA is also governed by the provisions in s. 400.464, F.S.

¹³ *Id.*

¹⁴ Centers for Medicare & Medicaid Services, *Medicare & Home Health Care*, <https://www.medicare.gov/sites/default/files/2018-07/10969-medicare-and-home-health-care.pdf> (last visited Feb. 6, 2020).

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 440.13 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 Banking and Insurance on January 15, 2020:

Authorizes an employer or workers' compensation insurer to use a licensed nurse registry to place authorized compensable attendant care services for the benefit of an injured worker under the Workers' Compensation Law. The underlying bill referred to the nurse registry providing attendant care services.

B. Amendments:

None.

By the Committee on Banking and Insurance; and Senator Baxley

597-02276-20

2020880c1

1 A bill to be entitled
2 An act relating to the nurse registry; amending s.
3 440.13, F.S.; authorizing the use of licensed nurse
4 registries for the placement of attendant care
5 provided for workers' compensation purposes;
6 reenacting s. 440.134(16), F.S., relating to workers'
7 compensation managed care arrangements, to incorporate
8 the amendment made to s. 440.13, F.S., in a reference
9 thereto; providing an effective date.

10
11 Be It Enacted by the Legislature of the State of Florida:

12
13 Section 1. Paragraph (b) of subsection (2) of section
14 440.13, Florida Statutes, is amended to read:

15 440.13 Medical services and supplies; penalty for
16 violations; limitations.—

17 (2) MEDICAL TREATMENT; DUTY OF EMPLOYER TO FURNISH.—

18 (b)1. The employer shall provide appropriate professional
19 or nonprofessional attendant care performed only at the
20 direction and control of a physician when such care is medically
21 necessary. The physician shall prescribe such care in writing.
22 The employer or carrier shall not be responsible for such care
23 until the prescription for attendant care is received by the
24 employer and carrier, which shall specify the time periods for
25 such care, the level of care required, and the type of
26 assistance required. A prescription for attendant care shall not
27 prescribe such care retroactively. The value of nonprofessional
28 attendant care provided by a family member must be determined as
29 follows:

597-02276-20

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30 ~~a.1.~~ If the family member is not employed or if the family
31 member is employed and is providing attendant care services
32 during hours that he or she is not engaged in employment, the
33 per-hour value equals the federal minimum hourly wage.

34 ~~b.2.~~ If the family member is employed and elects to leave
35 that employment to provide attendant or custodial care, the per-
36 hour value of that care equals the per-hour value of the family
37 member's former employment, not to exceed the per-hour value of
38 such care available in the community at large. A family member
39 or a combination of family members providing nonprofessional
40 attendant care under this paragraph may not be compensated for
41 more than a total of 12 hours per day.

42 ~~c.3.~~ If the family member remains employed while providing
43 attendant or custodial care, the per-hour value of that care
44 equals the per-hour value of the family member's employment, not
45 to exceed the per-hour value of such care available in the
46 community at large.

47 2. The employer or carrier may use a nurse registry
48 pursuant to s. 400.506 for the placement of authorized
49 compensable attendant care services.

50
51 Failure of the carrier to timely comply with this subsection
52 shall be a violation of this chapter and the carrier shall be
53 subject to penalties as provided for in s. 440.525.

54 Section 2. For the purpose of incorporating the amendment
55 made by this act to section 440.13(2)(b), Florida Statutes, in a
56 reference thereto, subsection (16) of section 440.134, Florida
57 Statutes, is reenacted to read:

58 440.134 Workers' compensation managed care arrangement.—

597-02276-20

2020880c1

59 (16) When a carrier enters into a managed care arrangement
60 pursuant to this section the employees who are covered by the
61 provisions of such arrangement shall be deemed to have received
62 all the benefits to which they are entitled pursuant to s.
63 440.13(2) (a) and (b). In addition, the employer shall be deemed
64 to have complied completely with the requirements of such
65 provisions. The provisions governing managed care arrangements
66 shall govern exclusively unless specifically stated otherwise in
67 this section.

68 Section 3. This act shall take effect July 1, 2020.

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 584

INTRODUCER: Health Policy Committee and Senator Harrell

SUBJECT: Council on Physician Assistants

DATE: February 19, 2020 **REVISED:** _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 584 amends ss. 458.347(9) and 459.022(9), F.S., to increase the number of members on the Council on Physician Assistants (Council) from five members to six. The bill alters the composition of the Council to:

- Reduce the number of physicians licensed under ch. 458, F.S., who are appointed by the chairperson of the Board of Medicine (BOM) from three to two with the requirement that at least one BOM-appointed member must supervise a physician assistant (PA) in his or her practice;
- Maintain the Board of Osteopathic Medicine’s (BOOM) representation on the Council at one member who is a physician licensed under ch. 459, F.S.; and
- Increase the number of PAs on the Council from one to three, with all being appointed by the State Surgeon General.

The bill provides that at least two physician members of the Council must supervise PAs in their practices. Finally, the bill requires that in the event of a tie vote in the election of the Council’s chair, the State Surgeon General will select the chair from among the Council’s members.

The bill provides an effective date of July 1, 2020.

II. Present Situation:

Department of Health

The Legislature created the Department of Health (DOH) to protect and promote the health of all residents and visitors in the state.¹ The DOH is charged with the regulation of health practitioners for the preservation of the health, safety, and welfare of the public. The Division of Medical Quality Assurance (MQA) is responsible for the boards² and professions within the DOH.³

Physicians Assistants (PAs)

The DOH licenses PAs in Florida, either under s. 458.347(7), F.S., if the physician assistant works with a physician, or s. 459.022(7), F.S., if he or she works with an osteopathic physician. PAs are regulated by the BOM if licensed under ch. 458, F.S., or the BOOM if licensed under ch. 459, F.S., and the Council.

The boards and the Council are responsible for adopting the principles that a supervising physician must use for developing a PA's scope of practice, developing a formulary of drugs that may not be prescribed by a PA, and approving educational programs.⁴ The boards make disciplinary decisions as to whether a doctor or PA has violated the provisions of his or her practice act. In June, 2019, there were 8,658 PAs holding active Florida licenses, 1,069 active out of state, and 66 active military.⁵

Scope of Practice

Physician Assistants may practice only under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.⁶ A supervising physician may delegate to a PA tasks and procedures that are within the scope of practice of the supervising physician.⁷ The supervising physician is responsible and liable for any acts or omissions of his or her PA⁸ and may not supervise more than four PAs at a time.⁹

¹ Section 20.43, F.S.

² Under s. 456.001(1), F.S., the term "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH, MQA.

³ Section 20.43, F.S.

⁴ Sections 458.347(4) and (6), F.S., and 459.022(4) and (6), F.S.

⁵ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2018-2019*, available at http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1819.pdf, (last visited Feb. 4, 2020).

⁶ Sections 458.347(2)(f) and 459.022(2)(f), F.S., are identical and define "supervision" as "responsible supervision" and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.

⁷ Sections 458.347(12) and 459.022(12), F.S.

⁸ Fla. Admin. Code R. 64B8-30.012(1) and 64B15-6.010(1), (2019).

⁹ Section 458.347(3) and 459.022(3), F.S.

Physician's Assistants Education Curriculum

According to the American Academy of Physician Assistants, most PA programs last approximately 26 months, or three academic years, and award master's degrees. They include classroom instruction and clinical rotations.

PA students complete approximately 2,000 hours of clinical rotations, with an emphasis on primary care in ambulatory clinics, physician offices, and acute or long-term care facilities. PA rotations may, but are not required to, include:

- Family medicine;
- Internal medicine;
- Obstetrics and gynecology;
- Pediatrics;
- General surgery;
- Emergency medicine; and
- Psychiatry.¹⁰

PAs are authorized to perform only those services delegated by their supervising physicians. The delegated service must also be within a PA's ability to practice in accordance with his or her education and training, unless expressly prohibited under chs. 458 or 459, F.S., or by board rules.

Licensure of Physician Assistants

To be licensed as a PA in Florida, an applicant must:

- Pass the exam established by the National Commission on Certification of Physician Assistants;
- Complete the application and submit the application fee;¹¹
- Complete an approved PA training program;
- Acknowledge any prior felony convictions;
- Acknowledge any previous revocations or denials of licensure in any state; and
- If the applicant wishes to apply for prescribing authority, submit a copy of course transcripts and a copy of the course description from his or her PA training describing the course content in pharmacotherapy.¹²

Licenses are renewed biennially.¹³ At the time of renewal, a PA must demonstrate that he or she has met the continuing education requirements and must submit an acknowledgement that he or she has not been convicted of any felony in the previous two years.¹⁴

¹⁰ American Association of Physician Assistants, *Become a PA*, <https://www.aapa.org/career-central/become-a-pa/> (last visited Feb. 4, 2020).

¹¹ The application fee is \$100 (non-refundable) and the initial license fee is \$205. Florida Board of Medicine, Physician Assistant (PA), *Fees, available at* <https://flboardofmedicine.gov/licensing/physician-assistant-licensure/#tab-fees> (last visited Feb. 4, 2020).

¹² Sections 458.347(7) and 459.022(7), F.S.

¹³ For timely renewed licenses, the renewal fee is \$280 and the prescribing registration is \$150. An applicant may be charged an additional fee if the license is renewed after expiration or is more than 120 days delinquent. Florida Board of Medicine, *Renewals, Physician Assistants*, <http://flboardofmedicine.gov/renewals/physician-assistants/> (last visited Feb. 4, 2020).

¹⁴ Sections 458.347(7)(b)-(c) and 459.022(7)(b)-(c), F.S.

The Council on Physician Assistant (Council)

The Council was created within the DOH under statutory parameters. The Council must consist of five members, two of which must be physicians who supervise PAs in their practice, appointed as follows:

- Three physician BOM members, appointed by the chairperson of the BOM, one of which must supervise a PA in his or her practice;
- One physician BOOM member, appointed by the chairperson of the BOOM, who is not required to be supervising a PA in his or her practice; and
- Two PAs appointed by the State Surgeon General, with one licensed under ch. 458, F.S., and one licensed under ch. 459, F.S.

Council members are appointed for four-year terms and may not serve more than two consecutive terms. The Council must annually elect a chairperson from among the members and must:

- Recommend to the DOH regarding the licensure of PAs;
- Develop rules regulating the use of PAs by physicians to ensure the maintenance of continuity of supervision in every practice setting for consideration and possible adoption by the boards;
- Make recommendations to the boards regarding all matters relating to PAs; and
- Address concerns and problems of PAs to improve safety in the clinical practices.

The boards must consider adopting a Council-proposed rule at the regularly scheduled meeting following the submission of the proposed rule. A proposed rule submitted by the Council may not be adopted by either board unless both boards have approved of the identical language contained in the proposed rule. If either board rejects the Council's proposed rule, that board must specify its objection to the Council with particularity and include any recommendations for the modification of the proposed rule.

When the Council finds that an applicant for a PA license has failed to meet the requirements for licensure, the Council may enter an order to:

- Refuse to certify the applicant for licensure;
- Approve the applicant for licensure with restrictions on the scope of practice or license; or
- Approve the applicant for conditional licensure. Such conditions may include:
 - Placing the licensee on probation;
 - Placing specific conditions on the licensee including requiring the licensee to:
 - Undergo treatment;
 - Attend continuing education courses;
 - Work under the direct supervision of a supervising physician; or
 - Take corrective action.

III. Effect of Proposed Changes:

CS/SB 584 amends ss. 458.347(9) and 459.022(9), F.S., to increase the number of members on the Council on Physician Assistants (Council) from five members to six. The bill alters the composition of the Council to:

- Reduce the number of physicians licensed under ch. 458, F.S., who are appointed by the chairperson of the Board of Medicine (BOM) from three to two with the requirement that at least one BOM-appointed member must supervise a physician assistant (PA) in his or her practice;
- Maintain the Board of Osteopathic Medicine's (BOOM) representation on the Council at one member who is a physician licensed under ch. 459, F.S.; and
- Increase the number of PAs on the Council from one to three, with all being appointed by the State Surgeon General.

The bill provides that at least two physician members of the Council must supervise PAs in their practices. The bill also requires that in the event of a tie vote in the election of the Council's chair, the State Surgeon General will select the chair from among the Council's members. Finally, the bill removes obsolete language from ss. 458.347 and 459.022, F.S.

The bill 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:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 458.347 and 459.022.

IX. Additional Information:

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

CS by Health Policy on February 18, 2020:

See below for a comparison of the membership of the PA Council under the CS versus the underlying bill and current law:

PA Council	Current law	SB 584	CS/SB 584
Total members	5	5	6
BOM physicians	3	1	2
BOOM physicians	1	1	1
Total physicians	4	2	3
PAs	1	3	3
Physicians who supervise a PA	2	2	At least 2

The CS also:

- Provides that if the election of a chairperson ends in a tie vote, the State Surgeon General will select the chairperson from among the Council members; and
- Removes obsolete language from ss. 458.347 and 459.022, F.S.

B. Amendments:

None.

By Senator Harrell

25-00787-20

2020584__

1 A bill to be entitled
2 An act relating to the Council on Physician
3 Assistants; amending ss. 458.347 and 459.022, F.S.;
4 revising requirements relating to the Council on
5 Physician Assistants membership; conforming provisions
6 to changes made by the act; providing an effective
7 date.

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

10
11 Section 1. Paragraphs (a) and (b) of subsection (9) of
12 section 458.347, Florida Statutes, are amended to read:

13 458.347 Physician assistants.—

14 (9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on
15 Physician Assistants is created within the department.

16 (a) The council shall consist of five members appointed as
17 follows:

18 1. The chairperson of the Board of Medicine shall appoint
19 one member ~~three members~~ who is a physician and member ~~are~~
20 ~~physicians and members~~ of the Board of Medicine who supervises.
21 ~~One of the physicians must supervise~~ a physician assistant in
22 the physician's practice.

23 2. The chairperson of the Board of Osteopathic Medicine
24 shall appoint one member who is a physician and ~~a~~ member of the
25 Board of Osteopathic Medicine who supervises a physician
26 assistant in the physician's practice.

27 3. The State Surgeon General or his or her designee shall
28 appoint three ~~a~~ fully licensed physician assistants ~~assistant~~
29 licensed under this chapter or chapter 459.

25-00787-20

2020584__

30 (b) ~~Two of the members appointed to the council must be~~
31 ~~physicians who supervise physician assistants in their practice.~~
32 Members shall be appointed to terms of 4 years, except that of
33 the initial appointments, two members shall be appointed to
34 terms of 2 years, two members shall be appointed to terms of 3
35 years, and one member shall be appointed to a term of 4 years,
36 as established by rule of the boards. Council members may not
37 serve more than two consecutive terms. The council shall
38 annually elect a chairperson from among its members.

39 Section 2. Paragraphs (a) and (b) of subsection (9) of
40 section 459.022, Florida Statutes, are amended to read:

41 459.022 Physician assistants.—

42 (9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on
43 Physician Assistants is created within the department.

44 (a) The council shall consist of five members appointed as
45 follows:

46 1. The chairperson of the Board of Medicine shall appoint
47 one member ~~three members~~ who is a physician and member ~~are~~
48 ~~physicians and members~~ of the Board of Medicine who supervises.
49 ~~One of the physicians must supervise~~ a physician assistant in
50 the physician's practice.

51 2. The chairperson of the Board of Osteopathic Medicine
52 shall appoint one member who is a physician and ~~a~~ member of the
53 Board of Osteopathic Medicine who supervises a physician
54 assistant in the physician's practice.

55 3. The State Surgeon General or her or his designee shall
56 appoint three ~~a~~ fully licensed physician assistants ~~assistant~~
57 licensed under chapter 458 or this chapter.

58 (b) ~~Two of the members appointed to the council must be~~

25-00787-20

2020584__

59 ~~physicians who supervise physician assistants in their practice.~~
60 Members shall be appointed to terms of 4 years, except that of
61 the initial appointments, two members shall be appointed to
62 terms of 2 years, two members shall be appointed to terms of 3
63 years, and one member shall be appointed to a term of 4 years,
64 as established by rule of the boards. Council members may not
65 serve more than two consecutive terms. The council shall
66 annually elect a chairperson from among its members.

67 Section 3. This act shall take effect July 1, 2020.

THE FLORIDA SENATE
APPEARANCE RECORD

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

2/18/20
Meeting Date

584
Bill Number (if applicable)

Topic PA Council

Amendment Barcode (if applicable)

Name Corinne Mixon

Job Title Lobbyist

Address 571 N. Adams
Street

Phone 766-5795

Tallahassee FL 32301
City State Zip

Email corinnemixon@gmail.com

Speaking: For Against Information

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

Representing Florida Academy of Physician Assistants

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.

THE FLORIDA SENATE
APPEARANCE RECORD

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

2/18/2020

Meeting Date

SB0584

Bill Number (if applicable)

Topic Council on Physicians Assistants

Amendment Barcode (if applicable)

Name David Poole

Job Title Director of Legislative Affairs

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Email david.poole@aidshhealth.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.

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 626
INTRODUCER: Health Policy Committee and Senator Pizzo
SUBJECT: Donation and Transfer of Human Tissue
DATE: February 19, 2020 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Williams	Brown	HP	Fav/CS
2.			ACJ	
3.			AP	

Please see Section IX. for Additional Information:
COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 626 relates to the donation and transfer of human tissue. The bill allows the donation of blood, plasma, organs, skin, or other human tissue by a person with human immunodeficiency virus (HIV), without the donor committing a third-degree felony that would apply under current law, if the donation is made specifically for a recipient who is infected with HIV and knows the donor is infected with HIV

The bill provides an effective date of July 1, 2020.

II. Present Situation:

The Human Immunodeficiency Virus (HIV)

HIV is a virus that can lead to acquired immunodeficiency syndrome (AIDS) if not treated. Unlike some other viruses, the human body cannot rid itself of HIV completely, even with treatment.¹

¹ Centers for Disease Control and Prevention, *About HIV/AIDS* (updated December 2, 2019), available at <https://www.cdc.gov/hiv/basics/whatishiv.html> (last visited Feb. 12, 2020).

HIV is spread through specific activities that result in contact with an infected person's blood, other bodily fluids, mucous membranes, or damaged tissue.² In the United States, HIV is mainly transmitted through unprotected anal or vaginal sex and the sharing of used needles and syringes, rinse water, or other equipment used to prepare drugs for injection.³ Less common methods of HIV transmission are through:

- The passage of HIV from mother to child during pregnancy, childbirth, and breastfeeding; and
- Being pierced with an HIV-contaminated needle or other sharp object.⁴

Rare methods of HIV transmission include the following activities with an untreated HIV positive person:

- Oral sex;
- Transfusion of blood and blood products;
- Organ or tissue transplants contaminated with HIV;
- Eating food that has been pre-chewed by a person with HIV;
- Human bites that break the skin by an HIV-positive person;
- Contact with open wounds or mucus membranes of an HIV-positive person; and
- Deep, open-mouth kissing if both persons have mouth sores or bleeding gums.⁵

HIV does not survive long outside the human body, such as on surfaces, and it cannot reproduce outside a human host. HIV is not spread by:

- Mosquitoes, ticks, or other insects;
- Saliva, tears, or sweat that is not mixed with the blood of an HIV-positive person;
- Hugging, shaking hands, sharing toilets, sharing dishes, or closed-mouth kissing with someone who is HIV-positive; or
- Other sexual activities that do not involve the exchange of body fluids.⁶

Once transmitted, HIV attacks the infected person's immune system, specifically, the lymphocytes known as CD4 cells or T Cells, which normally participate in an immune response.⁷ Untreated, HIV reduces a body's ability to fight off infections and disease and can lead to AIDS, the most severe form of HIV infection.⁸ There is no effective cure for HIV, but antiretroviral therapy (ART) can slow or prevent the disease's progression and dramatically prolong the lifespan of an infected person.⁹ When treated, an infected person can expect to live nearly as long as a person without HIV.¹⁰ ART can also reduce the amount of HIV in a person's blood, known

² Centers for Disease Control and Prevention, *HIV Transmission* (updated August 6, 2019), available at <https://www.cdc.gov/hiv/basics/transmission.html> (last visited Feb. 12, 2020).

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Supra* note 1.

⁸ *Id.*

⁹ *Id.*

¹⁰ Centers for Disease Control and Prevention, *HIV Care Saves Lives infographic* (last updated November 25, 2014), available at <https://www.cdc.gov/vitalsigns/hiv-aids-medical-care/infographic.html> (last visited Feb. 12, 2020).

as the viral load.¹¹ Persons who attain an undetectable viral load have effectively no risk of transmitting HIV through sexual conduct.¹²

In the United States, about 53 percent of an estimated 1.1 million people with HIV had achieved an undetectable viral load by the end of 2015.¹³ In Florida, 64 percent of the 119,661 people living with HIV had achieved an undetectable viral load.¹⁴

HIV Harm Reduction in Florida

The Florida Department of Health currently has a four-part plan to eliminate HIV transmission and reduce HIV-related deaths. The components of this plan are:¹⁵

- Implementing routine HIV and sexually transmitted infections (STIs) screening in health care settings and priority testing in non-health care settings;
- Providing rapid access to treatment and ensure retention in care (test and treat);
- Improving and promoting access to antiretroviral pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP); and
- Increasing HIV awareness and community response through outreach, engagement, and messaging.

PrEP involves the daily use of antiretroviral medications to reduce the risk of HIV transmission to HIV-negative individuals. In July 2012, the U.S. Food and Drug Administration approved the use of Truvada (TDF/FTC) for use as PrEP for HIV prevention in sexually active HIV-negative individuals. PrEP is used in conjunction with other prevention methods to reduce HIV transmissions.¹⁶

Post Exposure Prophylaxis (PEP) involves taking antiretroviral medications as soon as possible after a potential exposure to HIV to reduce the likelihood of HIV transmissions. To be effective, PEP must begin prior to 72 hours after exposure and consists of two or three antiretroviral medications that must be taken for 28 days. A physician must determine what treatment is appropriate based on the nature of the exposure. Starting PEP after a potential exposure does not guarantee that someone exposed to HIV will not be diagnosed with HIV. nPEP refers to a PEP directed toward non-occupational exposure, such as when someone is exposed to HIV through sexual intercourse or injection drug use, as opposed to occupational exposure, or exposure that occurs in a workplace setting, such as a needle stick in a doctor's office or health care facility.¹⁷

¹¹ *Supra* note 1.

¹² *Id.*

¹³ The annual number of new HIV diagnoses in the United States decreased by 11 percent overall, but trends varies for different groups of people, with 2018 resulting in approximately 37,832 new HIV diagnoses. Centers for Disease Control and Prevention, *HIV in the United States and Dependent Areas* (December 2019), available at <https://www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-atag glance.pdf> (last visited Feb. 12, 2020).

¹⁴ Florida reported an estimated 4,906 new HIV diagnoses in 2018. Florida Department of Health, *HIV Data Center* (last modified September 17, 2019), available at <http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/index.html> (last visited Feb. 12, 2020).

¹⁵ Florida Department of Health, HIV AIDS, “*Florida’s Plan to Eliminate HIV Transmission and Reduce HIV-related Deaths*” (last modified February 3, 2020), available at <http://www.floridahealth.gov/diseases-and-conditions/aids/index.html> (last visited Feb. 12, 2020).

¹⁶ *Id.*

¹⁷ *Id.*

National Criminal HIV Exposure Laws

Nearly two-thirds of all states criminalize certain conduct related to HIV exposure.¹⁸ Such laws attempt to deter HIV transmission by:

- Criminalizing behaviors that result in HIV exposure for other persons;
- Criminalizing behaviors that result in STD or other communicable or infectious disease exposure, which may include HIV exposure;
- Increasing sentence lengths for certain crimes committed by a person infected with HIV; and
- Increasing sentence lengths for certain crimes committed by a person infected with an STD, which may include HIV.¹⁹

Additionally, all 50 states have criminal laws, such as assault, battery, reckless endangerment, and attempted murder, under which the state can prosecute a person with HIV for engaging in certain behaviors.²⁰

In light of scientific advancements in HIV treatment and prevention, the U.S. Department of Justice (DOJ) recommends that states reform HIV criminal exposure laws to eliminate HIV-specific penalties, except when a person knows he or she is HIV positive and:

- Commits a sex crime with the risk of transmission (e.g., rape or other sexual assault);
- Evidence clearly demonstrates that the person intended to transmit HIV; and
- The person's behavior posed a significant risk of transmission.²¹

Florida Law

STDs and Non-Disclosure

Under Florida law, a person commits a third-degree felony²² if the person knows he or she has HIV, has been informed of the risk of transmission through sexual intercourse, and has sexual intercourse with another person, unless that person consented with knowledge of the diagnosis.²³ A person commits a first-degree felony²⁴ for a second or subsequent non-disclosure offense.²⁵ Conviction for a non-disclosure offense does not require the intent to transmit or the actual transmission of HIV.

¹⁸ J. Stan Lehman, et al., *Prevalence and Public Health Implications of State Laws that Criminalize Potential HIV Exposure in the United States*, AIDS and Behavior (March 15, 2014), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4019819/> (last visited Feb. 12, 2020).

¹⁹ Centers for Disease Control and Prevention, *HIV and STD Criminal Laws* (July 1, 2019), available at <https://www.cdc.gov/hiv/policies/law/states/exposure.html> (last visited Feb. 12, 2020).

²⁰ *Id.*

²¹ *Id.*

²² A third degree felony is punishable by up to 5 years imprisonment and a \$5,000 fine. See ss. 775.082(3)(e) and 775.083(1)(c), F.S.

²³ See ss. 384.24(2) and 384.34(5), F.S.

²⁴ A first degree felony is punishable by up to 30 years imprisonment and a \$10,000 fine. See ss. 775.082(3)(b)1. and 775.083(1)(b), F.S.

²⁵ *Supra*, note 23.

Florida law does not currently define “sexual intercourse.” However, the Florida Supreme Court has defined sexual intercourse to include penile-vaginal penetration and acts of oral and anal intercourse.²⁶

Criminal Transmission of HIV

A person convicted of committing or attempting to commit a specified offense involving the transmission of bodily fluids from one person to another must undergo HIV testing.²⁷ Specified offenses include:²⁸

- Sexual battery;²⁹
- Incest;³⁰ lewd or lascivious offenses on a person under 16;³¹
- Assault³² or aggravated assault;³³
- Battery³⁴ or aggravated battery;³⁵
- Child abuse³⁶ or aggravated child abuse;³⁷
- Abuse of an elderly person or disabled adult³⁸ or aggravated abuse of an elderly person or disabled adult;³⁹
- Sexual performance by a minor (person under 18 years of age);⁴⁰
- Prostitution;⁴¹
- Human trafficking;⁴² and
- Donation of blood, plasma, organs, skin, or other human tissue under certain conditions.⁴³

A person who tests positive for HIV following a conviction for a specified offense, who is informed of the result, and who later commits another specified offense, commits criminal transmission of HIV.⁴⁴ An offender may be convicted of, and sentenced separately for, criminal transmission of HIV and for the underlying offense.⁴⁵ A conviction for criminal transmission of HIV does not require the intent to transmit or the actual transmission of HIV.⁴⁶

²⁶ *Debaun v. State*, 213 So. 3d 747 (Fla. 2017), Supreme Ct. Case # SC13-2336, available at <http://onlinedocketssc.flcourts.org/> (last visited Feb. 12, 2020).

²⁷ Section 775.0877(1), F.S.

²⁸ *Id.*

²⁹ Section 794.011, F.S.

³⁰ Section 826.04, F.S.

³¹ Section 800.04, F.S.

³² Sections 784.011, 784.07(2)(a), and 784.08(2)(d), F.S.

³³ Sections 784.021, 784.07(2)(c), and 784.08(2)(b), F.S.

³⁴ Sections 784.03, 784.07(2)(b), 784.08(2)(c), F.S.

³⁵ Sections 784.045, 784.07(2)(d), and 784.08(2)(a), F.S.

³⁶ Section 827.03(2)(c), F.S.

³⁷ Section 827.03(2)(a), F.S.

³⁸ Section 825.102(1), F.S.

³⁹ Section 825.102(2), F.S.

⁴⁰ Section 827.071, F.S.

⁴¹ Sections 796.07 and 796.08, F.S.

⁴² Sections 787.06(3)(b), (d), (f), and (g), F.S.

⁴³ Section 381.0041(11)(b), F.S.

⁴⁴ Section 775.0877(3), F.S.

⁴⁵ *Id.*

⁴⁶ *Id.*

Court-Ordered Hepatitis and HIV Testing

At the request of a victim,⁴⁷ a court must order an offender charged with the commission of a specified offense to undergo Hepatitis and HIV testing if the offense:

- Involves the transmission of bodily fluids from one person to another;⁴⁸ or
- Is a sexual offense and the victim was a minor, a disabled adult, or an elderly person.⁴⁹

The specified offenses include all the offenses that form the basis for a conviction of criminal transmission of HIV, except human trafficking.⁵⁰

Organ, Blood, Plasma, Skin, and Tissue Donation

Due to increased life expectancy, the number of HIV-positive persons in need of organ transplants has increased.⁵¹ However, the number of people on the organ transplant waiting list far outweighs the number of available organs.⁵² This shortage disproportionately affects persons with HIV, who have a higher mortality rate than persons without HIV on the organ transplant waiting list.⁵³

For decades, federal law prohibited persons with HIV from donating organs for transplantation, including to HIV-positive recipients.⁵⁴ However, in 2013, the HIV Organ Policy Equity (HOPE) Act legalized HIV-positive organ donations for transplantation into HIV-positive candidates under approved research protocols designed to evaluate the feasibility, effectiveness, and safety of such organ transplants.⁵⁵

Although authorized by federal law, it is a third-degree felony in Florida for an HIV-positive person to donate blood, plasma, organs, skin, or other human tissue when he or she knew of the HIV infection and was informed that transmission could occur through such donation.⁵⁶

Release of Information

A person who maliciously disseminates any false information or report about the existence of any STD, including HIV, commits a third degree felony.⁵⁷ A person who obtains information identifying a person with an STD, including HIV, who knew or should have known the nature of the information and who maliciously, or for monetary gain, spreads such information to anyone

⁴⁷ A request may also come from a victim's legal guardian or the parents of a minor victim pursuant to s. 960.003, F.S. See s. 775.0877(2), F.S.

⁴⁸ Section 960.003(2)(a), F.S.

⁴⁹ Section 960.003(2)(b), F.S.

⁵⁰ *Id.*

⁵¹ Christine Durand, M.D., *The Transformation of Transplantation*, HIV Specialist (July 2018), available at https://aahivm.org/wp-content/uploads/2018/07/FINALHIVspecialist_July2018FINAL-1.pdf (last visited Feb. 12, 2020).

⁵² *Id.*

⁵³ *Id.*

⁵⁴ UNOS, *At Two Years, HOPE Act Still Offering Hope* (December 1, 2017), available at <https://unos.org/at-two-years-hope-act-still-offering-hope/> (last visited Feb. 12, 2020).

⁵⁵ *Id.*

⁵⁶ Section. 381.0041(11)(b), F.S.

⁵⁷ Section 384.34(3), F.S.

other than a physician or a nurse employed by the DOH or to a law enforcement agency, commits a third degree felony.⁵⁸

STD Rules of the DOH

The DOH promulgates rules regulating STD testing, confidentiality of information, disease reporting, quarantine orders, and notification requirements.⁵⁹ A person who violates DOH rules related to STDs⁶⁰ is subject to a \$500 fine for each violation.⁶¹ The DOH can impose the fine in addition to other penalties provided by ch. 384, F.S.⁶²

III. Effect of Proposed Changes:

Section 1 amends s. 381.0041, F.S., to allow the donation of blood, plasma, organs, skin, or other human tissue by a person with HIV, without an otherwise applicable penalty of a felony of the third degree, if the donation is made specifically for a recipient who is infected with HIV and knows the donor is infected with HIV.

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.

⁵⁸ Section 384.34(6), F.S.

⁵⁹ Fla. Admin. Code R. 64D-3.

⁶⁰ For example: Fla. Admin. Code R. 64D-3.029, requires practitioners, hospitals, and laboratories to report to DOH diseases or conditions identified by DOH as being of public health significance, including HIV, within specified timeframes.

⁶¹ Section 384.34(4), F.S.

⁶² *Id.* Other penalties include criminal misdemeanor penalties for violations of s. 384.29, F.S., relating to the confidentiality of information and records held by the DOH, and for violations of s. 384.26, F.S., relating to the confidentiality of information gathered by the DOH during an investigation into the source and spread of an STD.

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

None.

B. Private Sector Impact:

Authorizing persons with HIV to donate organs and tissue may make more organs and tissue available to other persons with HIV and increase participation in clinical research trials authorized by the federal HOPE Act.⁶³

C. Government Sector Impact:

The Department of Health has not provided an analysis for CS/SB 626. The bill is not anticipated to have a fiscal impact on state or local governments.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0041 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 February 18, 2020:

The CS:

- Provides that, without the penalty of a felony of the third degree that would otherwise apply, a donation of blood, plasma, organs, skin, or other human tissue by an HIV infected person may be made for a recipient who is HIV positive and who knows that the donor is infected with HIV; and
- Removes all other provisions from the bill.

B. Amendments:

None.

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

⁶³ *Supra* note 54.

By Senator Pizzo

38-00459B-20

2020626__

1 A bill to be entitled
2 An act relating to HIV prevention; providing a short
3 title; amending s. 381.0041, F.S.; providing that it
4 is a felony for certain persons who have human
5 immunodeficiency virus (HIV) infection to donate human
6 tissue to persons who are not HIV infected, with an
7 exception; amending s. 384.23, F.S.; providing
8 definitions; amending s. 384.24, F.S.; expanding the
9 scope of unlawful acts by a person infected with a
10 sexually transmissible disease; providing that certain
11 actions are not sufficient evidence to establish
12 intent on the part of the person who transmits the
13 disease; providing a definition; amending s. 384.34,
14 F.S.; providing applicability of criminal penalties
15 for specified violations; removing a fine for
16 specified rule violations; providing an effective
17 date.

18
19 Be It Enacted by the Legislature of the State of Florida:

20
21 Section 1. This act may be cited as the "HIV Prevention
22 Justice Act."

23 Section 2. Paragraph (b) of subsection (11) of section
24 381.0041, Florida Statutes, is amended to read:

25 381.0041 Donation and transfer of human tissue; testing
26 requirements.-

27 (11)

28 (b) Any person who has human immunodeficiency virus
29 infection, who knows he or she is infected with human

38-00459B-20

2020626__

30 immunodeficiency virus, and who has been informed that he or she
31 may communicate this disease by donating blood, plasma, organs,
32 skin, or other human tissue who donates blood, plasma, organs,
33 skin, or other human tissue for use in another person commits ~~is~~
34 ~~guilty of~~ a felony of the third degree, punishable as provided
35 in s. 775.082, s. 775.083, or s. 775.084. This paragraph does
36 not apply if the donation is made specifically for a recipient
37 who knows that the donor is infected with human immunodeficiency
38 virus.

39 Section 3. Section 384.23, Florida Statutes, is amended to
40 read:

41 384.23 Definitions.—As used in this chapter:

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

43 (2) "County health department" means agencies and entities
44 as designated in chapter 154.

45 (3) "Sexual conduct" means conduct between persons,
46 regardless of gender, which is capable of transmitting a
47 sexually transmissible disease, including, but not limited to,
48 contact between a:

49 (a) Penis and a vulva or an anus; or

50 (b) Mouth and a penis, a vulva, or an anus.

51 (4) ~~(3)~~ "Sexually transmissible disease" means a bacterial,
52 viral, fungal, or parasitic disease determined by rule of the
53 department to be sexually transmissible, to be a threat to the
54 public health and welfare, and to be a disease for which a
55 legitimate public interest will be served by providing for
56 prevention, elimination, control, and treatment. The department
57 must, by rule, determine which diseases are to be designated as
58 sexually transmissible diseases and shall consider the

38-00459B-20

2020626__

59 recommendations and classifications of the Centers for Disease
60 Control and Prevention and other nationally recognized medical
61 authorities in that determination. Not all diseases that are
62 sexually transmissible need be designated for the purposes of
63 this act.

64 (5) "Substantial risk of transmission" means a reasonable
65 probability of disease transmission as proven by competent
66 medical or epidemiological evidence.

67 Section 4. Section 384.24, Florida Statutes, is amended to
68 read:

69 384.24 Unlawful acts.—

70 (1) It is unlawful for any person who has chancroid,
71 gonorrhea, granuloma inguinale, lymphogranuloma venereum,
72 genital herpes simplex, chlamydia, nongonococcal urethritis
73 (NGU), pelvic inflammatory disease (PID)/acute salpingitis, or
74 syphilis, when such person knows that he or she is infected with
75 one or more of these diseases and ~~when such person~~ has been
76 informed that he or she could ~~may~~ communicate this disease to
77 another person through sexual conduct ~~intercourse~~, to act with
78 the intent to transmit the disease, to engage in ~~have~~ sexual
79 conduct that poses a substantial risk of transmission to another
80 person when the ~~intercourse with any~~ other person is unaware
81 that the person is a carrier of the disease, and to transmit the
82 disease to the, ~~unless such other person has been informed of~~
83 ~~the presence of the sexually transmissible disease and has~~
84 ~~consented to the sexual intercourse.~~

85 (2) It is unlawful for any person who has human
86 immunodeficiency virus infection, when such person knows he or
87 she is infected with human immunodeficiency virus ~~this disease~~

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88 and ~~when such person~~ has been informed that he or she could ~~may~~
89 communicate this disease to another person through sexual
90 conduct intercourse, to act with the intent to transmit the
91 disease, to engage in ~~have~~ sexual conduct that poses a
92 substantial risk of transmission to another person when the
93 intercourse with any other person is unaware that the person is
94 a carrier of the disease, and to transmit the disease to the,
95 ~~unless such other person has been informed of the presence of~~
96 ~~the sexually transmissible disease and has consented to the~~
97 ~~sexual intercourse.~~

98 (3) A person does not act with the intent set forth in
99 subsection (1) or subsection (2) if he or she complies in good
100 faith with a treatment regimen prescribed by his or her health
101 care provider or with the behavioral recommendations of his or
102 her health care provider or public health officials to limit the
103 risk of transmission, or if he or she offers to comply with such
104 behavioral recommendations, but such offer is rejected by the
105 other person with whom he or she is engaging in sexual conduct.
106 Evidence of the person's failure to comply with such a treatment
107 regimen or such behavioral recommendations is not, in and of
108 itself, sufficient to establish that he or she acted with the
109 intent set forth in subsection (1) or subsection (2). For
110 purposes of this subsection, the term "behavioral
111 recommendations" includes, but is not limited to, the use of a
112 prophylactic device to limit the risk of transmission of the
113 disease.

114 Section 5. Section 384.34, Florida Statutes, is amended to
115 read:

116 384.34 Penalties.—

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117 (1) Any person who violates ~~the provisions of~~ s. 384.24(1)
118 commits a misdemeanor of the first degree, punishable as
119 provided in s. 775.082 or s. 775.083.

120 (2) Any person who violates s. 384.24(2) commits a
121 misdemeanor of the first degree, punishable as provided in s.
122 775.082 or s. 775.083. Any person who is convicted of a
123 violation of s. 384.24(2) based on conduct occurring after July
124 1, 2020, and who subsequently commits a second or subsequent
125 violation of s. 384.24(2), commits a felony of the third degree,
126 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

127 (3)~~(2)~~ Any person who violates ~~the provisions of~~ s. 384.26
128 or s. 384.29 commits a misdemeanor of the first degree,
129 punishable as provided in s. 775.082 or s. 775.083.

130 (4)~~(3)~~ Any person who maliciously disseminates any false
131 information or report concerning the existence of any sexually
132 transmissible disease commits a felony of the third degree,
133 punishable as provided in ss. 775.082, 775.083, and 775.084.

134 ~~(4) Any person who violates the provisions of the~~
135 ~~department's rules pertaining to sexually transmissible diseases~~
136 ~~may be punished by a fine not to exceed \$500 for each violation.~~
137 ~~Any penalties enforced under this subsection shall be in~~
138 ~~addition to other penalties provided by this chapter. The~~
139 ~~department may enforce this section and adopt rules necessary to~~
140 ~~administer this section.~~

141 ~~(5) Any person who violates s. 384.24(2) commits a felony~~
142 ~~of the third degree, punishable as provided in s. 775.082, s.~~
143 ~~775.083, or s. 775.084. Any person who commits multiple~~
144 ~~violations of s. 384.24(2) commits a felony of the first degree,~~
145 ~~punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

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146 (5)~~(6)~~ Any person who obtains information that identifies
147 an individual who has a sexually transmissible disease, who knew
148 or should have known the nature of the information and
149 maliciously, or for monetary gain, disseminates this information
150 or otherwise makes this information known to any other person,
151 except by providing it either to a physician or nurse employed
152 by the Department of Health or to a law enforcement agency,
153 commits a felony of the third degree, punishable as provided in
154 s. 775.082, s. 775.083, or s. 775.084.

155 Section 6. This act shall take effect July 1, 2020.



The Florida Senate

Committee Agenda Request

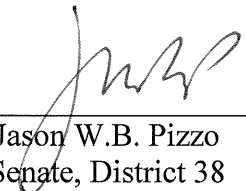
To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: November 6, 2019

I respectfully request that **SB 626**, relating to HIV Prevention, be placed on the:

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



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

THE FLORIDA SENATE
APPEARANCE RECORD

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

2/18/2020
Meeting Date

SB 626
Bill Number (if applicable)

Topic HIV ORGAN DONATION

Amendment Barcode (if applicable)

Name PAUL ARONS MD

Job Title CONSULTANT

Address 1706 BEECHWOOD CIRCLE N.
Street

Phone 850-545-8997

TALLAHASSEE FL 32301
City State Zip

Email paronsmd@gmail.com

Speaking: For Against Information

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

Representing FLORIDA HIV JUSTICE COALITION

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)

2/18/20
Meeting Date

SB 626
Bill Number (if applicable)

Topic HIV

Amendment Barcode (if applicable)

Name Jon Harris Maurer

Job Title Public Policy Dir.

Address 201 E. Park Ave., Ste. 200
Street

Phone 850-681-0980

Tallahassee FL 32301
City State Zip

Email _____

Speaking: For Against Information

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

Representing Equality Florida

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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

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

THE FLORIDA SENATE
APPEARANCE RECORD

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

2.18.20

Meeting Date

SB 626

Bill Number (if applicable)

Topic HIV Prevention

Amendment Barcode (if applicable)

Name Kara Gross

Job Title Legislative Director

Address 4343 West Flagler St.

Phone 786-363-4436

Street

Miami

FL

33134

Email kgross@aclufl.org

City

State

Zip

Speaking: For Against Information

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

Representing American Civil Liberties Union of Florida

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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

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

THE FLORIDA SENATE
APPEARANCE RECORD

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

2/18/2020

Meeting Date

SB0626

Bill Number (if applicable)

Topic HIV Prevention

Amendment Barcode (if applicable)

Name David Poole

Job Title Director of Legislative Affairs

Address 1825 Country Club Dr

Phone 850-766-3323

Street

Tallahassee

FL

32301

Email david.poole@aidshealth.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.

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 780

INTRODUCER: Senator Gainer

SUBJECT: Health Care Licensing Requirements

DATE: February 17, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Brown	HP	Pre-meeting
2.			AHS	
3.			AP	

I. Summary:

SB 780 creates s. 456.0231, F.S., to grant physicians who are employees of the U.S. Department of Veterans Affairs (VA) an exemption from Florida’s physician licensure requirements for the purpose of authorizing such physicians to provide medical treatment to veterans in Florida-licensed hospitals without being licensed to do so, if such physicians submit specified proof and an attestation to the Florida Department of Health (DOH).

The bill has an effective date of July 1, 2020.

II. Present Situation:

Regulation of Health Care Practitioners in Florida

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 boards and six councils, licenses and regulates seven types of health care facilities, and more than 200 license types, in over 40 health care professions.¹ Any person desiring to be a licensed health care professional in Florida must apply to the MQA in writing.² 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.³

¹ Florida Department of Health, Medical Quality Assurance, *Annual Report and Long Range Plan, 2018-2019*, available at: http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1819.pdf (last visited Feb. 13, 2020).

² Section 456.013, F.S.

³ See chs. 401, 456-468, 478, 480, 483, 484, 486, 490, and 491, F.S.

Licensing of Florida Physicians

The regulation of the practices of medicine and osteopathic medicine fall under chapters 458 and 459, F.S., respectively. The practice acts for both professions establish the regulatory boards, a variety of licenses, the application process with eligibility requirements, and financial responsibilities for the practicing physicians. The boards have the authority to establish, by rule, standards of practice and standards of care for particular settings.⁴ Such standards may include education and training, medication including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.⁵

The current licensure application fee for a medical doctor is \$350 and is non-refundable. Applications must be completed within one year. If a license is approved, the initial license fee is \$355. The entire process may take from two to six months from the time the application is received.⁶

For osteopathic physicians, the current application fee is non-refundable \$200, and if approved, the initial licensure fee is \$305.⁷ Applications must be completed within one year. The entire process may take from two to six months from the time the application is received. If an applicant is licensed in another state, the applicant may request that Florida “endorse” the exam scores of the others states licensing exam. The applicant must demonstrate that the out of state license was issued based on those exam scores. The applicant must also show that the exam was substantially similar to any exam that Florida allows for licensure.⁸

The general requirements for licensure under both practice acts are very similar with the obvious differences found in the educational backgrounds of the applicants. However, the practice acts are not identical in their licensure offerings as shown in the table below which compares some of the contents of the two practice acts. Where the practice acts share the most similarities are the qualifications for licensure. Both the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) require their respective applicants to meet these minimum qualifications:

- Complete an application form as designated by the appropriate regulatory board.
- Be at least 21 years of age.
- Be of good moral character.
- Have completed at least two years (medical) or three years (osteopathic) of pre-professional post-secondary education.
- Have not previously committed any act that would constitute a violation of this chapter or lead to regulatory discipline.

⁴ Sections 458.331(1)(v) and 459.015(1)(z), F.S.

⁵ *Id.*

⁶ Florida Board of Medicine, *Medical Doctor Unrestricted – Process*, available at: <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted> (last visited Feb. 13, 2020).

⁷ Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Fees*, available at: <https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/#tab-fees> (last visited Feb. 13, 2020).

⁸ Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure – Requirements*, available at: <https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure> (last visited Feb. 13, 2020).

- Have not had an application for a license to practice medicine or osteopathic medicine denied or a license revoked, suspended or otherwise acted upon in another jurisdiction by another licensing authority.
- Must submit a set of fingerprints to the DOH for a criminal background check.
- Demonstrate that he or she is a graduate of a medical college recognized and approved by the applicant’s respective professional association.
- Demonstrate that she or he has successfully completed a resident internship (osteopathic medicine) or supervised clinical training (medical) of not less than 12 months in a hospital approved for this purpose by the applicant’s respective professional association.
- Demonstrate that he or she has obtained a passing score, as established by the applicant’s appropriate regulatory board, on all parts of the designated professional examination conducted by the regulatory board’s approved medical examiners no more than five years before making application to this state; or, if holding a valid active license in another state, that the initial licensure in the other state occurred no more than five years after the applicant obtained a passing score on the required examination.⁹

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Chapters 458 and 459, F.S.		
Issue	Medical Physicians	Osteopathic Physicians
Regulatory Board	Board of Medicine s. 458.307, F.S.	Board of Osteopathic Medicine s. 459.004, F.S.
Rulemaking Authority	s. 458.309., F.S.	s. 459.005, F.S.
General Requirements for Licensure	s. 458.311, F.S.	s. 459.0055, F.S.
Licensure Types:		
<i>Restricted License</i>	s. 458.310, F.S.	No provision
<i>Restricted License Certain foreign physicians</i>	s. 458.3115, F.S.	No provision
<i>Licensure by Endorsement</i>	s. 458.313, F.S.	No provision
<i>Temporary Certificate (Approved Cancer Centers)</i>	s. 458.3135, F.S.	No provision
<i>Temporary Certificate (Training Programs)</i>	s. 458.3137, F.S.	No provision
<i>Medical Faculty Certificate</i>	s. 458.3145, F.S.	s. 459.0077, F.S.
<i>Temporary Certificate Areas of Critical Need</i>	s. 458.315, F.S.	s. 459.0076, F.S.
<i>Temporary Certificate Areas of Critical Need – Active Duty Military & Veterans</i>	s. 458.3151, F.S.	s. 459.00761, F.S.
<i>Public Health Certificate</i>	s. 458.316, F.S.	No provision
<i>Public Psychiatry Certificate</i>	s. 458.3165, F.S.	No provision

⁹ See ss. 458.311, F.S. and 459.0055, F.S.

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Chapters 458 and 459, F.S.		
Issue	Medical Physicians	Osteopathic Physicians
<i>Limited Licenses</i>	s. 458.317, F.S.	s. 459.0075, F.S.
<i>Expert Witness</i>	s. 458.3175, F.S.	s. 459.0066, F.S.
License Renewal	s. 458.319, F.S. \$500/max/biennial renewal	s. 459.008, F.S.
Financial Responsibility <i>Condition of Licensure</i>	s. 458.320, F.S.	s. 459.0085, F.S.
Penalty for Violations	s. 458.327, F.S.	s. 459.013, F.S.

In Florida, to practice medicine an individual must become a licensed medical doctor through licensure by examination¹⁰ or licensure by endorsement.¹¹ Florida does not recognize automatically another state’s medical license or provide licensure reciprocity. Licensure by endorsement requires the medical physician to meet the following requirements:

- Be a graduate of an allopathic United States Medical School recognized and approved by the United States Office of Education (AMG) and completed at least one year of residency training;
- Be a graduate of an allopathic international medical school (IMG) and have a valid Educational Commission for Foreign Medical Graduates (ECFMG) certificate and completed an approved residency of at least two years in one specialty area; or
- Be a graduate who has completed the formal requirements of an international medical school except the internship or social service requirements, passed parts I and II of the National Board of Medical Examiners (NBME) or ECFMG equivalent examination, and completed an academic year of supervised clinical training (5th pathway) and completed an approved residency of at least two years in one specialty area.
- And both of the following:
 - Passed all parts of a national examination (the NBME; the Federation Licensing Examination offered by the Federation of State Medical Boards of the United States, Inc.; or the United States Medical Licensing Exam); and
 - Be licensed in another jurisdiction and actively practiced medicine in another jurisdiction for at least two of the immediately preceding four years; or passed a board-approved clinical competency examination within the year preceding filing of the application or; successfully completed a board approved postgraduate training program within two years preceding filing of the application.¹²

Financial Responsibility

As a condition of licensure all Florida-licensed allopathic physicians are required to maintain professional liability insurance or other financial responsibility to cover potential claims for medical malpractice as a condition of licensure, with specified exemptions.¹³ Physicians who perform surgeries in a certain setting or have hospital privileges must maintain professional

¹⁰ Section 458.311, F.S.

¹¹ Section 458.313, F.S.

¹² Florida Board of Medicine, *Medical Doctor-Unrestricted; Licensure by Endorsement*, available at: <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted> (last visited Feb. 13, 2020).

¹³ Section 458.320, F.S.

liability insurance or other financial responsibility to cover an amount not less than \$250,000 per claim.¹⁴ Physicians without hospital privileges must carry sufficient insurance or other financial responsibility in coverage amounts of not less than \$100,000 per claim.¹⁵ Certain physicians who are exempt from the requirement to carry professional liability insurance or other financial responsibility must provide notice to their patients.¹⁶

Florida-licensed osteopathic physicians have similar financial responsibility requirements as allopathic physicians¹⁷. With specified exceptions, the DOH must suspend, on an emergency basis, any licensed allopathic or osteopathic physician who fails to satisfy a medical malpractice claim against him or her within specified time frames.¹⁸

Disciplinary Process: Fines and Sanctions

Chapter 456, F.S., contains the general regulatory provisions for health care professions and occupations under the Division of Medical Quality Assurance (MQA) in the DOH. Section 456.072, F.S., specifies 40 acts that constitute grounds for which disciplinary actions may be taken against a health care practitioner. Section 458.331, F.S., identifies 43 acts that constitute grounds for which disciplinary actions may be taken against a medical physician and s. 459.015, F.S., identifies those acts which are specific to an osteopathic physician. Some parts of the review process are public and some are confidential.¹⁹

Complaints and allegations are received by the MQA unit for determination of legal sufficiency and investigation. A determination of legal sufficiency is made if the ultimate facts show that a violation has occurred.²⁰ The complainant is notified by letter as to the whether the complaint will be investigated and if any additional information is needed. Complaints which involve an immediate threat to public safety are given the highest priority.

The DOH is responsible for reviewing each report to determine if discipline against the provider is warranted.²¹ Authorization for the discipline of allopathic and osteopathic physicians can be found in state law and administrative rule.²² If held liable for one of the offenses, the fines and sanctions by category and by offense are based on whether it is the physician's first, second, or third offense.²³ The boards may issue a written notice of noncompliance for the first occurrence

¹⁴ Section 458.320(2), F.S.

¹⁵ Section 458.320(1), F.S.

¹⁶ Section 458.320(5)(f) and (g), F.S.

¹⁷ Section 459.0085, F.S.

¹⁸ Sections 458.320(8) and 459.0085(9), F.S.

¹⁹ Florida Department of Health, Division of Medical Quality Assurance, *Enforcement Process*, available at: http://www.floridahealth.gov/licensing-and-regulation/enforcement/_documents/enforcement-process-chart.pdf (last updated Nov. 2019) (last visited Feb. 13, 2020).

²⁰ Florida Department of Health, *Consumer Services – Administrative Complaint Process*, available at: <http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/consumer-services.html> (last visited Feb. 13, 2020).

²¹ See ss. 458.351(5) and 459.026(5), F.S.

²² See ss. 458.307 and 459.004, F.S., for the regulatory boards, and ss. 64B8-8 and 64B15-19, F.A.C., for administrative rules relating to disciplinary procedures.

²³ *Id.*

of a single minor violation.²⁴ The amount of fines assessed can vary depending on the severity of the situation, such as improper use of a substance to concealment of a material fact. A penalty may come in the form of a reprimand, a licensure suspension, or revocation followed by some designated period of probation if there is an opportunity for licensure reinstatement. Other sanctions may include supplemental continuing education requirements which require proof of completion before the license can be reinstated.

Disciplinary Process: Emergency Procedures

When a third report of a professional liability claim has been submitted, within a five-year period, against a licensed physician, the DOH is required to initiate an emergency investigation and the BOM or BOOM must conduct an emergency probable cause hearing to determine if a physician should be disciplined for committing medical malpractice, gross medical malpractice, or repeated medical malpractice.²⁵

Disciplinary Process: Physician's Consent

During an investigation of a complaint, every Florida-licensed physician is deemed to have given his or her consent to the following:²⁶

- To render a handwriting sample to an agent of the DOH and waive any objections to its use as evidence;
- To waive the confidentiality and authorize the preparation and release of medical reports, including symptoms, diagnosis, treatment prescribed, relevant history, and progress, pertaining to his or her mental or physical condition; and
- To waive any objection to the admissibility of the reports as constituting privileged communications.

The DOH may issue subpoenas *duces tecum*, requiring the names and addresses of some or all of the patients of a licensed physician against whom a complaint has been filed pursuant to s. 456.073, F.S.²⁷

Itemized Patient Billing

All licensed allopathic and osteopathic physicians are required, upon request, to provide to a patient an itemized statement of the specific services rendered and the charge for each service.²⁸

Florida Background Checks

Effective January 1, 2013, all applicants for initial physician licensure must undergo a Level 2 background screening²⁹ and use a Livescan provider³⁰ to submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to applicant. The results of the search are returned to the Care Provider Background Screening Clearinghouse and made

²⁴ Sections 64B8-8.011 and 64B15-19.0065, F.A.C. A minor violation is deemed to not endanger the public health, safety, and welfare and does not demonstrate a serious inability to practice.

²⁵ See ss. 458.3311 and 459.0151, F.S.

²⁶ See ss. 458.339 and 459.017, F.S.

²⁷ See ss. 458.343 and 459.019, F.S.

²⁸ See ss. 458.323 and 459.012, F.S.

²⁹ Sections 435.04 and 458.311(1)(g), FS.

³⁰ Section 435.12, F.S.

available to the DOH for consideration during the licensure process. The fingerprints submitted by the applicant are retained by FDLE and the Clearinghouse. All costs for conducting a criminal history background screening are borne by the applicant.³¹

Applicants for physician licensure can use any FDLE-approved Livescan provider to submit their fingerprints. The applicant is fully responsible for selecting the service provider and ensuring the results are reported to the DOH. An applicant must use a DOH form available on its website and take it to the Livescan provider.³²

A physician licensed in Florida must undergo a Level 2 background screening every five years. Effective January 1, 2019, the fee to retain fingerprints within the Clearinghouse is \$43.25, plus minimal service fee. Once fingerprints have been retained by the Clearinghouse, they are good for five years. Clearinghouse renewals can only be requested within a specific timeframe that is based on the retained print expiration date.

VA Practitioners in Florida

Health care practitioners practicing in VA facilities in Florida are not required to be licensed in Florida. In order for a practitioner to practice at any VA facility, the VA requires the practitioner to have an active, unrestricted license from any state.³³ Thus, a VA health care practitioner may treat any veteran in a VA facility located in Florida, regardless of the state of licensure. However, a VA practitioner may not provide medical services to any patient, veteran or otherwise, outside of a VA facility unless he or she holds a Florida license. If a VA practitioner is not licensed in Florida and provides such services outside a VA facility, the practitioner could be prosecuted for the unlicensed practice of a health care practitioner.

VA Background Checks

All VA employees are subject to an evaluation process for the purpose of determining their suitability for work through a background investigation process. The level of investigation is determined by the sensitivity of the position in question, which is then rated as low, moderate, or high risk. At a minimum, VA employees should receive a Tier 1 investigation to verify that the individual is suitable for employment. Most medical facility staff, including physicians, nurses, pharmacists, and laboratory technicians, are required to receive this type of investigation.³⁴

In March 2018, the VA Office of Inspector General published the findings of an investigation conducted to evaluate controls over the adjudication of background investigations at VA medical facilities for the five-year period ending September 30, 2016. The report included the following:³⁵

³¹ Florida Board of Medicine, *Board of Medicine, Medical Doctor – Licensure Requirements*, available at: <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted> (last visited Feb. 13, 2020).

³² *Id.*

³³ U.S. Department of Veterans Affairs, *Navigating the Hiring Process*, available at: <https://www.vacareers.va.gov/ApplicationProcess/NavigatingHiringProcess> (last visited Feb. 13, 2020).

³⁴ VA Office of Inspector General, *Veterans Health Administration, Audit of Personnel Suitability Program*, p. 1, available at: <https://www.va.gov/oig/pubs/VAOIG-17-00753-78.pdf> (last visited Feb. 13, 2020).

³⁵ *Id.* pp. i-ii

- The VA did not provide effective governance of the personnel suitability program necessary to ensure that background investigation requirements were met at medical facilities nationwide;
- While background investigations were required for most medical facility staff, about 6,200 employees who were working at the facilities did not have a background investigation initiated, including health care practitioners who were employed to provide direct patient care to veterans;³⁶
- VA adjudicators had not been reviewing background investigations timely, and suitability program staff were not maintaining official personnel records as required;
- The VA office responsible for evaluating compliance with personnel suitability program requirements, including the background investigation process, lacked sufficient staff to conduct regular oversight;
- The VA personnel suitability program was allowed to operate unmonitored and without assurance that background investigations were properly initiated and adjudicated; and
- The VA could not reliably attest to the suitability of its largest workforce, thereby exposing veterans and employees to individuals who have not been properly vetted.

III. Effect of Proposed Changes:

SB 780 creates s. 456.0231, F.S., to grant physicians who are employees of the VA an exemption from Florida's physician licensure requirements when providing medical treatment to veterans in a Florida-licensed hospital, if such physicians meet certain criteria and furnish specified documentation to the DOH.

The bill defines "physician" as a person who holds an active, unencumbered license to practice allopathic medicine or osteopathic medicine issued by another state; the District of Columbia; or a possession, commonwealth, or territory of the United States.

To be exempt from Florida licensure requirements pertaining to medical doctors under ch. 458, F.S., or osteopathic physicians under ch. 459, F.S., such a physician must submit the following to the DOH:

- Proof that the physician holds an active, unencumbered license to practice allopathic medicine or osteopathic medicine, as applicable, issued by another state; the District of Columbia; or a possession, commonwealth, or territory of the United States;
- Proof of current employment with the VA; and
- An attestation that he or she will only provide medical services:
 - To veterans.
 - Pursuant to his or her employment with the VA.
 - In Florida-licensed hospitals.

The bill requires the DOH to notify the physician within 15 business days after receipt of the proof and attestation described above that the physician is exempt.

The bill authorizes the DOH to adopt rules to administer the bill's provisions.

³⁶ *Id.* p. 4

The bill has 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:

SB 780 may provide an avenue for veterans who do not live near a VA facility and/or face transportation problems with getting to a VA facility, to receive medical services from VA physicians at a Florida-licensed hospital that is more accessible.

C. Government Sector Impact:

The bill may increase the workload on DOH staff due to the need to process the exemptions authorized under the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill is entitled, “An act relating to health care licensing requirements,” but the bill’s effects are limited to the creation of a licensure *exemption* that may be issued to certain *physicians* to allow them to practice medicine in Florida hospitals without being licensed by the State of

Florida to do so. The bill's title could apply to any licensed health care practitioner or any licensed health care facility and does not seem to adequately represent the bill's effects.

Under the bill, individuals exempt from the licensure requirements of chs. 458 and 459, F.S., will also be exempt from the BOM and BOOM standards of practice. Under current law, the BOM and BOOM have the authority to investigate and discipline licensed physicians. Under the bill, certain physicians will not have a Florida license; therefore, the boards would not have authority or jurisdiction to discipline physicians that are exempt under the bill. If physicians who are exempt under this bill fail to meet the standard of care or cause patient harm, it does not appear that Florida will have the authority to discipline these physicians, and it is unknown if the state or territory where they have an active license would have jurisdiction.

A physician may have a license in multiple states. Under the bill, as long as a physician has an active, unencumbered license in one state or territory, he or she would be able to practice in Florida hospitals, even if there were extensive disciplinary actions in other states. Checking previous disciplinary actions in other states is part of Florida's licensing process, which will not apply under the bill.

There are also a wide range of statutory and regulatory requirements throughout the Florida Statutes that apply only to physicians licensed under Florida law. Examples include provisions on kickbacks, required disclosures to patients, reporting of adverse incidents, and other reporting requirements. Since physicians exempted under the bill would be unlicensed, it appears that they would not be subject to any of those provisions.

Each physician exempted from licensure under the bill will result in a deferral of criminal background checks and fingerprinting, which would normally occur before a physician is allowed to practice in the state outside of a VA facility. Therefore, a physician exempted under the bill who has committed a Florida-licensure disqualifying offense may still be able to practice in Florida hospitals under the bill.

The bill provides that physicians employed by the VA can become exempt from Florida's physician licensure statutes and that the DOH must notify them of their exemption upon the receipt of specified documentation. However, the bill does not provide any circumstances for such an exemption to expire or be revoked for any reason. The bill is silent as to whether an exemption remains in effect after the physician is no longer employed by the VA or is no longer licensed to practice medicine by another state, the District of Columbia, or a possession, commonwealth, or territory of the United States.

The bill provides that as a condition of receiving the exemption, a physician must attest that he or she will only provide medical services to veterans, pursuant to his or her employment with the U.S. Department of Veterans Affairs, in Florida-licensed hospitals. However, because the bill does not authorize the DOH to revoke an exemption for any reason, the physician could technically remain exempt from Florida's physician licensure requirements, regardless of whether he or she abides by the attestation, with no expiration date for the exemption.

On lines 25-39, the bill requires a physician seeking exemption to submit the proof and attestation described above. However, the bill provides no guidance to the DOH regarding what

constitutes such proof or what form the attestation must take. The bill also provides the DOH no specific authority to deny a person the exemption for any reason, including inadequate proof or an inadequate attestation.

VIII. Statutes Affected:

This bill creates section 456.0231 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

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

By Senator Gainer

2-00971-20

2020780__

1 A bill to be entitled
 2 An act relating to health care licensing requirements;
 3 creating s. 456.0231, F.S.; defining the term
 4 "physician"; exempting certain health care
 5 practitioners from specified licensing requirements
 6 when providing certain services to veterans in this
 7 state; requiring such health care practitioners to
 8 submit certain information to the Department of
 9 Health; requiring the department to notify such health
 10 care practitioners of their exemption within a certain
 11 timeframe; authorizing the department to adopt rules;
 12 providing an effective date.

13
 14 Be It Enacted by the Legislature of the State of Florida:

15
 16 Section 1. Section 456.0231, Florida Statutes, is created
 17 to read:

18 456.0231 Exemption of health care license requirements for
 19 the treatment of veterans.-

20 (1) As used in this section, the term "physician" means a
 21 person who holds an active, unencumbered license to practice
 22 allopathic medicine or osteopathic medicine issued by another
 23 state, the District of Columbia, or a possession, commonwealth,
 24 or territory of the United States.

25 (2) A physician must submit to the department all of the
 26 following to be exempt from the licensure requirements of
 27 chapters 458 and 459:

28 (a) Proof that he or she holds an active, unencumbered
 29 license to practice allopathic medicine or osteopathic medicine

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30 issued by another state, the District of Columbia, or a
31 possession, commonwealth, or territory of the United States.

32 (b) Proof of current employment with the United States
33 Department of Veterans Affairs.

34 (c) An attestation that he or she will only provide medical
35 services:

36 1. To veterans.

37 2. Pursuant to his or her employment with the United States
38 Department of Veterans Affairs.

39 3. In hospitals licensed under chapter 395.

40 (3) The department shall notify the physician within 15
41 business days after receipt of the documentation required by
42 subsection (2) that the physician is exempt from the licensure
43 requirements of chapters 458 and 459.

44 (4) The department may adopt rules to administer this
45 section.

46 Section 2. This act shall take effect July 1, 2020.

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 714

INTRODUCER: Health Policy Committee and Senator Hutson

SUBJECT: Testing for and Treatment of Influenza and Streptococcus

DATE: February 20, 2020

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 714 amends the definition of the “practice of the profession of pharmacy” to include the testing for and treatment of influenza by a pharmacist under a written protocol with a primary care supervising physician that includes specific terms and conditions.

The bill authorizes a pharmacist to test for and treatment influenza, if the pharmacist:

- Completes a certification program with specific requirements approved by the Board of Medicine (BOM), in consultation with the Board of Osteopathic Medicine (BOOM) and the Board of Pharmacy (BOP), that must be developed and implemented within 90 days of the bill’s effective date;
- Uses a specific instrument and a waived test;
- Uses a specific testing system that meets certain criteria;
- Obtains a complete medical history on a BOM-approved form;
- Provides pharmacy signage recommending follow-up for patients tested;
- Provides the patient with the name and contact information of the supervising physician;
- Provides the patient with a BOM-approved pamphlet or brochure that includes advising the patient:
 - To seek follow-up care if the test is positive; and
 - That the pharmacist and pharmacy are liable for damages from adverse reactions;
- Treats patients only with medications approved by the BOM and reviewed annually;
- Reviews the patient’s prescription history for contraindications;

- Maintains at least \$250,000 of professional liability insurance; and
- Maintains, and makes available, medical records for five years using prescribed standards.

The bill also specifies certain persons whom a pharmacist may not test or treat for influenza and that a supervising physician may not supervise pharmacists employed at more than four pharmacy locations.

The bill takes effect upon becoming a law.

II. Present Situation:

The Practice of Pharmacy

Pharmacy is the third largest health profession behind nursing and medicine.¹ The BOP, in conjunction with the Department of Health (DOH), regulates the practice of pharmacists and pharmacies pursuant to ch. 465, F.S.² There are seven types of pharmacies eligible for various operating permits issued by the DOH:

- Community pharmacy;
- Institutional pharmacy;³
- Nuclear pharmacy;⁴
- Special pharmacy;⁵
- Internet pharmacy;⁶
- Non-resident sterile compounding pharmacy;⁷ and
- Special sterile compounding pharmacy.⁸

Pharmacist Licensure

To be licensed as a pharmacist in Florida, a person must:⁹

- Complete an application and remit an examination fee;

¹ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited Feb. 13, 2020).

² Sections 465.004 and 465.005, F.S.

³ See ss. 465.003(11)(a)2. and 465.019, F.S.

⁴ The term “nuclear pharmacy” includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals. See ss. 465.003(11)(a)3. and 465.0193, F.S.

⁵ The term “special pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection. See ss. 465.003(11)(a)4. and 465.0196, F.S.

⁶ The term “internet pharmacy” includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. See ss. 465.003(11)(a)5. and 465.0197, F.S.

⁷ The term “nonresident sterile compounding pharmacy” includes a pharmacy that ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida, a nonresident pharmacy registered under s. 465.0156, F.S., or an outsourcing facility, must hold a nonresident sterile compounding permit See s. 465.0158, F.S.

⁸ See Fla. Admin. Code R. 64B16-2.100 and 64B16-28.802 (2019). An outsourcing facility is considered a pharmacy and needs to hold a special sterile compounding permit if it engages in sterile compounding.

⁹ Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. See s. 465.0075, F.S.

- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;¹⁰
- Have completed a BOP-approved internship; and
- Successfully complete the BOP-approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial renewal period.¹¹ Pharmacists who are certified to administer vaccines or epinephrine autoinjections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.¹² Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for biennial licensure renewal.¹³

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:¹⁴

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;¹⁵
- Administering vaccines to adults;¹⁶
- Administering epinephrine injections;¹⁷ and
- Administering antipsychotic medications by injection.¹⁸

A pharmacist may not alter a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.¹⁹

¹⁰ If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist.

¹¹ Section 465.009, F.S.

¹² Section 465.009(6), F.S.

¹³ Section 465.1893, F.S.

¹⁴ Section 465.003(13), F.S.

¹⁵ A Class III institutional pharmacy are those pharmacies affiliated with a hospital. *See* s. 465.019(2)(d), F.S.

¹⁶ *See* s. 465.189, F.S.

¹⁷ *Id.*

¹⁸ Section 465.1893, F.S.

¹⁹ Section 465.003(13), F.S.

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Boards of Medicine (BOM), Board of Osteopathic Medicine (BOOM), and the BOP.²⁰ The formulary may only include:²¹

- Medicinal drugs of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);
- Medicinal drugs recommended by the FDA's Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Medicinal drugs containing an antihistamine or decongestant as a single active ingredient or in combination;
- Medicinal drugs containing fluoride in any strength;
- Medicinal drugs containing lindane in any strength;
- Over-the-counter proprietary drugs under federal law that have been approved for reimbursement by the Florida Medicaid Program; and
- Topical anti-infectives, excluding eye and ear topical anti-infectives.

A pharmacist may order, within his or her professional judgment and subject to the stated conditions:²²

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

²⁰ Section 465.186, F.S.

²¹ Id.

²² Fla. Admin. Code R. 64B16-27.220, (2019).

- Topical Antiviral for herpes simplex infections of the lips.²³

One category of pharmacist has a broader scope of practice than other pharmacists. A consultant pharmacist, also known as a senior care pharmacist, provides expert advice on the use of medications to individuals or older adults, wherever they live.²⁴ In addition to the training and education received as a part of a degree program in pharmacy, a consultant pharmacist must complete a consultant pharmacy course and a period of assessment and evaluation under the supervision of a preceptor.²⁵

A consultant pharmacist may order and evaluate laboratory testing in addition to the services provided by a pharmacist. For example, a consultant pharmacist can order and evaluate clinical and laboratory testing for a patient residing in a nursing home upon authorization by the medical director of the nursing home.²⁶ Additionally, a consultant pharmacist may order and evaluate clinical and laboratory testing for individuals under the care of a licensed home health agency, if authorized by a licensed physician, podiatrist, or dentist.²⁷

Pharmacist Administration of Vaccines and Injections

A pharmacist may become certified to administer the immunizations or vaccines listed in the Centers for Disease Prevention and Control (CDC) Adult Immunization Schedule as of February 1, 2015, as well as those recommended for international travel as of July 1, 2015.²⁸ To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol under a supervising physician licensed under ch. 458, or ch. 459, F.S.;²⁹ which must:³⁰
 - Specify the categories and conditions among patients to whom the pharmacist may administer such vaccines;
 - Be appropriate to the pharmacist's training and certification for administering such vaccine;
 - Outline the process and schedule for the review of the administration of vaccines by the pharmacists pursuant to the written protocol; and
 - Be submitted to the BOP;
- Successfully complete a BOP-approved vaccine administration certification program that consists of at least 20 hours of continuing education;³¹
- Pass an examination and demonstrate vaccine administration technique;³²

²³ Fla. Admin. Code R. 64B16-27.220 (2019).

²⁴ American Society of Consultant Pharmacists, *What is a Consultant Pharmacist*, available at <http://www.ascp.com/page/whatisacp> (last visited Feb. 13, 2020).

²⁵ Fla. Admin. Code R. 64B16-26.300(3), (2019).

²⁶ Section 465.0125(1), F.S.

²⁷ Section 465.0125(2), F.S. To qualify to order and evaluate such testing, the consultant pharmacist or doctor of pharmacy must complete 3 hours of board-approved training, related to laboratory and clinical testing.

²⁸ Section 465.189, F.S. A registered intern may also administer immunizations or vaccinations under the supervision of a certified pharmacist.

²⁹ Section 465.189(1), F.S.

³⁰ Section 465.189(7), F.S.

³¹ Section 465.189(6), F.S., Fla. Admin. Code R. 64B16-26.1031,(2019), provides more detail regarding subject matter that must be included in the certification course.

³² *Id.*

- Must maintain and make available patient records using the same standards for confidentiality and maintenance of such records as required by s. 456.057, F.S., and maintain the records for at least five years;³³ and
- Maintain at least \$200,000 of professional liability insurance.³⁴

A pharmacist may also administer epinephrine using an autoinjector delivery system, within the framework of the established protocol with the supervising physician, to treat any allergic reaction resulting from a vaccine.³⁵ A pharmacist administering vaccines must provide the DOH with vaccination records for inclusion in the state's registry of immunization information.³⁶

Pharmacist Administration of Antipsychotic Medication by Injection

In 2017, the Legislature authorized a licensed pharmacist to administer an injection of a long-acting antipsychotic medication³⁷ approved by the United States Food and Drug Administration.³⁸ To be eligible to administer such injections, a pharmacist must:³⁹

- Be authorized by and acting within the framework of a protocol with the prescribing physician;
- Practice at a facility that accommodates privacy for nondeltoid injections and conforms with state rules and regulations for the appropriate and safe disposal of medication and medical waste;⁴⁰ and
- Complete an approved eight-hour continuing education course that includes instruction on the safe and effective administration of behavioral health and antipsychotic medications by injection, including potential allergic reactions.

A separate prescription from a physician is required for each injection a pharmacist administers.⁴¹

³³ Section 456.057, F.S., requires certain health care practitioners to develop and implement policies, standards, and procedures to protect the confidentiality and security of medical records, provides conditions under which a medical record may be disclosed without the express consent of the patient, provides procedures for disposing of records when a practice is closing or relocating, and provides for enforcement of its provisions.

³⁴ Section 465.189(3), F.S.

³⁵ Section 465.189(2), F.S.

³⁶ Section 465.189(5), F.S.

³⁷ A long-acting injectable antipsychotic medication may be prescribed to treat symptoms of psychosis associated with schizophrenia or as a mood stabilizer in individuals with bipolar disorder. A long-acting injectable may last from two to 12 weeks. It may be prescribed for individuals who have difficulty remembering to take daily medications or who have a history of discontinuing medication. National Alliance on Mental Illness, *Long-Acting Injectables*, available at <https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Long-Acting-Injectables> (last visited Feb 13, 2020).

³⁸ Chapter 2017-134, Laws of Fla., codified at s. 465.1893, F.S.

³⁹ *Id.*

⁴⁰ Section 381.0098, F.S., and Fla. Admin. Code R. 64E-16, (2019), regulate the disposal of biomedical waste.

⁴¹ Section 465.1893(1)(b), F.S.

Diagnostic Tests for Influenza and Streptococcus

Influenza

Influenza (flu) is a contagious viral respiratory illness that infects the nose, throat, and sometimes the lungs. It can cause mild to severe illness, and at times can lead to death.⁴² There are four types of flu virus: Types A, B, C, and D. The influenza A and B viruses are responsible for seasonal flu epidemics each year.⁴³ Influenza type C infections generally cause mild illness and are not thought to cause human flu epidemics. Influenza D viruses primarily affect cattle and are not known to infect or cause illness in people. Influenza A viruses are the only influenza viruses known to cause flu pandemics, i.e., global epidemics of flu disease.⁴⁴

Flu Symptoms

Flu is different from a cold. Flu usually comes on suddenly. People who have flu often feel some, or all, of these symptoms:

- Fever or feeling feverish/chills;
- Cough;
- Sore throat;
- Runny or stuffy nose;
- Muscle or body aches;
- Headaches;
- Fatigue (tiredness); and

Some people may have vomiting and diarrhea, though this is more common in children than adults.⁴⁵

Flu Complications

Most people who get the flu will recover in a few days to less than two weeks, but some people will develop moderate complications as a result of flu, including:

- Ear infections;
- Sinus infections; and
- Worsening of chronic medical conditions, such as:
 - Congestive heart failure;
 - Asthma; or
 - Diabetes.⁴⁶

Serious complications can also be triggered by flu and can cause:

- Heart inflammation (myocarditis);

⁴² Centers for Disease Control and Prevention, *Key Facts about Influenza (Flu)*, (last reviewed July 10, 2019) available at <https://www.cdc.gov/flu/about/keyfacts.htm> (last visited Feb 13, 2020).

⁴³ Center for Disease Control and Prevention, *Influenza (Flu)*, available at <https://www.cdc.gov/flu/about/viruses/index.htm> (last visited Feb. 13, 2020).

⁴⁴ Center for Disease Control and Prevention, *Types of Influenza Viruses*, (November 18, 2019) available at <https://www.cdc.gov/flu/about/viruses/types.htm> (last visited Feb. 13, 2020).

⁴⁵ See note 43. It's important to note that not everyone with flu will have a fever.

⁴⁶ Center for Disease Control and Prevention, *Flu Symptoms & Complications*, (September 18, 2019) available at <https://www.cdc.gov/flu/symptoms/symptoms.htm> (last visited Feb. 13, 2020).

- Brain inflammation (encephalitis);
- Muscle tissue inflammation (myositis, rhabdomyolysis);
- Multi-organ failure (respiratory and kidney failure); and
- Death.⁴⁷

Most people who get sick with flu will have a mild illness, will not need medical care or antiviral drugs, and will recover in less than two weeks. However people with the following health and age factors are at a higher risk of experiencing serious flu complications:

- Adults 65 years and older;
- Children younger than two years old;
- Pregnant women and women up to two weeks after the end of pregnancy;
- American Indians and Alaska Natives;
- People who live in nursing homes and other long-term care facilities;
- People who are obese with a body mass index (BMI) of 40 or higher;
- People younger than 19 years of age on long-term aspirin or salicylate medications;
- People with a weakened immune system due to disease (HIV, some cancers like leukemia) or medications (such as those receiving chemotherapy or radiation treatment for cancer, or persons with chronic conditions requiring chronic corticosteroids or other drugs that suppress the immune system);
- People with:
 - Asthma;
 - Neurologic and neurodevelopment conditions;
 - Blood disorders (such as sickle cell disease);
 - Chronic lung disease (chronic obstructive pulmonary disease and cystic fibrosis);
 - Endocrine disorders (such as diabetes mellitus);
 - Heart disease (congenital heart disease, congestive heart failure and coronary artery disease);
 - Kidney disorders;
 - Liver disorders; and
 - Metabolic disorders (inherited metabolic disorders and mitochondrial disorders).⁴⁸

Diagnostic Tests for Flu

In recent years, the FDA has approved several rapid influenza diagnostic tests (RIDTs) to identify the influenza A and B virus nucleoprotein antigens in respiratory specimens and display the result as either positive or negative. These tests can provide results within approximately 15 minutes and may be used to help with diagnosis and treatment decisions for patients. Some RIDTs use an analyzer reader device to standardize the result interpretations. However, a variety of factors can influence the accuracy of a RIDT, including the type of specimen tested, time from illness onset to collection of respiratory specimen for testing, and the prevalence of flu activity in

⁴⁷ Id.

⁴⁸ Center for Disease Control and Prevention, *People at High Risk For Flu Complications*, (last reviewed August 27, 2018), available at <https://www.cdc.gov/flu/highrisk/index.htm> (last visited Feb. 13, 2020).

the area. False positive results are more likely at the beginning or end of the flu season or during the summer. False negative results are more likely at the peak of the flu season.⁴⁹

Rapid molecular assays are a new tests available to detect influenza virus infection and include the Reverse Transcription-Polymerase Chain Reaction (RT-PCR) test, and other nucleic acid amplification tests. These tests can detect influenza viral ribonucleic acid (RNA) or nucleic acids in respiratory specimens with high sensitivity and high specificity, but the detection does not necessarily indicate a live virus or ongoing viral replication. Rapid molecular assays can provide results in approximately 15-30 minutes. These tests are more accurate than RIDTs and the Infectious Diseases Society of America recommends the rapid molecular assays over RIDT for detecting the flu virus in outpatients. As with RIDTs, the accuracy of rapid molecular assays may be affected by the source of the specimen, specimen handling, and the timing of the collection of the specimen. False negative results may occur due to improper or clinical specimen collection or handling or if the specimen is collected when the patient is no longer shedding detectable flu virus. Although a false positive is rare, it can occur through lab contamination or other factors.⁵⁰

Testing is not needed for all patients with signs and symptoms of flu to make antiviral treatment conditions. A health care practitioner may diagnose an individual with the flu based on symptoms and his or her clinical judgment, irrespective of the test results.⁵¹

Some pharmacies may currently provide flu testing, as well as other health screenings.⁵² However, these pharmacies vary by the types of patients seen, the array of services offered, the type of health care practitioner available, and the type of medications prescribed.

Reporting of Diseases to the Department of Health

Any licensed physician, chiropractic physician, nurse, midwife, medical examiners, hospitals, laboratories, or veterinarians licensed in this state must immediately report the diagnosis or suspected diagnosis of a disease of public health importance to the DOH. The DOH, by rule, has designated the diseases and conditions that must be reported, as well as the timeframes for such reports. A suspected or confirmed diagnosis of the flu that is caused by a by novel or pandemic strain must be reported immediately. However, strep throat is not among the diseases or conditions that must be reported. The practitioner must report the disease or condition on a form developed by the DOH, which includes information such as the patient's name, demographic information, diagnosis, test procedure used, and treatment given. The practitioner must make the patient's medical records for such diseases available for onsite inspection by the DOH.⁵³

⁴⁹ Center for Disease Control and Prevention, *Rapid Influenza Diagnostic Tests*, (last reviewed October 25, 2016), available at https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm (last visited Feb. 13, 2020).

⁵⁰ Centers for Disease Control and Prevention, *Information on Rapid Molecular Assays, RT-PCR, and other Molecular Assays for Diagnosis of Influenza Virus Infection*, (last reviewed October 21, 2019), available at <https://www.cdc.gov/flu/professionals/diagnosis/molecular-assays.htm> (last visited Feb. 13, 2020).

⁵¹ Id.

⁵² See examples: CVS Pharmacy offers services through its MinuteClinic®, which is staffed by nurse practitioners or physician assistants (see CVS, *MinuteClinic® Services*, available at <https://www.cvs.com/minuteclinic/services?WT.ac=MC-Home-Badge1-services> (last visited Feb. 13, 2020)

⁵³ Section 381.0031, F.S., and Fla. Admin. Code R. 64D-3.029 and 64D-3.030, (2019). See also Florida Department of Health, *Health Care Practitioner Reporting Guidelines for Reportable Diseases and Conditions in Florida*, (October 20,

III. Effect of Proposed Changes:

Section 1 amends s. 381.0031, F.S., which requires certain health care practitioners, hospitals, and federally-certified laboratories which diagnoses or suspects the existence of a disease of public health significance to report that fact to the DOH. The bill adds the licensed pharmacist with written protocol with a physician that includes ordering and evaluating laboratory and clinical tests to those required to report.

Section 2 amends the definition of the “practice of the profession of pharmacy” to include the testing for, and treatment of, influenza pursuant to s. 465.1895, F.S., which is created by the bill.

Section 3 creates s. 465.1895, F.S., which permits a pharmacist to test for and treat influenza if the pharmacist meets all of the following requirements:

- Enters into a written protocol with a supervising physician licensed under chapters 458 or 459, F.S., which meets the requirements for a written protocol pursuant to BOM rules, adopted in consultation with the BOOM and the BOP, that includes, at a minimum:
 - Terms and conditions required by s. 465.189(7), F.S., which includes;
 - That the pharmacist, or his designee, must follow up with the patient three days later to determine whether the patient’s condition has improved; and
 - If the patient’s condition has not improved, the pharmacist must do all of the following:
 - Recommend that the patient seek treatment with the patient’s primary care physician or, if the patient has no primary care physician, from the pharmacist’s supervising physician;
 - Inform the patient’s primary care physician that the patient’s condition failed to improve three days after treatment or, if the patient has no primary care physician, the pharmacist must so inform the pharmacist’s supervising physician; and
 - Document in the patient’s records whether the follow-up occurred or whether attempts to contact the patient were unsuccessful.
 - Instructions for the treatment of influenza based on the patient’s age, symptoms, and test results, including negative results;
 - A process and schedule for the supervising physician to review the pharmacist’s actions under the written protocol;
 - A process and schedule for the pharmacist to notify the supervising physician of the patient’s condition, tests administered, test results, and course of treatment; and
 - A procedure to notify the patient’s primary care provider within two business days after providing any such testing or treatment, when the patient has one.
- Uses instruments and waived tests, as defined in 42 C.F.R. s. 493.2.
- Uses a testing system that:
 - Provides automated readings in order to reduce user subjectivity or interpretation of results;
 - Is capable of directly or indirectly interfacing with electronic medical records systems;
 - Is capable of electronically reporting daily deidentified test results to the appropriate agencies; and

- Uses an instrument that incorporates both internal and external controls and external calibration that show the reagent and assay procedure is performing properly. External controls must be used in accordance with local, state, and federal regulations and accreditation requirements.
- Is certified through a certification program approved by the BOM, in consultation with the BOOM and the BOP. The program must:
 - Be developed and implemented within 90 days of the effective date of the bill.
 - Require eight hours of BOM-approved continuing education with a curriculum approved by the Accreditation Council for Pharmacy Education; and
 - Provide instructional services, including at a minimum, point-of-care testing for influenza and the safe and effective treatment of influenza.
- Has obtained a full past and present history from the patient on a form promulgated and adopted by rule of the BOM which allows the patient to check off medical conditions from a list and add other conditions that are not listed.
- Prominently displays signage indicating that any patient tested and treated at the pharmacy is advised to seek follow-up care from his or her primary care physician or, if the patient has no primary care physician, from the pharmacist's supervising physician.
- Provides the patient with the name and contact information of the pharmacist's supervising physician and a pamphlet or brochure that meets criteria established by BOM rule informing the patient that:
 - If the test indicates that the patient has influenza, the patient is advised to seek follow-up care from the patient's primary care physician or, if the patient has no primary care physician, from the pharmacist's supervising physician; and
 - If the pharmacist treats the patient for influenza, the pharmacist and the pharmacy where the testing and treating occurred are liable for damages the patient suffers as a result of an adverse reaction to the treatment.
- Treats only with limited medications designed to treat influenza which are approved by the BOM and which the BOM reviews annually.
- Reviews the patient's current prescriptions and recent prescription history to check for relative contraindications involving the intended treatment.
- Maintains at least \$250,000 of professional liability insurance.
- Maintains, and makes available, patient records, including the required patient history, test results, and the name and contact information of the pharmacist's supervising physician, for at least five years, using the same standards for confidentiality and record maintenance as required under s. 456.057, F.S.

The bill specifies that a pharmacist may not test for or treat influenza for a patient who:

- Is younger than 18 years of age;
- Is older than 75 years of age;
- Refuses to provide a medical history; or
- Provides a medical history indicating a history of conditions relating to:
 - Heart disease;
 - Bronchial disorders;
 - Pneumonia;
 - Chronic obstructive pulmonary disease;
 - Asthma; or

- Any other medical conditions the BOM specifies annually by rule.

The bill requires that a supervising physician who enters into a written protocol with a pharmacist must be a primary care physician who is actively practicing in the community in which the pharmacist tests and treats according to BOM rule. A supervising physician may not supervise pharmacists employed at more than four pharmacy locations.

The bill provides that the supervising physician's decision to enter into a written protocol with a pharmacist for the testing and treatment of flu and strep is a professional decision and no person may interfere with that decision regarding entering into such a protocol.

Implementation of s. 465.1895, F.S., as created by the bill, is contingent on the enactment of an appropriation within the General Appropriations Act which is sufficient to fund the BOM's required duties under the bill.

Section 4 provides that the bill takes effect upon becoming a law.

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 Department of Health did not provide a fiscal impact estimate for this bill. The BOM may incur an unknown amount of recurring costs to carry out its responsibilities under the bill, and implementation of those duties is subject to the enactment of an appropriation within the General Appropriations Act which is sufficient to fund the BOM's required duties under the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.0031 and 465.003.

This bill creates section 465.1895 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.)

CS by Health Policy on February 18, 2020:

The CS:

- Removes from the definition of the “practice of professional pharmacy” the testing for and treatment of streptococcus from the underlying bill;
- Changes the underlying bill’s rulemaking authority from the BOP to the BOM for rules to:
 - Establish requirements for pharmacist’s written protocol with supervising physician to test and treat for influenza;
 - Approve pharmacist’s required certification program to test for and treat influenza; and
 - Approve the pharmacist’s required one-time, one hour continuing education course required by the certification program.
- Adds the following additional requirements for a pharmacist to test for and treat influenza:
 - Obtain a complete medical history on a BOM approved form;
 - Provide pharmacy signage recommending follow-up for patients tested;
 - Provide the patient with the name and contact information of the supervising physician; and
 - Provide the patient with a BOM approved pamphlet or brochure that includes advising the patient:

- To seek follow-up care if the test is positive; and
 - That the pharmacist and pharmacy are liable for damages from adverse reactions.
 - Treat patients only with medications approved by the BOM, and reviewed annually; and
 - Review the patient's prescription history for contraindications.
- Specifies patients the pharmacist may not test for or treat for influenza.

B. Amendments:

None.

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

"00714__" Not Found!!!!

THE FLORIDA SENATE
APPEARANCE RECORD

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

2/18/20

Meeting Date

714

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Noland

Job Title _____

Address 4427 Herrichel Street

Phone 904-233-3051

Street

Jacksonville, FL

32210

Email nolandlaw@aol.com

City

State

Zip

Speaking: For Against Information

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

Representing Florida Chapter, American College of Physicians

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)

2/18/2020

Meeting Date

SB0714

Bill Number (if applicable)

Topic Testing and Treatment of Influenza and Streptococcus

Amendment Barcode (if applicable)

Name David Poole

Job Title Director of Legislative Affairs

Address 1825 Country Club Dr

Phone 850-766-3323

Street

Tallahassee

FL

32301

Email david.poole@aidshealth.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

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

2/18

Meeting Date

714

Bill Number (if applicable)

Topic testing for and treatment of Influenza

Amendment Barcode (if applicable)

Name Dr. Christie Alexander

Job Title Family physician

Address 13241 Batram Park Blvd ste B21 Phone 800-223-3237
Street

Jacksonville FL 32258 Email _____
City State Zip

Speaking: For Against Information

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

Representing Florida Academy of Family Physicians

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)

2/18/20

Meeting Date

SB 714

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Ronald Giffler

Job Title President

Address 1430 Piedmont Dr. E.

Phone 850 224-6496

Street

Tallahassee

FL

32308

Email ronaldgiffler@aff.net

City

State

Zip

Speaking: For Against Information

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

Representing Florida Medical Association

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

2.18.20
Meeting Date

714
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Lauren Whritenour

Job Title Legislative Director

Address 109 E. Jefferson St. Suite A
Street

Phone 850 509 3610

Tallahassee FL 32301
City State Zip

Email lauren.claire.henderson@gmail.com

Speaking: For Against Information

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

Representing EPIC RX

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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THE FLORIDA SENATE

APPEARANCE RECORD

February 18, 2020

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

SB714

Meeting DateBill Number (if applicable)Topic Testing and Treating for Influenza and StreptococcusAmendment Barcode (if applicable)Name Michael JacksonJob Title Executive Vice President and CEOAddress 610 North Adams StreetPhone (850) 222-2400*Street*TallahasseeFlorida32301Email mjackson@pharmview.com*City**State**Zip*Speaking: For Against InformationWaive Speaking: In Support Against
(The Chair will read this information into the record.)Representing Florida Pharmacy AssociationAppearing at request of Chair: Yes NoLobbyist 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)

2-18-20

Meeting Date

714

Bill Number (if applicable)

Topic HEALTHCARE

Amendment Barcode (if applicable)

Name SAL NUZZO

Job Title VP POLICY

Address 100 N DUVAL

Phone 830-322-9941

Street

TALL.

City

FL

State

32301

Zip

Email SNUZZO@JAMESMADISON.ORG

Speaking: For Against Information

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

Representing THE JAMES MADISON INSTITUTE

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)

2-18-20

Meeting Date

714

Bill Number (if applicable)

Topic Testing & Treating Flu

Amendment Barcode (if applicable)

Name JAKE FARMER

Job Title Director of Gov Affairs

Address 227 S Adams St

Phone 352 359 6835

Street

Tallahassee

City

FL

State

32301

Zip

Email Jake@frf.org

Speaking: For Against Information

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

Representing Florida Retail Federation

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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THE FLORIDA SENATE
APPEARANCE RECORD

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

2/18/20
Meeting Date

714
Bill Number (if applicable)

Topic Testing and Treatment of Flu & Strep

Amendment Barcode (if applicable)

Name Chris Chaney

Job Title Lobbyist

Address 204 South Monroe St

Phone 222-8900

Tallahassee FL 32301
City State Zip

Email cc@cardenaspartners.com

Speaking: For Against Information

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

Representing Associated Industries of Florida

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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

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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)

2/18/20

Meeting Date

714

Bill Number (if applicable)

Topic Test and Treat

Amendment Barcode (if applicable)

Name Jared Willis

Job Title Dir. of Gov't Relations

Address 2544 Blairstone Pines Dr.

Phone 284-1996

Street

Tallahassee

FL

City

32301

State

Email _____

Speaking: For Against Information

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

Representing FL 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
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 1470

INTRODUCER: Health Policy Committee and Senator Book

SUBJECT: Informed Consent

DATE: February 20, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Fav/CS
2.	_____	_____	JU	_____
3.	_____	_____	RC	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1470 creates s. 456.51, F.S., and prohibits a health care provider from performing any examination of, or providing medical care or treatment to, a patient, with or without anesthesia, without first obtaining the patient's written informed consent or the written informed consent of the patient's representative, with exceptions.

The bill prohibits an attending health care practitioner from allowing medical or nursing students, resident physicians, interns, or fellows in fellowship training, from observing or participating in the patient's care or treatment while under anesthesia, with exceptions including the patient's, or the patient's legal representative's, written informed consent on forms with specific disclosures and requirements.

The bill permits the patient to revoke his or her consent verbally or in writing and provides for discipline of practitioners by the applicable regulatory boards or the Department of Health for violations.

The bill provides an effective date of July 1, 2020.

II. Present Situation:

The Department of Health

The Legislature created the Department of Health (DOH) to protect and promote the health of all residents and visitors in the state.¹ The DOH is charged with the regulation of health practitioners for the preservation of the health, safety, and welfare of the public. The Division of Medical Quality Assurance (MQA) is responsible for the regulatory boards² and professions within the DOH.³

In Florida, allopathic and osteopathic physicians, advanced practice registered nurses (APRNs) working under a protocol with a supervising physician that includes pelvic examination, licensed midwives, and physician assistants supervised by a physician who's practice includes pelvic examinations, may perform pelvic examinations and are subject to regulation by their respective board or council.⁴

Examinations Under Anesthesia

An examination under anesthesia (EUA) is any operative or invasive procedure done while the patient is sedated, in order to improve patient tolerance, alleviate pain or anxiety, or improve the quality of the exam.⁵ There are many types of EUAs.

One of the most common is the pelvic examination under anesthesia. It is an integral part of a women's annual well-woman examination,⁶ labor and child birth, and the evaluation of numerous abnormal gynecological and obstetrical conditions.⁷ It remains an important skill necessary for medical and nursing students to master before becoming physicians or APRNs. Pelvic examinations, both in the office and while under anesthesia, are also a crucial component of a physician's preoperative evaluation for gynecologic procedures to ensure safe completion of a planned procedure. Pelvic examination skills are, therefore, very important for physicians across specialties and must continue to be taught and mastered during undergraduate medical education.⁸

¹ Section 20.43, F.S.

² Under s. 456.001(1), F.S., the term "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH, MQA.

³ Section 20.43, F.S.

⁴ *Supra*, note 2; and chs. 458, 459, 464, and 467, F.S.

⁵ Farlex, The Free Medical Dictionary, *Examination Under Anesthesia*, available at <https://medical-dictionary.thefreedictionary.com/examination+under+anesthesia> (last visited Feb. 19, 2020).

⁶ A pelvic examination usually involves an examination of woman's vulva, vagina, uterus, ovaries, and fallopian tubes. It may also include examination of the bladder and the rectum. Melissa Conrad Stoppler, MD, *Pelvic Exam*, MedicineNet, available at https://www.medicinenet.com/pelvic_exam/article.htm#why_is_a_pelvic_exam_performed (last visited Feb. 12, 2020).

⁷ Hammoud, Maya M. MD, MBA; Spector-Bagdady, Kayte JD, MBe; O'Reilly, Meg MD, MPH; Major, Carol MD; Baecher-Lind, Laura MD, MPH, *Obstetrics & Gynecology*, *Consent for the Pelvic Examination Under Anesthesia by Medical Students*, December 2019 - Volume 134 - Issue 6 - p 1303-1307, available at https://journals.lww.com/greenjournal/Fulltext/2019/12000/Consentfor_the_Pelvic_Examination_Under.24.aspx (last visited Feb. 12, 2020).

⁸ *Id.*

Another common EUA is the eye examination under anesthesia done to diagnose different eye problems in children and adults. The eye EUA is especially safer and easier for children because a child will be asleep while the doctor uses bright lights and instruments near or on the eyes. This is often an outpatient procedure.⁹

Another common EUA is typically carried out on a patient that may have signs of bladder Cancer. A urologist, is a healthcare provider who specializes in bladder cancer and other health conditions related to the urinary tract. The procedure allows urologists to feel the bladder from the inside of the patient's body to check for signs of tumors. It also allows the urologist to carry out a more thorough physical exam of the outer surface of the bladder than is possible during a digital rectum exam or pelvic exam.¹⁰

Informed Consent

Informed consent for medical treatment is fundamental in both ethics and law.¹¹ Informed consent is a process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.¹² A patient must be competent to make a voluntary decision about whether to undergo a procedure. Foregoing the process of consent within medicine can result in violations of both autonomy and basic rights, as well as trust.¹³

The idea of informed consent was established in 1914 in a case in which a patient was operated on without her consent.¹⁴ In determining whether she had a cause of action against the hospital in which the operation was formed, the judge in the case opined that “every human being of adult years and sound mind has a right to determine what shall be done to his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable for damages.”¹⁵

Florida Requirements for Informed Consent

The only general law in Florida on medical consent appears in ch. 766, F.S., Medical Malpractice and Related matters.¹⁶ However, Florida physicians and physicians practicing within

⁹ University of Pennsylvania Medical Center, Children’s Hospital of Pittsburgh, *Eye Examination Under Anesthesia*, available at <https://www.chp.edu/our-services/ophthalmology/ophthalmology-patient-procedures/eye-examination-under-anesthesia> (last visited Feb. 19, 2020).

¹⁰ American Cancer Society, *Tests for Bladder Cancer*, available at <https://www.cancer.org/cancer/bladder-cancer/detection-diagnosis-staging/how-diagnosed.html> (last visited Feb. 19, 2020).

¹¹ American Medical Association, *Informed Consent: Code of Medical Ethics Opinion 2.1.1*, available at <https://www.ama-assn.org/delivering-care/ethics/informed-consent> (last visited Feb. 12, 2020).

¹² William Gossman, Imani Thornton, John Hipskind, *Informed Consent* (July 10, 2019), available at <https://www.ncbi.nlm.nih.gov/books/NBK430827/> (last visited Feb. 12, 2020).

¹³ Phoebe Friesen, *Educational Pelvic Exams on Anesthetized Women: Why Consent Matters (Abstract)*, 32 *BIOETHICS* 298 (April 23, 2018), available at <https://onlinelibrary.wiley.com/doi/abs/10.1111/bioe.12441> (last visited Feb. 12, 2020).

¹⁴ *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

¹⁵ *Id.*

¹⁶ Section 766.103, F.S., provides: No recovery shall be allowed in any court in this state against any physician, chiropractor, podiatric physician, dentist, APRN, or PA in an action brought for treating, examining, or operating on a patient without his or her informed consent when: 1) The action of the practitioner in obtaining the consent of the patient, or another person authorized to give consent for the patient, was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community; and 2) A

a postgraduate training program approved by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) must explain the medical or surgical procedure to be performed to the patient and obtain the informed consent of the patient. The physician is not required to obtain or witness the signature of the patient on a written form evidencing informed consent; and there is no requirement that the patient must use a written document, although hospitals and facilities where procedures are performed typically require consent in writing.^{17, 18}

Pelvic Examinations of Patients Under Anesthesia

In recent years, articles have detailed reports of medical students performing pelvic examinations, without consent, on women who are anesthetized.¹⁹ This practice has been common since the late 1800s, and in 2003, a study reported that 90 percent of medical students who completed obstetrics and gynecology rotations at four Philadelphia-area hospitals performed pelvic examinations on anesthetized patients for educational purposes.²⁰

Several medical organizations have taken positions that pelvic examinations under anesthesia by students in a teaching environment should require the patient's informed consent:

- The American Medical Association Council on Ethical and Judicial Affairs recommends that in situations where the patient will be temporarily incapacitated (e.g., anesthetized) and where student involvement is anticipated, involvement should be discussed before the procedure is undertaken, whenever possible.²¹

reasonable person, from the information provided under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, recognized among practitioners in the same or similar community who perform similar treatments or procedures; or 3) The patient would reasonably, under all the surrounding circumstances, have undergone the treatment or procedure had he or she been advised by practitioner in accordance with the provisions of the first.

¹⁷ Fla. Adm. Code R. 64B8-9.007, and 64B15-14.006 (2019).

¹⁸ See The Joint Commission, Hospital National Patient Safety Goals, (effective Jan. 1, 2020), *Introduction to the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery*, pp.14-15, available at https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/npsg_chapter_hap_jan2020.pdf (last visited Feb. 13, 2020). The same standard applies to Ambulatory Health Care facility accreditation, available at https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/npsg_chapter_ahc_jan2020.pdf (last visited Feb. 12, 2020).

¹⁹ For examples, see: Paul Hsieh, *Pelvic Exams on Anesthetized Women Without Consent: A Troubling and Outdated Practice*, FORBES (May 14, 2018), available at <https://www.forbes.com/sites/paulhsieh/2018/05/14/pelvic-exams-on-anesthetized-women-without-consent-a-troubling-and-outdated-practice/#74d152df7846> (last visited Feb. 12, 2020); Dr. Jennifer Tsai, *Medical Students Regularly Practice Pelvic Exams on Unconscious Patients. Should They?*, ELLE (June 24, 2019), available at <https://www.elle.com/life-love/a28125604/nonconsensual-pelvic-exams-teaching-hospitals/> (last visited Feb. 13, 2020); Lorelei Laird, *Pelvic Exams Performed without Patients' Permission Spur New Legislation*, ABA JOURNAL (Sept. 2019), available at <http://www.abajournal.com/magazine/article/examined-while-unconscious> (last visited Feb. 13, 2020); and Amanda Eisenberg, *New Bills Would Ban Pelvic Exams without Consent*, POLITICO (March 14, 2019), available at <https://www.politico.com/states/new-york/albany/story/2019/03/13/new-bills-would-ban-pelvic-exams-without-consent-910976> (last visited Feb. 12, 2020).

²⁰ John Duncan, Dan Luginbill, Matthew Richardson, Robin Fretwell Wilson, *Using Tort Law to Secure Patient Dignity: Often Used as Teaching Tools for Medical Students, Unauthorized Pelvic Exams Erode Patient Rights, Litigation Can Reinstate Them*, 40 TRIAL 42 (Oct. 2004), available at https://www.researchgate.net/publication/256066192_Using_Tort_Law_to_Secure_Patient_Dignity (last visited Feb. 13, 2020).

²¹ AMA Council on Ethical and Judicial Affairs, *Medical Student Involvement in Patient Care: Report of the Council on Ethical and Judicial Affairs*, AMA Journal of Ethics (March 2001), available at <https://journalofethics.ama-assn.org/article/medical-student-involvement-patient-care-report-council-ethical-and-judicial-affairs/2001-03> (last visited Feb. 13, 2020).

- The Association of American Medical Colleges, reversing its prior policy position, offered that “performing pelvic examinations on women under anesthesia, without their knowledge or approval ... is unethical and unacceptable.”²²
- The Committee on Ethics of the American College of Obstetricians and Gynecologists resolved that “pelvic examinations on an anesthetized woman that offer her no personal benefit and are performed solely for teaching purposes should be performed only with her specific informed consent obtained before her surgery.”²³

Forty-two states do not require the informed consent to pelvic examinations under anesthesia by students and residents. California, Hawaii, Illinois, Iowa, Maryland, Oregon, Utah, and Virginia prohibit unauthorized pelvic examinations.²⁴

The Association of American Medical Colleges (AAMC) has found that most teaching hospitals inform patients that trainees will be involved in their care and, generally, patients approve of the trainees’ involvement.²⁵ The chief health care officer for the AAMC notes that recent articles on unauthorized pelvic examinations rely on studies from more than 10 years ago and before more detailed informed consent forms were used.²⁶ Typically, students and residents practice pelvic examinations with special mannequins and standardized patients who are specifically trained for this purpose.²⁷

III. Effect of Proposed Changes:

CS/SB 1470 creates s. 456.51, F.S., and prohibits a health care provider from performing any examination, or providing medical care or treatment, to a patient, with or without anesthesia, without first obtaining the patient’s written informed consent, or the written informed consent of the patient’s representative, unless;

- A court orders the performance of an examination of or the provision of medical care or treatment to the patient, with or without anesthesia; or
- The performance of an examination or the provision of medical care or treatment is medically necessary to diagnose or treat the patient in a medical emergency.

The bill prohibits an attending health care practitioner from allowing medical or nursing students, resident physicians, interns, or fellows in fellowship training from observe or participate in the patient’s care or treatment while under anesthesia, unless:

²² Robin Fretwell Wilson, *Autonomy Suspended: Using Female Patients to Teach Intimate Exams Without Their Knowledge or Consent*, 8 J OF HEALTH CARE LAW AND POLICY 240, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=880120 (last visited Feb. 13, 2020).

²³ American College of Obstetricians and Gynecologists, Committee on Ethics, *Professional Responsibilities in Obstetric-Gynecologic Medical Education and Training* (August 2011), available at <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Professional-Responsibilities-in-Obstetric-Gynecologic-Medical-Education-and-Training?IsMobileSet=false> (last visited Feb. 13, 2020).

²⁴ Lorelei Laird, *Pelvic Exams Performed without Patients’ Permission Spur New Legislation*, ABA JOURNAL (September 2019), available at <http://www.abajournal.com/magazine/article/examined-while-unconscious> (last visited Feb. 13, 2020).

²⁵ Stacy Weiner, *What “Informed Consent” Really Means* (January 24, 2019), available at <https://www.aamc.org/news-insights/what-informed-consent-really-means> (last visited Feb. 13, 2020).

²⁶ Id.

²⁷ See note 32.

- A court orders the performance of an examination of or the provision of medical care or treatment to the patient, with or without anesthesia;
- The performance of an examination or the provision of medical care or treatment is medically necessary to diagnose or treat the patient in a medical emergency; or
- The attending health care practitioner obtains a separate written informed consent form from the patient, or the patient's legal representative, authorizing the medical or nursing students, resident physicians, interns, or fellows in fellowship training to:
 - Be present and observe only; or
 - Participate in the examination of or provision of medical care or treatment to the patient.

The separate written informed consent form must include:

- The name and title of the patient's attending health care practitioner;
- The name and title of any supervising medical educator;
- A statement that any observation or participation in the patient's medical care or treatment will be:
 - Directly related to the patient's diagnosis and medical care and treatment plan;
 - Part of medical research being conducted; or
 - Part of the clinical training being provided.
- A series of check boxes that allow the patient or the patient's legal representative to indicate whether he or she consents or withholds consent to:
 - The presence of students to observe the examination of or the provision of medical care and treatment to the patient while under anesthesia is for the purpose of conducting medical research or receiving clinical training; or
 - The participation of the students in the examination of or provision of medical care and treatment to the patient while anesthesia is for the purpose of conducting medical research or receiving clinical training.
- Three signature lines:
 - One for the patient or the patient's legal representative;
 - One for the attending health care practitioner, and
 - One for the supervising medical educator, if different from the attending health care practitioner.

The bill permits a patient to revoke or amend his or her consent, verbally or in writing, at any time before the procedure begins or before the anesthesia is administered, whichever occurs earlier.

If a patient consents to have medical or nursing students, resident physicians, interns, or fellows observe or participate in the examination of or the provision of medical care or treatment to the patient while under anesthesia, the patient's attending health care practitioner must:

- Inform the patient of his or her right to amend or revoke his or her consent at any time before the procedure begins or before anesthesia is administered, whichever occurs earlier; and
- Document in the patient's medical record the name of each medical or nursing student, resident physician, intern, or fellow who observed or participated in the examination of or the provision of medical care or treatment to the patient while the patient was under anesthesia.

The bill provides for discipline by the applicable board, or the department if there is no board, of a patient's attending health care practitioner and a supervising medical educator, if different from the attending health care practitioner, if either fails to comply with the informed consent requirements.

The bill 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:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 456.51 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 February 19, 2020:

The CS expands the underlying bill's requirement for informed consent by prohibiting a health care practitioner from performing any examination of, or providing medical care or treatment to, a patient, with or without anesthesia, unless the health care practitioner first obtains written informed consent from the patient or the patient's legal representative. The underlying bill applied only to pelvic examinations of an unconscious patient or a patient under anesthesia.

- B. **Amendments:**

None.

By Senator Book

32-00942A-20

20201470__

1 A bill to be entitled
2 An act relating to informed consent for pelvic
3 examinations; creating s. 456.51, F.S.; defining the
4 terms "health care provider" and "pelvic examination";
5 specifying circumstances under which a health care
6 provider may perform a pelvic examination on an
7 anesthetized or unconscious patient; specifying
8 procedures for obtaining consent for a pelvic
9 examination; providing that a patient may revoke or
10 amend consent verbally or in writing within a
11 specified timeframe; prohibiting a student or resident
12 from observing or performing a pelvic examination on a
13 patient without the patient's consent; requiring a
14 health care provider to notify the patient of certain
15 information before the patient is anesthetized and
16 rendered unconscious; providing for disciplinary
17 action against a health care provider who fails to
18 comply with certain provisions; providing an effective
19 date.

20
21 Be It Enacted by the Legislature of the State of Florida:

22
23 Section 1. Section 456.51, Florida Statutes, is created to
24 read:

25 456.51 Health care providers; consent for pelvic
26 examinations.-

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

28 (a) "Health care provider" means a health care practitioner
29 as defined in s. 456.001 or a paramedic or an emergency medical

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30 technician certified under part III of chapter 401.

31 (b) "Pelvic examination" means a medical examination that
32 requires contact with the patient's sexual organs.

33 (2) A health care provider may not perform a pelvic
34 examination on an anesthetized or unconscious patient unless:

35 (a) The health care provider obtains consent from the
36 patient or the patient's representative in accordance with
37 subsection (3);

38 (b) A court orders performance of the pelvic examination
39 for the collection of evidence;

40 (c) The performance of the pelvic examination is within the
41 scope of care for a procedure or diagnostic examination
42 scheduled to be performed on the patient; or

43 (d) The pelvic examination is immediately necessary for
44 diagnosis and treatment of the patient.

45 (3) To obtain consent to perform a pelvic examination on an
46 anesthetized or unconscious patient, the health care provider
47 must do all of the following before the patient is anesthetized
48 or rendered unconscious:

49 (a) Provide the patient or the patient's representative
50 with a written or electronic document that:

51 1. Is provided separately from any other notice or
52 agreement.

53 2. Contains a heading at the top of the document in at
54 least 18-point bold type which states the following: "CONSENT
55 FOR EXAMINATION OF PELVIC REGION".

56 3. Specifies the nature and purpose of the pelvic
57 examination.

58 4. Lists the name and title of one or more health care

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59 providers whom the patient or the patient's representative may
60 authorize to perform the pelvic examination.

61 5. States whether there may be a student or resident who
62 the patient or the patient's representative authorizes to
63 perform an additional pelvic examination or observe or otherwise
64 be present at the pelvic examination, either in person or
65 through electronic means, for educational or training purposes.

66 6. Provides the patient or the patient's representative
67 with a series of check boxes that allow the patient or the
68 patient's representative to:

69 a. Consent to the pelvic examination for diagnosis or
70 treatment and to the presence of, or an additional examination
71 performed by, a student or resident for educational or training
72 purposes;

73 b. Consent to the pelvic examination only for diagnosis or
74 treatment and refuse to consent to the presence of, or an
75 additional examination performed by, a student or resident for
76 educational or training purposes; or

77 c. Refuse to consent to the pelvic examination.

78 (b) Obtain the signature of the patient or the patient's
79 representative on the written or electronic document while
80 witnessed by a third party.

81 (c) Sign the written or electronic document.

82 (4) A patient may revoke or amend his or her consent,
83 verbally or in writing, at any time before being anesthetized or
84 rendered unconscious.

85 (5) A student or resident may not observe or perform a
86 pelvic examination on a patient unless the patient has executed
87 a consent form in accordance with subsection (3) authorizing the

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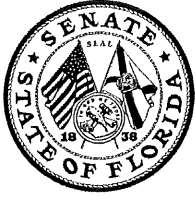
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88 student or resident to do so.

89 (6) If a patient consents to have a student or resident
90 observe or perform a pelvic examination on the patient, before
91 the patient is anesthetized and rendered unconscious, the health
92 care provider must notify the patient of the name of each
93 student or resident who will be observing or performing a pelvic
94 examination on the patient and inform the patient of the right
95 to amend or revoke his or her consent.

96 (7) A health care provider who fails to comply with this
97 section is subject to discipline by the applicable board, or the
98 department if there is no board.

99 Section 2. This act shall take effect July 1, 2020.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Children, Families, and Elder Affairs, *Chair*
Appropriations
Appropriations Subcommittee on Education
Appropriations Subcommittee on Health and Human
Services
Health Policy
Rules

JOINT COMMITTEE:

Joint Legislative Budget Commission

SENATOR LAUREN BOOK

32nd District

January 16, 2020

Chair Gayle Harrell
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Harrell:

I respectfully request that **SB 1470—Informed Consent for Pelvic Examinations** be placed on the agenda for the next Committee on Health Policy meeting.

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

Thank you,

A handwritten signature in cursive script that reads "Lauren Book".

Senator Lauren Book
Senate District 32

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

REPLY TO:

- 967 Nob Hill Road, Plantation, Florida 33324 (954) 424-6674
- 202 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: www.flsenate.gov

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore



2020 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Florida Department of Health

<u>BILL INFORMATION</u>	
BILL NUMBER:	HB 1289
BILL TITLE:	Informed Consent for Pelvic Examinations
BILL SPONSOR:	Jenne
EFFECTIVE DATE:	7/1/2020

<u>COMMITTEES OF REFERENCE</u>
1) Health Quality Subcommittee
2) Health Care Appropriations Subcommittee
3) Health & Human Services Committee
4) Click or tap here to enter text.
5) Click or tap here to enter text.

<u>CURRENT COMMITTEE</u>
Health Quality Subcommittee

<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:	Click or tap here to enter text.
LEAD AGENCY ANALYST:	Click or tap here to enter text.
ADDITIONAL ANALYST(S):	Click or tap here to enter text.
LEGAL ANALYST:	Click or tap here to enter text.
FISCAL ANALYST:	Click or tap here to enter text.

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The bill creates a statutory section in chapter 456, F.S., to address performing a pelvic examination on an anesthetized or unconscious patient and provides circumstances under which an exam may be performed and obtaining informed consent.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Currently there is not a provision in Florida law that requires obtaining informed consent specific to performing a pelvic examination on an anesthetized or unconscious patient.

In an article in U.S. News and World Report from May 2019, several states considered legislation to require informed consent that explicitly addresses performing a pelvic examination on an anesthetized or unconscious patient. According to the article, seven states have such a requirement for informed consent.

2. EFFECT OF THE BILL:

The bill creates s. 456.51, F.S., which is titled “Health care providers; consent for pelvic examinations.” As used in this section “health care provider” conforms to the definition of “health care practitioner” in s. 456.001 (4), F.S., and includes a paramedic or an emergency medical technician certified under chapter 401, F.S. The bill provides a definition for “pelvic examination” which means a medical examination that requires contact with the patient’s sexual organs.

A health care provider may not perform a pelvic examination on an anesthetized or unconscious patient unless:

- The provider obtains consent from the patient or patient representative;
- A court orders the examination for collecting evidence;
- The examination is within the scope of care for a procedure or diagnostic examination that is scheduled to be performed on the patient, or;
- There is an immediate need for the examination for the patient’s diagnosis and treatment,

To obtain consent when performing a pelvic examination on an anesthetized or unconscious patient, the provider must comply with these requirements before the patient is anesthetized or becomes unconscious.

Provide the patient or patient’s representative with a written or electronic document that:

- Is separate from any other notice or agreement.
- Includes a heading at the top of the document in at least 180-point bold type with this language: “CONSENT FOR EXAMINATION OF PELVIC REGION”
- Specifies the nature and purpose of the examination
- Lists name and title of one or more of the health care providers who has been authorized by the patient or patient’s representative to perform the examination
- States whether there may be a student or resident may provide an additional examination or observe or be present during the examination for educational purposes, whether in person or by electronic means. This situation is subject to authorization from the patient or the patient’s representative.
- Provides a series of check boxes that allow the patient or patient representative to:
 - Consent to the examination for diagnosis or treatment, or an additional examination performed by a student or resident for education or training;
 - Consent to the examination only for diagnosis and treatment;
 - Refuse to consent to the examination.

• Have the patient or patient’s representative sign the written or electronic document with a third-party witness. A health care provider who fails to comply with the provisions in this section is subject to discipline under their respective practice act.

A health care provider who fails to comply with the provisions in this section is subject to discipline under their respective practice act.

The bill is effective July 1, 2020.

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:	
Is the change consistent with the agency's core mission?	Y <input type="checkbox"/> N <input type="checkbox"/>
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:	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:	Click or tap here to enter text.
Date Due:	Click or tap here to enter text.
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:	Click or tap here to enter text.
Board Purpose:	Click or tap here to enter text.
Who Appoints:	Click or tap here to enter text.
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:	None
Expenditures:	None
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT?

Y N

Revenues:	None
Expenditures:	DOH/MQA may experience an increase in workload associated with additional complaints, investigation, and prosecution for non-compliance of this legislation, yet it is anticipated that current resources 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.	Click or tap here to enter text.
Bill Section Number:	Click or tap here to enter text.

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.	Click or tap here to enter text.
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FEDERAL IMPACT

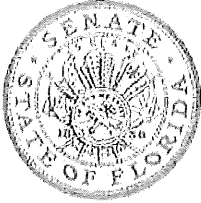
1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y N

If yes, describe the anticipated impact including any fiscal impact.	Click or tap here to enter text.
----------------------------------------------------------------------	----------------------------------

ADDITIONAL COMMENTS

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	There are very few health care practitioners under s. 456.001 that would be authorized under their scope of practice to perform pelvic examinations in any circumstances. It may be clearer to specifically note which of those practitioners would be authorized to do this type of examination and limit this bill and the required consent to those practitioners to prevent unauthorized practitioners from perceiving that pelvic examinations may be permissible in their scope of practice. No other legal issues, concerns or comments identified at this time.
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THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Military and Veterans Affairs and Space, *Vice Chair*
Education
Health Policy
Infrastructure and Security

JOINT COMMITTEE:

Joint Administrative Procedures Committee

SENATOR JANET CRUZ

18th District

February 13, 2020

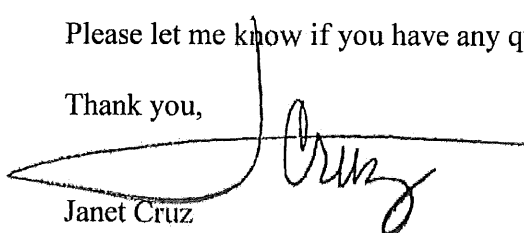
The Honorable Gayle Harrell
Health Policy Committee
530 Knott Building
404 South Monroe Street
Tallahassee, Florida 32399-1100

Dear Chair Harrell,

I respectfully request to be excused from the Health Policy Committee meeting on February 18, 2020. Major General James O. Eifert, The Adjutant General of Florida has invited me to attend the Deployment Ceremony for the Florida National Guard 290th at MacDill Air Force Base in Tampa. It would be my privilege to attend this event and honor these servicemen and women before they are deployed.

Please let me know if you have any questions or concerns regarding this request.

Thank you,


Janet Cruz
State Senator, District 18

CC: Celia Georgiades, Health Policy Committee – Administrative Assistant

REPLY TO:

- 210A S. MacDill Avenue, Tampa, Florida 33609 (813) 348-1017 FAX: (888) 263-3681
- 218 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5018

Senate's Website: www.flsenate.gov

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

CourtSmart Tag Report

Room: KN 412

Case No.:

Type:

Caption: Senate Health Policy Committee

Judge:

Started: 2/18/2020 10:04:28 AM

Ends: 2/18/2020 11:34:06 AM

Length: 01:29:39

10:04:27 AM Meeting called to order
10:04:44 AM Chair
10:04:51 AM Acknowledgement of staff
10:05:22 AM Chair
10:05:39 AM Senator Cruz is excused
10:05:46 AM Roll Call - Quorum is present
10:05:51 AM Chair
10:06:27 AM Tab 6 - SB 714 by Senator Hutson - Testing for Treatment of Influenza and Streptococcus
10:06:38 AM Delete -all amendment 684054 by Senator Hutson
10:07:47 AM Questions on amendment?
10:08:48 AM Appearance Cards on amendment? None
10:09:03 AM Debate on amendment? None
10:09:07 AM Objections? None
10:09:12 AM Amendment is Adopted
10:09:18 AM Back on bill as amended
10:09:24 AM Questions?
10:09:26 AM Senator Mayfield
10:10:15 AM Senator Hutson
10:11:05 AM Senator Mayfield
10:11:42 AM Senator Hutson
10:12:33 AM Appearance Cards?
10:12:38 AM Chris Nuland, FL Chapter American College of Physicians, waives in opposition
10:12:43 AM David Poole, Dir. Legislative Affairs, waives in opposition
10:12:59 AM Dr. Christine Alexander, Family Physician, Florida Academy of Family Physicians, speaking against
10:16:04 AM Ronald Giffler, President, FMA speaking in opposition
10:17:10 AM Lauren Whritenouv, EPIC RX, waives in support
10:17:18 AM Michael Jackson, FL Pharmacy Association, waives in support
10:17:26 AM Sal Nuzzo, The James Madison Institute, waives in support
10:17:35 AM Jake Farmer, Florida Retail Federation, waives in support
10:17:44 AM
10:18:01 AM Chris Chaney, Associated Indus. of Florida, waives in support
10:18:03 AM Jared Willis, FL Osteopathic Medical Association, waives in opposition
10:18:04 AM Debate?
10:18:07 AM Senator Baxley
10:19:36 AM Senator Rouson
10:21:07 AM Senator Hooper
10:23:31 AM Senator Mayfield
10:28:55 AM Senator Berman
10:29:50 AM Chair
10:30:07 AM Senator Hutson to close
10:30:50 AM Roll Call SB 714 - Favorable
10:31:52 AM Tab 1 - Coronavirus: Potential Impact on Florida
10:33:13 AM Dr. John Sinnot, M.D, College of Int. Medison of Univ. of S. Florida and Tampa General, speaking on the international
10:51:36 AM Questions?
10:52:35 AM Senator Berman
10:53:07 AM Dr. Sinnot
10:53:22 AM Senator Berman
10:53:38 AM Dr. Sinnot
10:54:10 AM Senator Rouson
10:54:54 AM Dr. Sinnot
10:55:44 AM Chair

10:55:50 AM Dr. Sinnot
10:56:59 AM Chair
10:57:24 AM Dr. Sinnot
10:57:32 AM Chair
10:57:37 AM Dr. Scott Rivkees, Florida Surgeon General, speaking on Florida
11:09:12 AM Questions?
11:10:12 AM Senator Berman
11:10:41 AM Dr. Rivkees
11:10:51 AM Senator Berman
11:11:10 AM Dr. Rivkees
11:11:46 AM Senator Berman
11:11:59 AM Dr. Rivkees
11:12:39 AM Senator Berman
11:12:54 AM Dr. Rivkees
11:13:19 AM Senator Berman
11:13:38 AM Dr. Rivkees
11:14:03 AM Senator Berman
11:14:07 AM Senator Diaz
11:14:26 AM Dr. Rivkees
11:14:48 AM Senator Rouson
11:15:17 AM Dr. Rivkees
11:16:02 AM Senator Rouson
11:16:07 AM Dr. Rivkees
11:16:53 AM Chair
11:17:05 AM Greg Pound, self
11:17:58 AM Chair
11:18:20 AM Tab 2 - CS/SB 880 - by Senator Baxley - Nurse Registry
11:18:48 AM Questions? None
11:18:52 AM Appearance Cards?
11:18:56 AM Debate? None
11:19:00 AM Senator Baxley waives close
11:19:06 AM Roll Call on CS/SB 880 - favorable
11:19:29 AM Tab 4 - SB 626 by Senator Pizzo - HIV Prevention
11:19:49 AM Amendment 551452 by Senator Pizzo
11:20:03 AM Questions on amendment? None
11:20:11 AM Appearance Cards? None
11:20:16 AM Debate? None
11:20:20 AM Objection to amendment? None. Amendment is adopted.
11:20:29 AM Back on bill as amended
11:20:35 AM Questions? None
11:20:40 AM Appearance Cards?
11:20:43 AM David Poole, Director of Leg. Affairs, waives in support
11:20:51 AM Kara Gross, Leg. Director, American Civil Liberties Union of Florida, waive in support
11:20:57 AM Jon Harris Maurer, Public Policy Director, Equality Florida, waives in support
11:21:02 AM Dr. Paul Arons, Consultant, FL HIV Justice Coalition, waives in support
11:21:15 AM Debate? None
11:21:21 AM Senator Pizzo to close
11:21:27 AM Roll Call SB 626 - Favorable
11:22:05 AM Tab 7 - SB 1470 by Senator Book - Informed Consent for Pelvic Examinations
11:23:28 AM Amendment 544728 by Senator Book
11:25:00 AM Questions of amendment ? None
11:25:08 AM Appearance cards on amendment? None
11:25:13 AM Debate on amendment? None
11:25:16 AM Objection? None. Amendment is adopted
11:25:26 AM Back on bill as amended
11:25:31 AM Questions?
11:25:33 AM Appearance Cards? None
11:25:36 AM Debate?
11:25:38 AM Senator Berman
11:25:56 AM Chair
11:26:26 AM Senator Book to close
11:26:59 AM Roll Call on SB 1470 - Favorable

11:27:18 AM Tab 5 - SB 780 by Senator Gainer has been TP'd
11:27:50 AM Vice- Chair Berman in chair
11:27:57 AM Tab-3- SB 584 by Senator Harrell - Council on Physician Assistants
11:28:53 AM Amendment 407060 by Senator Harrell
11:29:26 AM Questions on amendment?
11:29:42 AM Senator Rouson
11:29:49 AM Senator Harrell
11:30:30 AM Senator Berman
11:30:54 AM Senator Harrell
11:31:35 AM Appearance Cards on amendment? None
11:31:38 AM Debate on amendment? None
11:31:42 AM Senator Harrell to close on amendment
11:31:49 AM Amendment is adopted
11:31:54 AM Back on bill as amended
11:31:59 AM Questions?
11:32:04 AM Appearance Cards?
11:32:05 AM David Poole, Dir. of Leg. Affairs, Council on Phy. Asst., waives in support
11:32:15 AM Corrine Mixon, Lobbyist, FL Academy of Physicians Assistants, waives in support
11:32:18 AM Debate? None
11:32:23 AM Senator Harrell to close
11:32:33 AM Roll Call on SB 584 - Favorable
11:32:59 AM Senator Harrell back in chair
11:33:15 AM Chair
11:33:35 AM Senators wishing to vote on missed bills? None. Any other business before the committee? None
11:33:51 AM Senator Mayfield moves to adjourn. Without objection. We are adjourned.