

**The Florida Senate**  
**COMMITTEE MEETING EXPANDED AGENDA**

**HEALTH POLICY**  
**Senator Diaz, Chair**  
**Senator Brodeur, Vice Chair**

**MEETING DATE:** Wednesday, February 17, 2021

**TIME:** 9:00—11:30 a.m.

**PLACE:** Pat Thomas Committee Room, 412 Knott Building

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

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
PUBLIC TESTIMONY WILL BE RECEIVED FROM ROOM A3 AT THE DONALD L. TUCKER CIVIC CENTER, 505 W. PENSACOLA STREET, TALLAHASSEE, FL. 32301			
1	<b>SB 362</b> Harrell (Similar H 407)	Pediatric Cardiac Care; Revising requirements for members of the pediatric cardiac technical advisory panel; extending sovereign immunity to apply to all individuals who are members of a site visit review team; requiring pediatric cardiac programs to include certain cases in the program's required surgical volume; providing that pediatric cardiac surgical centers that are deemed by the panel to be noncompliant with certain standards must come into compliance with those standards within a specified timeframe, etc.  HP      02/17/2021 Fav/CS JU RC	Fav/CS Yeas 10 Nays 0
2	<b>SB 700</b> Rodriguez (Compare H 247, S 660)	Telehealth; Requiring the Agency for Health Care Administration to reimburse the use of telehealth services under certain circumstances and subject to certain limitations; authorizing telehealth providers to prescribe specified controlled substances through telehealth under certain circumstances; authorizing out-of-state physician telehealth providers to engage in formal supervisory relationships with certain nonphysician health care practitioners in this state; authorizing registered pharmacy technicians to compound and dispense medicinal drugs under certain circumstances; exempting certain registered pharmacy technicians from specified prohibitions, etc.  HP      02/17/2021 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0

**COMMITTEE MEETING EXPANDED AGENDA**

Health Policy

Wednesday, February 17, 2021, 9:00—11:30 a.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	<b>SB 866</b> Hooper (Identical H 789)	H. Lee Moffitt Cancer Center and Research Institute; Increasing, at specified timeframes, the percentage of cigarette tax proceeds paid to the Board of Directors of the H. Lee Moffitt Cancer Center and Research Institute for certain purposes, etc.  HP 02/17/2021 Favorable FT AP	Favorable Yeas 10 Nays 0
4	<b>SB 780</b> Gainer	Health Care Licensure Requirements; Requiring certain physicians to submit specified information to the Department of Health to be exempt from specified licensure requirements; requiring the department to notify such health care practitioners of their exemption within a specified timeframe, etc.  HP 02/17/2021 Favorable MS RC	Favorable Yeas 10 Nays 0
5	<b>SB 768</b> Baxley (Compare H 459, CS/S 494, S 898)	Immunizations; Requiring certain persons licensed to practice pharmacy to report specified vaccination data to the Department of Health's immunization registry, with exceptions; authorizing certain pharmacists and registered interns to administer specified immunizations and vaccines to children within a specified age range under certain circumstances; requiring authorized pharmacists and registered interns to obtain a certain medical consent form before administering a vaccine to a child younger than 18 years of age, etc.  HP 02/17/2021 Favorable CF RC	Favorable Yeas 6 Nays 4

Other Related Meeting Documents

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

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

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

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BILL: CS/SB 362

INTRODUCER: Health Policy Committee and Senator Harrell

SUBJECT: Pediatric Cardiac Care

DATE: February 18, 2021

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	<b>Fav/CS</b>
2.			JU	
3.			RC	

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**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 362 amends s. 395.1055, F.S., to:

- Modify the composition of the Pediatric Cardiac Technical Advisory Panel (panel), as established within the Agency for Health Care Administration (AHCA).
- Clarify that time spent as an alternate member of the panel does not count toward member term limits.
- Require the panel to meet at least quarterly rather than biannually.
- Require the chair and vice chair of the panel, in consultation with the AHCA, to develop the agendas for panel meetings.
- Require the annual report submitted by the panel to the Governor and the Legislature to be composed by the panel and signed by the chair and vice chair of the panel.
- Establish that all members of a site review team are agents of the state for purposes of s. 768.28, F.S., relating to sovereign immunity in tort actions.
- Require pediatric cardiac programs to include certain cases in their required surgical volume.
- Authorize site visit teams to conduct virtual site inspections during a declared state of emergency.
- Authorize the panel to alter certain requirements for virtual site inspections.
- Establish that pediatric cardiac surgical centers that are deemed by the panel to be noncompliant with the AHCA's standards for such programs must come into compliance with those standards within 24 months.

- Authorize the panel to recommend that a center have its license to perform congenital cardiac surgery revoked if the center does not come into compliance within 24 months.
- Authorize the Secretary of Health Care Administration to accept or modify the panel's recommendations for corrective actions or revocation of licensure and to require the Secretary to enforce compliance with the AHCA's standards accordingly.
- Require that data in quarterly reports submitted by the Surgeon General to the Secretary of Health Care Administration follow the guidelines and suggestions established by the Cardiac Subcommittee on the Children's Medical Services' Genetics and Newborn Screening Advisory Council in consultation with the panel.

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

## **II. Present Situation:**

### **Technical Advisory Panel for Pediatric Cardiac Programs**

During the 2017 and 2018 legislative sessions, the Technical Advisory Panel for Pediatric Cardiac Programs (panel) was established to develop procedures and standards for measuring outcomes of pediatric catheterization programs and pediatric cardiac cardiovascular programs, and to make recommendations about regulatory guidelines for pediatric open heart surgery programs.<sup>1</sup> The panel is housed administratively at the Agency for Health Care Administration (AHCA), and appointments to the panel are made by the Secretary of Health Care Administration and the chief executive officers of specified hospitals in accordance with statutory guidelines. Members of the panel must have technical expertise in pediatric cardiac medicine. Members serve without compensation and are not reimbursed for any travel costs or per diem.<sup>2</sup>

The Secretary of Health Care Administration appoints three at-large members, and three alternate at-large members, one of whom is a cardiologist who is board-certified in caring for adults with congenital heart disease and two board-certified pediatric cardiologists. Neither of the latter at-large members may be employed by any of the hospitals who have specific representation on the panel. The panel has 10 other members who are appointed by the chief executive officers of their 10 respective hospitals, which are named in statute, plus an alternate member for each hospital. A hospital-appointed member, either the voting member or the alternate, must be a pediatric cardiologist or pediatric cardiovascular surgeon.

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<sup>1</sup> Chapter 2017-151, s. 1, and ch. 2018-24, s. 32, Laws of Fla.

<sup>2</sup> Section 395.1055(10)(a), F.S.

<b>Cardiac Program Technical Advisory Panel Membership<sup>3</sup></b>			
<b>Member/Type of Member</b>	<b>Voting</b>	<b>Alternate</b>	<b>Non-Voting</b>
<b>3 At-Large Members with different program affiliations appointed by Secretary of Health Care Administration:</b>			
<i>1 Cardiologist- Board Certified in caring for adults with congenital health disease</i>	■	■	
<i>1 Pediatric Cardiologist – Board Certified</i>	■	■	
<i>1-Pediatric Cardiologist – Board Certified</i>	■	■	
<b>Members appointed by the CEO of the following hospitals:</b>			
Johns Hopkins All Children’s Hospital in St. Petersburg	■	■	
Arnold Palmer Hospital for Children in Orlando	■	■	
Nicklaus Children’s Hospital in Miami	■	■	
St. Joseph’s Children’s Hospital in Tampa	■	■	
University of Florida Health Shands Hospital in Gainesville	■	■	
University of Miami Holtz Children’s Hospital in Miami	■	■	
Wolfson Children’s Hospital in Jacksonville	■	■	
Florida Hospital for Children in Orlando	■	■	
Nemours Children’s Hospital in Orlando	■	■	
<b>Secretary of Health Care Administration may appoint following nonvoting members:</b>			
Secretary of Health Care Administration			■
Surgeon General			■
Deputy Secretary of Children’s Medical Services			■
Any current or past Director of Children’s Medical Services			■
A parent of a child with congenital heart disease			■
An adult with congenital heart disease			■
A representative from the Florida Chapter of the American Academy of Pediatrics			■
A representative from the Florida Chapter of the American College of Cardiology			■
A representative from the Greater Southeast Affiliate of the American Heart Association			■
A representative from the Adult Congenital Heart Association			■
A representative from the March of Dimes			■
A representative from the Florida Association of Children’s Hospitals			■
A representative from the Florida Society of Thoracic and Cardiovascular Surgeons			■

The panel is required to meet at least biannually, or more frequently, upon the call of the Secretary of Health Care Administration. Meetings may be held telephonically or by other electronic means.<sup>4</sup> Records of the panel’s meetings and those of its subcommittees, including draft standards, meeting minutes, and handouts, are posted on the AHCA’s website.<sup>5</sup>

At the request of the Secretary of Health Care Administration, the pediatric cardiac technical advisory panel shall recommend in-state physician experts to conduct an announced or unannounced onsite visit to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center to ensure compliance with s. 395.1055, F.S., and

<sup>3</sup> Section 395.1055(10)(b) and (c), F.S.

<sup>4</sup> Section 395.1055(10)(d), F.S.

<sup>5</sup> See Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel*, available at <http://ahca.myflorida.com/SCHS/PCTAP/index.shtml> (last visited Feb. 12, 2021).

rules adopted thereunder.<sup>6</sup> Each member of a site visit team must submit a written report of his or her findings to the panel, and the panel submits an advisory opinion, based on the reports, to the Secretary of Health Care Administration which includes recommendations and suggested actions for corrections.<sup>7</sup>

The panel must provide the AHCA with recommendations for rules for pediatric cardiac programs which must include:

- Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery services, including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures;
- Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs; and
- Specific steps to be taken by the AHCA and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.<sup>8</sup>

The AHCA is required to adopt rules for pediatric cardiac programs based on the recommendations of the panel.<sup>9</sup>

### ***Activities and Progress of the Panel***

To develop recommendations for pediatric cardiac care, the panel organized itself into three subcommittees: Surgical Rule Subcommittee, Cardiology Rule Subcommittee, and Public Reporting and Transparency Subcommittee.<sup>10</sup> Fourteen public subcommittee meetings were held in 2018.<sup>11</sup> The subcommittees' recommendations were compiled into draft standards and submitted to the AHCA in February 2019.<sup>12</sup> The AHCA presented preliminary draft language in mid-September 2019 and was vetted by the full panel during public meetings on September 20 and October 15.<sup>13</sup> The panel approved the draft language during its October 2019 meeting.<sup>14</sup>

The licensure standards developed by the panel were presented for public comment at a workshop held February 27, 2020, for AHCA's Proposed Rule 59A-3.248<sup>15</sup> relating to Pediatric Cardiac Programs.<sup>16</sup> Comments received were incorporated into the draft rule and approved by

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<sup>6</sup> Section 395.1055(14), F.S.

<sup>7</sup> *Id.*

<sup>8</sup> Section 395.1055(12), F.S.

<sup>9</sup> *Id.*

<sup>10</sup> Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel Annual Report 2019* (Jan. 2020) available at <https://ahca.myflorida.com/SCHS/PCTAP/docs/PCTAPAnnualReport2019.pdf> (last visited Feb. 12, 2021).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> Proposed Rule 59A-3.248, Fla. Admin. Register, available at <https://www.flrules.org/gateway/ruleno.asp?id=59A-3.248> (last visited Feb 12, 2021).

<sup>16</sup> Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel Annual Report 2020* (Dec. 2020) available at <https://ahca.myflorida.com/SCHS/PCTAP/docs/PCTAPAnnualReport2020.pdf> (last visited Feb. 12, 2021).

the panel.<sup>17</sup> The AHCA is currently preparing to submit the proposed language to the Joint Administrative Procedures Committee and to publish the rule for final public review.<sup>18</sup>

The full panel met 24 times in 2018, seven times in 2019, and four times in 2020.<sup>19</sup> The draft minutes from the July 30, 2020 meeting reflect that the panel discussed the proposed rule, the possibility of virtual site visits, compliance with the Sunshine Law, and the delay in posting surgical outcome data due to the Society of Thoracic Surgeons (STS) transitioning warehouse vendors.<sup>20</sup> The panel also asked AHCA for guidance as to whether serving as an alternate member counts toward a member's term limit.<sup>21</sup>

The panel has submitted two annual reports to the Governor, President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the Surgeon General.<sup>22</sup> The reports summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.<sup>23</sup>

### III. Effect of Proposed Changes:

**Section 1** amends s. 395.1055, F.S., to:

- Modify the composition of the panel, by:
  - Providing that the none of the at-large members or alternate at-large members who are appointed by the Secretary of Health Care Administration and are required to be board-certified in caring for adults with congenital heart disease or board-certified in pediatric cardiology, may be employed by any of the 10 hospitals whose CEOs make appointments, or affiliates of those hospitals; and
  - Requiring that for each member and corresponding alternate member appointed by the CEOs of the 10 hospitals, one must be a pediatric cardiologist and the other must be a pediatric cardiovascular surgeon.
- Clarify that time spent as an alternate member of the panel does not count toward member term limits.
- Require the panel to meet at least quarterly rather than biannually.
- Require the chair and vice chair of the panel, in consultation with the AHCA, to develop the agendas for panel meetings.
- Require the annual report submitted by the panel to the Governor and the Legislature to be composed by the panel and signed by the chair and vice chair of the panel.
- Establish that all members of a site review team are agents of the state for purposes of s. 768.28, F.S., relating to sovereign immunity in tort actions. Currently, only members of the panel are considered agents of the state.

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Agency for Health Care Administration, *Senate Bill 362 Analysis* (Feb. 17, 2021) (on file with the Senate Committee on Health Policy).

<sup>20</sup> Draft Minutes, Agency for Health Care Administration, Pediatric Cardiac Technical Advisory Panel (July 30, 2020) available at <https://ahca.myflorida.com/SCHS/PCTAP/docs/102920/DraftMinutes073020.pdf> (last visited Feb. 12, 2021)

<sup>21</sup> *Id.*

<sup>22</sup> *Supra* notes 10 and 16.

<sup>23</sup> Section 395.1055(10)(f), F.S.

- Require a pediatric cardiac program to include in its surgical volume cases involving children younger than 18 years of age with any type of acquired or congenital heart disease and adults with congenital heart disease. The bill provides that cases involving open surgical placement of a pacing wire count toward the surgical volume.
- Authorize a site visit team to conduct a virtual site inspection in lieu of an onsite inspection during a declared state of emergency.
- Authorize the panel to alter the requirements for the patient-specific data to be reviewed virtually in such virtual site inspections, as appropriate to comply with the federal Health Insurance Portability and Accountability Act and other laws governing the electronic sharing of protected medical information.
- Establish that a pediatric surgical center has 24 consecutive months following a site inspection to come into compliance if the panel determines, based on information in the site visit reports, that the center is noncompliant with the AHCA's standards for pediatric cardiac programs.
- Authorize the panel to recommend to the Secretary of Health Care Administration that a center have its license to perform congenital cardiac surgery revoked if the panel deems the center is still noncompliant with the standards after the 24-month period.
- Authorize the Secretary of Health Care Administration to accept or modify the panel's recommendation regarding the revocation of a center's license or recommendations of suggested actions for correction and to require the Secretary to enforce compliance with the AHCA's standards accordingly.
- Require that critical congenital heart disease screening data in quarterly reports submitted by the Surgeon General to the Secretary of Health Care Administration follow the guidelines and suggestions established by the Cardiac Subcommittee on the Children's Medical Services' Genetics and Newborn Screening Advisory Council in consultation with the panel.

**Section 2** provides the bill takes effect on July 1, 2021.

#### **IV. Constitutional Issues:**

**A. Municipality/County Mandates Restrictions:**

None.

**B. Public Records/Open Meetings Issues:**

None.

**C. Trust Funds Restrictions:**

None.

**D. State Tax or Fee Increases:**

None.



E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None. The AHCA does not expect this bill to have a fiscal impact.<sup>24</sup>

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 395.1055 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 17, 2021:**

The CS:

- Clarifies the qualifications required of members to serve on the panel.
- Requires the chair and vice chair of the panel, in consultation with the agency, to develop agendas for panel meetings.
- Requires the annual report submitted by the panel to the Governor and the Legislature to be composed by the panel and signed by the chair and vice chair of the panel.
- Authorizes the Secretary of Health Care Administration to accept or modify a panel's recommendation regarding the revocation of a center's license or recommendations of suggested actions for correction and requires the Secretary to enforce compliance with the AHCA's standards accordingly.

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<sup>24</sup> *Supra* note 19.

B. Amendments:

None.

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

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/17/2021	.	
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The Committee on Health Policy (Harrell) recommended the following:

**Senate Amendment**

Delete lines 41 - 68  
and insert:

(b) Voting members of the panel shall include the following individuals appointed in the following manner:

1. Three ~~3~~ at-large members, and three ~~3~~ alternate at-large members, each with different program affiliations, including one ~~1~~ cardiologist who is board-certified ~~board-certified~~ in caring for adults with congenital heart disease and two ~~2~~ board-



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certified pediatric cardiologists, none ~~neither~~ of whom may be employed by any of the hospitals specified in subparagraph 2. ~~subparagraphs 1.-10.~~ or ~~their~~ affiliates of those hospitals, and each of whom is appointed by the Secretary of Health Care Administration.

2. One member, ~~and 10 members,~~ and one ~~an~~ alternate ~~for each member,~~ from each of the following hospitals, ~~each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon,~~ each appointed by the chief executive officer of their respective hospital ~~the following hospitals:~~

a.1. ~~Johns Hopkins All Children's Hospital in St. Petersburg.~~

b.2. ~~Arnold Palmer Hospital for Children in Orlando.~~

c.3. ~~Joe DiMaggio Children's Hospital in Hollywood.~~

d.4. ~~Nicklaus Children's Hospital in Miami.~~

e.5. ~~St. Joseph's Children's Hospital in Tampa.~~

f.6. ~~University of Florida Health Shands Hospital in Gainesville.~~

g.7. ~~University of Miami Holtz Children's Hospital in Miami.~~

h.8. ~~Wolfson Children's Hospital in Jacksonville.~~

i.9. ~~Florida Hospital for Children in Orlando.~~

j.10. ~~Nemours Children's Hospital in Orlando.~~

3. For each member and corresponding alternate member appointed under subparagraph 2., one must be a pediatric cardiologist and the other must be a pediatric cardiovascular surgeon. Appointments made under subparagraph 2. ~~subparagraphs 1.-10.~~ are contingent upon the hospital's compliance with this section and rules adopted thereunder, as determined by the



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40 Secretary of Health Care Administration. A member appointed  
41 under subparagraph 2. ~~subparagraphs 1.-10.~~



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/17/2021	.	
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The Committee on Health Policy (Harrell) recommended the following:

**Senate Amendment (with directory and title amendments)**

Delete line 79

and insert:

or by other electronic means. The chair and vice chair of the panel, in consultation with the agency, shall develop the agendas for panel meetings.

(f) Beginning on January 1, 2020, and annually thereafter, the panel shall compose a report signed by the chair and vice chair of the panel and submit the a report to the Governor, the



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President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General. The report must summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.

===== D I R E C T O R Y   C L A U S E   A M E N D M E N T =====

And the directory clause is amended as follows:

Delete line 30

and insert:

Section 1. Paragraphs (b), (d), (f), and (g) of subsection (10),

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

And the title is amended as follows:

Between lines 7 and 8

insert:

requiring the panel's chair and vice chair, in consultation with the Agency for Health Care Administration, to develop panel meeting agendas; requiring a certain annual report composed and submitted by the panel to be signed by the panel's chair and vice chair;



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/17/2021	.	
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The Committee on Health Policy (Harrell) recommended the following:

**Senate Amendment (with title amendment)**

Delete line 117  
and insert:  
perform congenital cardiac surgery revoked. The Secretary of Health Care Administration may accept or modify the panel's recommendations and shall enforce compliance with the agency's standards accordingly.

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





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11 And the title is amended as follows:  
12       Between lines 22 and 23  
13 insert:  
14       authorizing the Secretary for Health Care  
15       Administration to accept or modify the panel's  
16       recommendations and requiring enforcement of the  
17       agency's standards accordingly;

By Senator Harrell

25-00635-21

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A bill to be entitled

An act relating to pediatric cardiac care; amending s. 395.1055, F.S.; revising requirements for members of the pediatric cardiac technical advisory panel; specifying that time spent as an alternate member does not count toward panel member term limits; revising the frequency with which the panel must meet; extending sovereign immunity to apply to all individuals who are members of a site visit review team; requiring pediatric cardiac programs to include certain cases in the program's required surgical volume; authorizing site visit teams to conduct virtual site inspections during a declared state of emergency; authorizing the panel to alter certain requirements for virtual site inspections; providing that pediatric cardiac surgical centers that are deemed by the panel to be noncompliant with certain standards must come into compliance with those standards within a specified timeframe; authorizing the panel to make a certain recommendation to the Secretary of Health Care Administration if a center does not come into compliance within such timeframe; requiring certain data submitted by the Surgeon General to the Secretary of Health Care Administration to follow specified guidelines and suggestions; providing an effective date.

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

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

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Section 1. Paragraphs (b), (d), and (g) of subsection (10), paragraph (c) of subsection (13), paragraph (c) of subsection (14), and subsection (15) of section 395.1055, Florida Statutes, are amended, and paragraphs (e) and (f) are added to subsection (14) of that section, to read:

395.1055 Rules and enforcement.—

(10) The agency shall establish a pediatric cardiac technical advisory panel, pursuant to s. 20.052, to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs.

(b) Voting members of the panel shall include: 3 at-large members, and 3 alternate at-large members with different program affiliations, including 1 cardiologist who is board certified in caring for adults with congenital heart disease and 2 board-certified pediatric cardiologists, none ~~neither~~ of whom may be employed by any of the hospitals specified in subparagraphs 1.-10. or their affiliates, each of whom is appointed by the Secretary of Health Care Administration, and 10 members, and an alternate for each member, one ~~each~~ of whom is a pediatric cardiologist and one of whom is ~~or~~ a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following hospitals:

1. Johns Hopkins All Children's Hospital in St. Petersburg.
2. Arnold Palmer Hospital for Children in Orlando.
3. Joe DiMaggio Children's Hospital in Hollywood.
4. Nicklaus Children's Hospital in Miami.
5. St. Joseph's Children's Hospital in Tampa.
6. University of Florida Health Shands Hospital in

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

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Gainesville.

7. University of Miami Holtz Children's Hospital in Miami.

8. Wolfson Children's Hospital in Jacksonville.

9. Florida Hospital for Children in Orlando.

10. Nemours Children's Hospital in Orlando.

Appointments made under subparagraphs 1.-10. are contingent upon the hospital's compliance with this section and rules adopted thereunder, as determined by the Secretary of Health Care Administration. A member appointed under subparagraphs 1.-10. whose hospital fails to comply with such standards may serve only as a nonvoting member until the hospital complies with such standards. A voting member may serve a maximum of two 2-year terms and may be reappointed to the panel after being retired from the panel for a full 2-year term. Time spent serving as an alternate member on the panel does not count toward a member's term limits.

(d) The panel shall meet quarterly ~~biannually~~, or more frequently upon the call of the Secretary of Health Care Administration. Such meetings may be conducted telephonically, or by other electronic means.

(g) Panel members and all members of a site visit review team are agents of the state for purposes of s. 768.28 throughout the good faith performance of the duties assigned to them by the Secretary of Health Care Administration.

(13) A pediatric cardiac program shall:

(c) Have a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons. The program's cardiac surgical volume must include

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cases involving children younger than 18 years of age with any type of acquired or congenital heart disease and adults with congenital heart disease. Cases involving open surgical placement of a pacing wire count toward the surgical volume.

(14)

(c) A site visit team shall conduct an onsite inspection of the designated hospital's pediatric medical and surgical programs, and each member shall submit a written report of his or her findings to the panel. During a declared state of emergency, a site visit team may conduct a virtual site inspection in lieu of an onsite inspection. The panel shall discuss the written reports and present an advisory opinion to the Secretary of Health Care Administration which includes recommendations and any suggested actions for correction.

(e) For virtual site inspections conducted during a declared state of emergency, the panel may alter the requirements for the patient-specific data to be reviewed virtually as appropriate to comply with the Health Insurance Portability and Accountability Act and other laws governing the electronic sharing of protected medical information.

(f) Following a site inspection, if the panel deems the information contained in the submitted reports to establish that the pediatric cardiac surgical center under inspection is noncompliant with the agency's standards for pediatric cardiac programs, the center has 24 consecutive months to come into compliance with such standards. If at the end of the 24-month period, the panel deems the center is still noncompliant with the standards, the panel may recommend to the Secretary of Health Care Administration that the center have its license to

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perform congenital cardiac surgery revoked.

(15) The Surgeon General shall provide quarterly reports to the Secretary of Health Care Administration consisting of data from the Children's Medical Services' critical congenital heart disease screening program for review by the advisory panel. Data submitted must follow the guidelines and suggestions established by the Cardiac Subcommittee of the Children's Medical Services' Genetics and Newborn Screening Advisory Council in consultation with the panel.

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



## THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

### COMMITTEES:

Health Policy, *Chair*  
Appropriations Subcommittee on Health  
and Human Services, *Vice Chair*  
Appropriations Subcommittee on Criminal  
and Civil Justice  
Children, Families, and Elder Affairs  
Military and Veterans Affairs and Space

### JOINT COMMITTEE:

Joint Committee on Public Counsel Oversight

**SENATOR GAYLE HARRELL**  
25th District

January 12, 2021

Senator Manny Diaz  
404 South Monroe Street  
Tallahassee, FL 32399

Chair Diaz,

I respectfully request that **SB 362 – Pediatric Cardiac Care** be placed on the next available agenda for the Health Policy Committee Meeting.

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

Thank you,

A handwritten signature in cursive script, appearing to read "Gayle", written in black ink.

Senator Gayle Harrell  
Senate District 25

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

### REPLY TO:

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**BILL GALVANO**  
President of the Senate

**DAVID SIMMONS**  
President Pro Tempore

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

2-17-21

Meeting Date

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

362

Bill Number (if applicable)

Topic Pediatric Cardiac Care

Amendment Barcode (if applicable)

Name Marnie George

Job Title Sr. Advisor - Buchanan Ingersoll & Rooney

Address 101 N. Monroe St. Suite 1090

Phone 850-510-8866

Street

Tallahassee FL 32303

Email marnie.george@bipe.com

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL Chapter Am College of Cardiology

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)

2/17/21

Meeting Date

362

Bill Number (if applicable)

Topic Pediatric Cardiac Care

Amendment Barcode (if applicable)

Name Doug Bell

Job Title

Address 119 S. Monroe St

Street

Phone 205-9000

City

State

Zip

Email doug.bell@unhdfirm.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FC AAP - The Pediatricians

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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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)

2/17/21

Meeting Date

362

Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title \_\_\_\_\_

Address 4427 Herschel St

Phone 904-233-3051

Street

Jacksonville FL 32210

City

State

Zip

Email nulandlaw@aol.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Society of Thoracic Cardiovascular Surgeons

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)





# 2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

## BILL INFORMATION

<b>BILL NUMBER:</b>	SB 362
<b>BILL TITLE:</b>	Pediatric Cardiac Care
<b>BILL SPONSOR:</b>	Senator Gayle Harrell
<b>EFFECTIVE DATE:</b>	July 1, 2021

## COMMITTEES OF REFERENCE

1) Health Policy
2) Judiciary
3) Rules
4)
5)

## CURRENT COMMITTEE

N/A

## SIMILAR BILLS

<b>BILL NUMBER:</b>	HB 407
<b>SPONSOR:</b>	Representative Michelle Salzman

## PREVIOUS LEGISLATION

<b>BILL NUMBER:</b>	SB 1126
<b>SPONSOR:</b>	Senator Gayle Harrell
<b>YEAR:</b>	2019
<b>LAST ACTION:</b>	Died in Senate Appropriations Subcommittee on Health & Human Services

## IDENTICAL BILLS

<b>BILL NUMBER:</b>	N/A
<b>SPONSOR:</b>	

**Is this bill part of an agency package?**

Y \_\_\_\_ N X

## BILL ANALYSIS INFORMATION

<b>DATE OF ANALYSIS:</b>	January 29, 2021
<b>LEAD AGENCY ANALYST:</b>	Nikole Helvey
<b>ADDITIONAL ANALYST(S):</b>	Jack Plagge
<b>LEGAL ANALYST:</b>	Bill Roberts
<b>FISCAL ANALYST:</b>	La-Shonna Austin

## POLICY ANALYSIS

### 1. EXECUTIVE SUMMARY

The Agency for Health Care Administration (Agency) provides staff support to the Pediatric Cardiac Technical Advisory Panel (PCTAP) which is made up of statutorily designated pediatric/congenital cardiologists and surgeons. The bill requires quarterly panel meetings, adds clarifying language to PCTAP membership eligibility and terms, allows site visits to be conducted virtually during a declared state of emergency, and adds authorization for the panel to revoke program licensure in programs that are consistently unable to meet recommended quality standards for 24 months.

The bill also adds a requirement for the Genetics and Newborn Screening Advisory Council of Children's Medical Services to consult with the PCTAP regarding guidelines for data standards and reports to be shared between the two groups.

### 2. SUBSTANTIVE BILL ANALYSIS

#### 1. PRESENT SITUATION:

The Pediatric Cardiac Technical Advisory Panel (PCTAP) was activated in 2017 and has held numerous public meetings. Section 395.1055, F.S., requires the Agency to establish a PCTAP to develop rule recommendations to procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs. The duties of the panel include making rule recommendations for standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services.

The Agency Secretary is required to consult with the PCTAP related to certificate of need (CON) applications for pediatric cardiac surgical centers, and may request announced and unannounced site visits to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center through the certificate of need process; however there is no current CON requirements for these programs.

The Agency Secretary may request the PCTAP conduct an onsite visit to of a designated hospital pediatric medical and surgical program which must include an inspection of the facility, interviews of staff and a review of medical records and reports, outcome data submitted to the Society of Thoracic Surgeons and the American College of Cardiology pursuant to s. 408.05(3)(l), F.S., and mortality and volume reports from the prior year. Panel members are agents of the state for purposes of s. 768.28, F.S., throughout the good faith performance of the duties assigned to them by the Secretary of the Agency for Health Care Administration.

The PCTAP has successfully completed recommendations for the Agency to establish rules regarding quality and performance of pediatric cardiac surgery programs. The recommended rule language is posted on the Agency's website at: <http://www.ahca.myflorida.com/SCHS/PCTAP/meetings.shtml>.

The PCTAP members continue to address topics around public transparency of program quality measures and planning for the implementation of periodic site visits at each licensed program.

Existing statute limits membership terms to two years and limits each member to two consecutive terms. Some of the first members who were appointed in 2017 will reach the end of their allowed terms in 2021.

#### 2. EFFECT OF THE BILL:

The bill excludes from term limits, years served as alternate PCTAP members and increases the required PCTAP meeting frequency from biannually to quarterly. The PCTAP met twenty-four times during calendar year 2018, seven times in 2019, and four times in 2020.

The bill extends the status of "agent of the state" for the purposes of liability protections under 768.28, F.S, to site visit participants who are not Panel members, allows site visits to be performed remotely during a declared state of emergency, and authorizes the PCTAP to establish requirements for data to be shared by hospital programs for virtual site visits.

The bill requires surgical volume minimums for children younger than 18 years of age (pediatric) and adults with congenital heart disease (no upper age limit). The recommended draft rule language provided to the Agency by the PCTAP includes minimum volume requirements which allow adult congenital patients to be included.

The bill also requires the open surgical placement of pacing wires will be included in volume tallies for these populations. The recommended draft rule language provided by the PCTAP includes the ability to include epicardial lead placement as a reportable surgical procedure for volume minimums.

The bill authorizes the PCTAP to recommend revocation for pediatric cardiac surgical programs that are consistently unable to achieve the quality thresholds established in rule. The Agency is currently authorized to initiate adverse action against a hospital pursuant to Chapters 408, Part II and 395, Part I, F.S., which authorizes immediate penalties for serious non-compliance or failure to timely correct minor deficiencies, and revocation or denial of a license for a pattern of deficient practice. Section 408.811 (4), F.S. states “A deficiency must be corrected within 30 calendar days after the provider is notified of inspection results unless an alternative timeframe is required or approved by the agency.” The bill does not waive the requirement to correct deficiencies timely. A recommendation from the PCTAP to revoke a program would be evaluated based upon the Agency’s enforcement authority.

The bill requires the Children’s Medical Services’ Genetic and Newborn Screening Advisory Council (GeNSAC) consult with the PCTAP regarding data collection and reporting requirements. The GeNSAC has a current task force dedicated to addressing data requirements for screenings for Critical Congenital Heart Disease (CCHD). Multiple PCTAP members currently participate in meetings of the task force and the larger GeNSAC.

**3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y \_\_\_ N X**

If yes, explain:	
Is the change consistent with the agency’s core mission?	Y ___ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	

**4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?**

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

**5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y \_\_\_ N X**

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

**6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQUIRED BY THIS BILL? Y \_\_\_ N X**

Board:	Pediatric Cardiac Technical Advisory Panel
Board Purpose:	To develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs.
Who Appointments:	The Secretary of the Agency for Health Care Administration and the CEO of 10 specific hospitals.
Appointee Term:	4 years
Changes:	Currently the 10 members, and an alternate for each member, appointed by the CEO of the 10 hospitals could be a pediatric cardiologist or a pediatric cardiovascular surgeon. The proposed bill will require that one be a pediatric cardiologist and the other a pediatric cardiovascular surgeon.
Bill Section Number(s):	Section 1

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## FISCAL ANALYSIS

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### 1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y \_\_\_ N X

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees? If yes, explain.	
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

### 2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y \_\_\_ N X

Revenues:	
Expenditures:	
Does the legislation contain a State Government appropriation?	
If yes, was this appropriated last year?	

### 3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y \_\_\_ N X

Revenues:	
Expenditures:	
Other:	

### 4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y \_\_\_ N X

If yes, explain impact.	
Bill Section Number:	

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## TECHNOLOGY IMPACT

### 1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y \_\_\_ N X

If yes, describe the anticipated impact to the agency including any fiscal impact.	
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## FEDERAL IMPACT

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

If yes, describe the anticipated impact including any fiscal impact.	
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**ADDITIONAL COMMENTS**

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**LEGAL – GENERAL COUNSEL’S OFFICE REVIEW**

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Issues/concerns/comments:	N/A
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**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.)

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

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BILL: CS/SB 700

INTRODUCER: Health Policy Committee and Senator Rodriguez

SUBJECT: Telehealth

DATE: February 19, 2021

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	<b>Fav/CS</b>
2.			AHS	
3.			AP	

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 700:

- Authorizes the Agency for Health Care Administration (AHCA), subject to limitations in the General Appropriations Act, to reimburse for telehealth services involving store-and-forward technology and remote patient monitoring services under the Medicaid program.
- Expands the definition of “telehealth” in s. 456.47, F.S., to include:
  - A telehealth provider’s supervision of health care services through the use of synchronous and asynchronous telecommunications technology.
  - Telephone calls, emails, fax transmissions, and other nonpublic-facing telecommunications.
- Authorizes a nonphysician health care practitioner who is required to maintain a formal supervisory relationship with a physician, including a physician who is registered as an out-of-state telehealth provider, to satisfy that requirement through telehealth.
- Authorizes a telehealth provider, practicing in a manner consistent with his or her scope of practice, to prescribe Schedule III, IV, and V controlled substances through telehealth.
- Prohibits the prescription of Schedule I and II controlled substances through telehealth.
- Creates a new type of pharmacy establishment, a “remote-site pharmacy,” where medicinal drugs are compounded or dispensed by a registered pharmacy technician (RPT) who is remotely supervised by an off-site pharmacist acting in the capacity of prescription department manager.

- Authorizes an off-site pharmacist to remotely supervise an RPT at a remote-site pharmacy and authorizes an RPT operating under such remote supervision to compound and dispense drugs.
- Provides for permitting and regulation of remote-site pharmacies by the Department of Health (DOH).
- Provides requirements for remote-site pharmacies.
- Prohibits a remote-site pharmacy from performing centralized prescription filling.
- Authorizes a pharmacist to serve as prescription department manager for up to three remote-site pharmacies that are under common control of the same supervising pharmacies and requiring him or her to visit the remote site on a schedule as determined by the Board of Pharmacy (BOP).
- Authorizes a pharmacist, at the direction of a physician, to administer certain extended-release medications.
- Creates exceptions to certain requirements that audiologists and hearing aid specialists must perform under current law when they are fitting and selling hearing aids to persons who are 18 years of age or older and who provide a medical clearance or a waiver.
- Makes it lawful for hearing aids to be sold or distributed through the mail to an ultimate consumer who is 18 years of age or older.

The bill is projected to have a negative fiscal impact on the DOH. *See* section V of this analysis.

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

## **II. Present Situation:**

This section will discuss the following topics in order:

- Telehealth
  - Terminology
  - Florida telehealth providers.
- Telemedicine coverage under Florida Medicaid.
- Controlled substance prescribing through telehealth.
  - Controlled substances generally.
  - Federal law.
  - Federal guidance during the Covid-19 public health emergency.
  - Florida law.
  - Florida DOH Emergency Order No. 20-002.
- Physician supervision
  - Physician supervision laws and rules governing the practice of advanced practice registered nurses, certified registered nurse anesthetists, and physician assistants.
  - Advanced practice registered nurses (APRNs).
  - Certified registered nurse anesthetists (CRNAs).
  - Physician supervision of CRNA's as a condition of participation in Medicare.
  - Physician assistants (PAs).
  - Physician assistant licensure.
  - Physician assistant scope of practice and physician supervision.
- Regulation of pharmacy establishments.

- Pharmacy permitting.
- Centralized prescription filling.
- Prescription department managers.
- Regulation of pharmacists.
  - Pharmacist licensure requirements.
  - Pharmacist scope of practice.
  - Pharmacists with a broader scope of practice.
  - Consultant pharmacists.
  - Collaborative pharmacy practice for chronic health conditions.
  - Testing or screening for and treatment of minor, nonchronic health conditions.
  - Pharmacist supervision of registered pharmacy interns.
- Registered pharmacy technicians.
  - Pharmacy technician registration requirements.
  - Pharmacy technician training programs.
  - Pharmacy technician scope of practice.
  - Pharmacist supervision of pharmacy technicians.
- Audiology
  - Audiologist scope of practice and licensure requirements.
  - Hearing aid specialist scope of practice and licensure requirements.
  - Florida telehealth in relation to audiology.
- The federal Health Insurance Portability and Accountability Act (HIPAA).
  - HIPAA Privacy Rule.
  - HIPAA Security Rule.
  - HIPAA Breach Notification Rule.
  - Notice of nonenforcement discretion during a public health emergency.
- Jurisdiction and venue for telehealth-related actions.

## **Telehealth**

### ***Terminology***

Section 456.47, F.S., defines the term “telehealth” as the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration. The term does not include audio-only telephone calls, e-mail messages, or facsimile transmissions.

“Synchronous” telehealth refers to the live, real-time, or interactive transmission of information between a patient and a health care provider during the same time period. The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

“Asynchronous” telehealth refers to the transfer of data between a patient and a health care provider over a period of time and typically in separate time frames. This is commonly referred to as “store-and-forward.”



Store-and-forward allows for the electronic transmission of medical information, such as digital images, documents, and pre-recorded videos through telecommunications technology to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service after the data has been collected.<sup>1</sup> The transfer of X-rays or MRI images from one health care provider to another health care provider for review in the future would be considered asynchronous telehealth through store-and-forward technology.

“Remote monitoring” refers to the collection, transmission, evaluation, and communication of individual health data to a health care provider from the patient’s location through technology such as wireless devices, wearable sensors, implanted health monitors, smartphones, and mobile apps.<sup>2</sup> Remote monitoring can be useful for ongoing condition monitoring and chronic disease management. Depending upon the patient’s needs, remote monitoring can be synchronous or asynchronous.

“Non-public facing communication technology” is a technology that, as a default, allows only the intended parties to participate in the communication. For example, Zoom, Skype, Apple FaceTime, and Facebook Messenger video chat.<sup>3</sup> Typically, these technologies employ end-to-end encryption, which allows only an individual and the person with whom the individual is communicating to see what is transmitted. In contrast, public-facing products such as TikTok, Facebook Live, or a public chat room are not acceptable forms of remote communication for telehealth because they are designed to be open to the public or allow wide or indiscriminate access to the communication.

### ***Florida Telehealth Providers***

In 2019, the Legislature passed and the Governor approved CS/CS/HB 23, which created s. 456.47, F.S. The bill became effective on July 1, 2019.<sup>4</sup> It authorized Florida-licensed health care providers<sup>5</sup> to use telehealth to deliver health care services within their respective scopes of practice. The bill also authorized out-of-state health care providers to use telehealth to deliver health care services to Florida patients if they register with the DOH or the applicable board<sup>6</sup> and meet certain eligibility requirements.<sup>7</sup> A registered out-of-state telehealth provider may use telehealth, within the relevant scope of practice established by Florida law and rule, to provide health care services to Florida patients but is prohibited from opening an office in Florida and from providing in-person health care services to patients located in Florida.

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<sup>1</sup> Center for Connected Health Policy, National Telehealth Policy Resource Center, *Store-and-Forward (Asynchronous)* available at <https://www.cchpca.org/about/about-telehealth/store-and-forward-asynchronous> (last visited Feb. 13, 2021).

<sup>2</sup> American Telemedicine Association, *Telehealth: Defining 21<sup>st</sup> Century Care*, available at [https://f.hubspotusercontent30.net/hubfs/5096139/Files/Resources/ATA\\_Telehealth\\_Taxonomy\\_9-11-20.pdf](https://f.hubspotusercontent30.net/hubfs/5096139/Files/Resources/ATA_Telehealth_Taxonomy_9-11-20.pdf) (last visited Feb. 13, 2021).

<sup>3</sup> U.S. Department for Health and Human Services Office for Civil Rights, *FAQs on Telehealth and HIPAA during the COVID-10 nationwide public health emergency* (Mar. 2020) available at <https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf> (Feb. 14, 2021).

<sup>4</sup> Chapter 2019-137, s. 6, Laws of Fla.

<sup>5</sup> Section 467.47(1)(b), F.S.

<sup>6</sup> Under s. 456.001(1), F.S., the term “board” is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH’s Division of Medical Quality Assurance.

<sup>7</sup> Section 467.47(4), F.S.

Telehealth providers who treat patients located in Florida must be one of the licensed health care practitioners listed below<sup>8</sup> and be either Florida-licensed, licensed under a multi-state health care licensure compact of which Florida is a member state, or registered as an out-of-state telehealth provider:

- Behavioral Analyst
- Acupuncturist
- Allopathic physician
- Osteopathic physician
- Chiropractor
- Podiatrist
- Optometrist
- Nurse
- Pharmacist
- Dentist
- Dental Hygienist
- Midwife
- Audiologist
- Speech Therapist
- Occupational Therapist
- Radiology Technician
- Electrologist
- Orthotist
- Pedorthist
- Prosthetist
- Medical Physicist
- Emergency Medical Technician
- Paramedic
- Massage Therapist
- Optician
- Hearing Aid Specialist
- Clinical Laboratory Personnel
- Respiratory Therapist
- Psychologist
- Psychotherapist
- Dietician/Nutritionist
- Athletic Trainer
- Clinical Social Worker
- Marriage and Family Therapist
- Mental Health Counselor

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<sup>8</sup> Section 467.47(1)(b), F.S. These are professionals licensed under s. 393.17; part III, ch. 401; ch. 457; ch. 458; ch. 459; ch. 460; ch. 461; ch. 463; ch. 464; ch. 465; ch. 466; ch. 467; part I, part III, part IV, part V, part X, part XIII, and part XIV, ch. 468; ch. 478; ch. 480; part II and part III, ch. 483; ch. 484; ch. 486; ch. 490; or ch. 491.

The Legislature in 2019 also passed HB 7067, which required an out-of-state telehealth provider to pay an initial registration fee of \$150 and a biennial registration renewal fee of \$150, but the bill was vetoed by the Governor and did not become law.<sup>9</sup>

On March 16, 2020, Surgeon General Scott Rivkees executed DOH Emergency Order 20-002 authorizing certain out-of-state physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses to provide telehealth in Florida without the need to register as a telehealth provider under s. 456.47(4), F.S.<sup>10</sup> This emergency order was extended<sup>11</sup> and will remain in effect until the expiration of the Governor's Executive Order No. 20-52 and extensions thereof.<sup>12</sup>

Five days later, the Surgeon General executed DOH Emergency Order 20-003<sup>13</sup> to also authorize certain out-of-state clinical social workers, marriage and family therapists, mental health counselors, and psychologists to provide telehealth in Florida without the need to register as a telehealth provider under s. 456.47(4), F.S. This emergency order was also extended<sup>14</sup> and will remain in effect until the expiration of Executive Order No. 20-52 and extensions thereof.

### **Florida Medicaid Program**

Florida Medicaid is the health care safety net for low-income Floridians. The national Medicaid program is a partnership of federal and state governments established to provide coverage for health services for eligible persons. Florida's program is administered by the AHCA and financed through state and federal funds.<sup>15</sup> The AHCA is responsible for maintaining a Medicaid state plan that is approved by the Centers for Medicare and Medicaid Services (CMS). Florida Medicaid services are delivered to Medicaid recipients through either the fee-for-service delivery system or a managed care delivery system, with most Medicaid recipients receiving their services through a Medicaid managed care plan.

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<sup>9</sup> Transmittal Letter from Governor Ron DeSantis to Secretary of State Laurel Lee (June 27, 2019) available at <https://www.flgov.com/wp-content/uploads/2019/06/06.27.2019-Transmittal-Letter-3.pdf> (last visited Feb. 14, 2021).

<sup>10</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-002* (Mar. 16, 2020) available at <http://floridahealthcovid19.gov/wp-content/uploads/2020/03/filed-eo-doh-no.-20-002-medical-professionals-03.16.2020.pdf> (last visited Feb. 14, 2021).

<sup>11</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-011* (June 30, 2020) available at <https://floridahealthcovid19.gov/wp-content/uploads/2020/06/DOH-Emergency-Order-DOH-No.-20-011.pdf> (last visited Feb. 14, 2021).

<sup>12</sup> Under s. 252.36(2), F.S., no state of emergency declared pursuant to the Florida Emergency Management Act, may continue for more than 60 days unless renewed by the Governor. The state of emergency declared in Executive Order 20-52, was extended by Executive Orders 20-114, 20-166, 20-192, 20-213, 20-276, and 20-316. Executive Order 20-316 will remain in effect until Feb. 27, 2020. Office of the Governor, State of Florida, *Executive Order 20-316* (Dec. 29, 2020) available at [https://www.flgov.com/wp-content/uploads/orders/2020/EO\\_20-316.pdf](https://www.flgov.com/wp-content/uploads/orders/2020/EO_20-316.pdf) (last visited Feb. 9, 2021).

<sup>13</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-003* (Mar. 21, 2020) available at <https://s33330.pcdn.co/wp-content/uploads/2020/03/DOH-EO-20-003-3.21.2020.pdf> (last visited Feb. 14, 2021).

<sup>14</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-005* (Apr. 21, 2020) available at <https://s33330.pcdn.co/wp-content/uploads/2020/04/DOH-Emergency-Order-20-005-extending-20-003.pdf> (last visited Feb. 14, 2021).

<sup>15</sup> Section 20.42, F.S.

### ***Telemedicine Coverage under the Florida Medicaid Program<sup>16</sup>***

In the 2018 negotiations for the re-procurement of Medicaid health plan contracts, health plans agreed to cover additional telemedicine modalities, including asynchronous remote patient monitoring and store-and-forward technologies. In addition, Medicaid health plans are required to cover telemedicine services in “parity” with face-to-face services, meaning the health plan must cover services via telemedicine, where appropriate, in a manner no more restrictive than the health plan would cover the service face-to-face.

Currently, Florida Medicaid reimburses for services delivered via asynchronous telemedicine in the managed care delivery system, but not in the fee-for-service delivery system. To qualify for payment, practitioners must be in a location other than their patients and use appropriate audio-visual equipment. Florida Medicaid does not reimburse for telehealth services such as chart reviews, telephone conversations, and email or fax transmissions. In response to the COVID-19 state of emergency, the AHCA took multiple steps to expand telemedicine to prevent recipients from having lapses in treatment due to access issues. One of those changes was to allow audio-only telehealth services in both managed care and fee-for-service delivery systems.

### **Controlled Substance Prescribing through Telehealth**

#### ***Controlled Substances Generally***

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. The scheduling of substances in Florida law is generally consistent with the federal scheduling of substances under 21 U.S.C. s. 812:

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples include heroin and lysergic acid diethylamide (LSD).
- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples include cocaine and morphine.
- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples include lysergic acid; ketamine; and some anabolic steroids.
- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples include alprazolam, diazepam, and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in

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<sup>16</sup> Agency for Health Care Administration, *Senate Bill 700 Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy.)

Schedule IV. Examples include low dosage levels of codeine, certain stimulants, and certain narcotic compounds.

### ***Federal Law<sup>17</sup>***

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008<sup>18</sup> amended the federal Controlled Substances Act, to prohibit a practitioner from issuing a “valid prescription” for a controlled substance through the Internet without having first conducted at least one in-person medical evaluation, except in certain circumstances. Thereafter, the prescriber may prescribe controlled substances to that patient via Internet or a phone call. The Act offers seven exceptions to the in-person exam. One such exception occurs when the Secretary of the federal Department of Health and Human Services (HHS) has declared a public health emergency.

### ***Federal Guidance During the COVID-19 Public Health Emergency***

On January 31, 2020, the Secretary of HHS issued a public health emergency.<sup>19</sup> On March 16, 2020, the federal Drug Enforcement Agency (DEA) published a COVID-19 Information page on the Diversion Control Division website, authorizing DEA-registered practitioners, authorized designated DEA-registered practitioners to issue prescriptions for all Schedule II-V controlled substances to patients without first conducting an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.
- The evaluation is conducted using an audio-visual, real-time, two-way interactive communication system.
- The practitioner is acting in accordance with applicable federal and state law.<sup>20</sup>

### ***Florida Law***

Section 456.44, F.S., as amended during the 2018 legislative session, CS/CS/HB 21,<sup>21</sup> authorizes prescribers to prescribe a three-day supply of a Schedule II opioid<sup>22</sup> or up to a seven-day supply if medically necessary. The prescribing limits on Schedule II opioids do not apply to prescriptions for acute pains related to: cancer, a terminal condition, pain treated with palliative care, or a traumatic injury with an Injury Severity Score of 9 or higher.<sup>23</sup>

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<sup>17</sup> 21 U.S.C. s. 829.

<sup>18</sup> Public Law No. 110-435 (2008).

<sup>19</sup> Determination that a Public Health Emergency Exists, Alex M. Azar II, Secretary of U.S. Department of Health and Human Services (January 31, 2020) available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (last visited Feb. 9, 2021).

<sup>20</sup> Diversion Control Division, U.S. Department of Justice Drug Enforcement Administration, *COVID-19 Information Page*, available at <https://www.deadiversion.usdoj.gov/coronavirus.html> (last visited Feb. 9, 2021). Letter from Thomas Prevostnik, Deputy Assistant Administrator, Diversion Control Division, U.S. Department of Justice Drug Enforcement Administration, to DEA Qualifying Practitioners and Other Practitioners, (Mar. 31, 2020) available at [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)/\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)/(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf) (last visited Feb. 9, 2021).

<sup>21</sup> Chapter 2018-13, Laws of Fla.

<sup>22</sup> All opioids are controlled substances. Opioids range in classification between Schedule I and Schedule V.

<sup>23</sup> Section 456.44(1)(a), F.S.

That section also requires a prescriber and dispenser to report to and review the Prescription Drug Monitoring Program database to review a patient's controlled substance dispensing history prior to prescribing or dispensing a Schedule II-IV controlled substance for patients 16 years older.<sup>24</sup> These limitations and requirements apply to practitioners providing services in-person and through telehealth.

Section 456.47(2)(c), F.S., as created by 2019 CS/CS/HB 23<sup>25</sup>, prohibits telehealth providers from prescribing any controlled substance unless the controlled substance is prescribed for:

- The treatment of a psychiatric disorder;
- Inpatient treatment at a licensed hospital;
- The treatment of a patient receiving hospice services; or
- The treatment of a resident of a nursing home facility.

### ***Florida DOH Emergency Order No. 20-002***

The same day that the HHS Secretary authorized qualified prescribers to prescribe Schedule II-V controlled substances, Surgeon General Rivkees issued DOH Emergency Order No. 20-002<sup>26</sup>, which suspended s. 456.47(2)(c), F.S., and authorized specified Florida-licensed prescribers<sup>27</sup> to issue a renewal prescription for a Schedule II-IV controlled substance only for an existing patient for the purpose of treating chronic nonmalignant pain without conducting another physical examination of the patient. This emergency order was extended<sup>28</sup> and will remain in effect until the expiration of Executive Order No. 20-52 and extensions thereof.<sup>29</sup>

### **Physician Supervision**

The Board of Medicine (BOM) defines levels of physician supervision.<sup>30</sup> Unless otherwise provided by law or rule, the definitions listed below will apply to all supervised licensees:

“Direct supervision” requires the physical presence of the supervising licensee on the premises so that the supervising licensee is reasonably available as needed.

“Indirect supervision” requires only that the supervising licensee practice at a location which is within close physical proximity of the practice location of the supervised licensee and that the

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<sup>24</sup> Section 893.055, F.S.

<sup>25</sup> Chapter 2019-137, Laws of Fla.

<sup>26</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-002* (Mar. 16, 2020) available at <http://floridahealthcovid19.gov/wp-content/uploads/2020/03/filed-eo-doh-no.-20-002-medical-professionals-03.16.2020.pdf> (last visited Feb. 14, 2021).

<sup>27</sup> Physicians, osteopathic physicians, physician assistants, or advanced practice registered nurses that have designated themselves as a controlled substance prescribing practitioner on their practitioner profiles pursuant to s. 456.44, F.S.

<sup>28</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-011* (June 30, 2020) available at <https://floridahealthcovid19.gov/wp-content/uploads/2020/06/DOH-Emergency-Order-DOH-No.-20-011.pdf> (last visited Feb. 14, 2021).

<sup>29</sup> Under s. 252.36(2), F.S., no state of emergency declared pursuant to the Florida Emergency Management Act, may continue for more than 60 days unless renewed by the Governor. The state of emergency declared in Executive Order 20-52, was extended by Executive Orders 20-114, 20-166, 20-192, 20-213, 20-276, and 20-316. Executive Order 20-316 will remain in effect until Feb. 27, 2020. Office of the Governor, State of Florida, *Executive Order 20-316* (Dec. 29, 2020) available at [https://www.flgov.com/wp-content/uploads/orders/2020/EO\\_20-316.pdf](https://www.flgov.com/wp-content/uploads/orders/2020/EO_20-316.pdf) (last visited Feb. 9, 2021).

<sup>30</sup> Fla. Admin. Code R. 64B8-2.001 (2020).

supervising licensee must be readily available for consultation as needed. “Close physical proximity” shall be within 20 miles or 30 minutes unless otherwise authorized by the BOM.

“Immediate Supervision” requires the physical presence of the supervising licensee in the same room as the supervised licensee.

The Board of Osteopathic Medicine (BOOM) has no similar rule.

***Physician Supervision Laws and Rules governing the practice of Advanced Practice Registered Nurses, Certified Registered Nurse Anesthetists, and Physician Assistants***

	<b>APRNs</b>	<b>CRNAs (specialized APRNs)</b>	<b>PAs</b>
Federal Conditions		<p>42 CFR s. 482.52</p> <p>As a condition of a hospital’s participation in the Medicare program, a CRNA who administers anesthesia must be under the supervision of an operating practitioner (a physician) or an anesthesiologist (a physician specialist) who is immediately available if needed, unless the CRNA is located in a state that has opted out of the supervision requirements. Florida has not opted out.</p> <p>An operating practitioner or an anesthesiologist is “immediately available” when they are physically located within the same area as the CRNA and are not otherwise occupied in a way that prevents an immediate hands-on intervention.<sup>31</sup></p> <p>Note: Beginning in March 2020, the federal Centers for Medicare and Medicaid began to waive the requirement that a CRNA is under the supervision of a physician in order to allow CRNAs to function to the fullest extent allowed by states and free up physicians to expand the capacity of both CRNAs and physicians throughout the public health emergency.<sup>32</sup></p>	

<sup>31</sup> Centers for Medicare & Medicaid Services, Medicare Learning Network MLN Booklet, *Advanced practice Registered Nurses, Anesthesiologist Assistants, and Physician Assistants* (Apr. 2020) available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Medicare-Information-For-APRNs-AAAs-PAs-Text-Only.pdf> (last visited Feb. 14, 2021).

<sup>32</sup> Centers for Medicare & Medicaid Services, Newsroom, *Trump Administration Makes Sweeping Regulatory Changes to Help U.S. Healthcare System Address Covid-19 Patient Surge* (Mar. 30, 2020) available at



	<b>APRNs</b>	<b>CRNAs (specialized APRNs)</b>	<b>PAs</b>
Florida Statutes	s. 464.012(3), F.S. A written protocol with an osteopathic or allopathic physician, or dentist that must be maintained on site at the location where he or she practices.	s. 464.012(3), F.S. A written protocol with an osteopathic or allopathic physician that must be maintained on site at the location where he or she practices.  s. 464.012(3)(b), F.S. An established protocol approved by the medical staff of the facility in which the anesthetic service is performed.	s. 458.347(1)(f), F.S. “Supervision” means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term “easy availability” includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.
Florida Rules	BON Rule 64B9-4.001(14), F.A.C. General Supervision – supervision whereby a practitioner currently licensed under Chapter 458, 459, or 466, F.S., authorizes procedures being carried out but need not be present when such procedures are performed. The APRN must be able to contact the practitioner when needed for consultation and advice either in person or by communication devices.	BON Rule 64B9-4.001(14), F.A.C. General Supervision – supervision whereby a practitioner currently licensed under Chapter 458, 459, or 466, F.S., authorizes procedures being carried out but need not be present when such procedures are performed. The APRN must be able to contact the practitioner when needed for consultation and advice either in person or by communication devices.	BOM Rule 64B8-30.012(2), F.A.C. The decision to permit the physician assistant to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. Furthermore, the supervising physician must be certain that the physician assistant is knowledgeable and skilled in performing the tasks and procedures assigned.  BOOM Rule 64B15-6.001(3), F.A.C. The term “responsible supervision” as used herein refers to the ability of the supervising physician to responsibly exercise control and provide direction over the services of the physician assistant. In providing supervision, the supervising physician shall periodically review the physician assistant’s performance. It requires the easy availability or physical



	APRNs	CRNAs (specialized APRNs)	PAs
			<p>presence of the supervising physician to the physician assistant. In determining whether supervision is adequate, the following factors should be considered:</p> <ul style="list-style-type: none"> <li>(a) The complexity of the task;</li> <li>(b) The risk to the patient;</li> <li>(c) The background, training and skill of the physician assistant;</li> <li>(d) The adequacy of the direction in terms of its form;</li> <li>(e) The setting in which the tasks are performed;</li> <li>(f) The availability of the supervising physician;</li> <li>(g) The necessity for immediate attention; and,</li> <li>(h) The number of other persons that the supervising physician must supervise.</li> </ul>

### ***Advanced Practice Registered Nurses (APRNs)***

In Florida, an advanced practice registered nurse (APRN),<sup>33</sup> is licensed in one of five roles:

- Advanced nursing practitioner (ANP);
- Certified nurse midwife (CNM);
- Certified registered nurse anesthetist (CRNA);
- Clinical nurse specialist (CNS); and
- Psychiatric nurse specialist (PNS).<sup>34</sup>

According to the Annual Report and Long-Range Plan 2019-2020,<sup>35</sup> published by the DOH's Division of Medical Quality Assurance, Florida has 32,215 current and active APRNs who are regulated under the Nurse Practice Act.<sup>36</sup> The Board of Nursing (BON), provides by rule the criteria for an applicant to be licensed as an APRN and the applicable regulatory standards for APRN nursing practices. Additionally, the BON is responsible for administratively disciplining an APRN who commits an act prohibited.<sup>37</sup>

To be eligible for licensure as an APRN, an applicant must:

- Be licensed as a registered nurse;

<sup>33</sup> Section 464.003(3), F.S.

<sup>34</sup> *Id.*

<sup>35</sup> Department of Health, Medical Quality Assurance, *Annual Report and Long-Range Plan 2019-2020*, available at [http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/\\_documents/2019-2020-annual-report.pdf](http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/2019-2020-annual-report.pdf) (last visited Feb. 11, 2020).

<sup>36</sup> Part I, ch. 464, F.S.

<sup>37</sup> Sections 464.018 and 456.072, F.S.

- Have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills; and
- Submit proof that the applicant holds a current national advanced practice certification from a BON-approved nursing specialty board.<sup>38</sup>

To be a BON-approved nursing specialty board, that board must:<sup>39</sup>

- Attest to the competency of nurses in a clinical specialty area;
- Require a written examination prior to certification;
- Require nurses to complete a formal program prior to eligibility for examination;
- Maintain program accreditation or review mechanism that adheres to criteria which are substantially equivalent to requirements in Florida; and
- Identify standards or scope of practice statements appropriate for each nursing special.

All APRNs must carry malpractice insurance or demonstrate proof of financial responsibility. Any applicant for licensure must submit proof of coverage or financial responsibility as a prerequisite to licensure/certification and biennial renewal.<sup>40</sup> The APRN must have professional liability coverage of at least \$100,000 per claim, with a minimum annual aggregate of at least \$300,000; or an unexpired irrevocable letter of credit in the amount of at least \$100,000 per claim with a minimum aggregate availability of at least \$300,000 and which is payable to the APRN as beneficiary.<sup>41</sup>

To begin practicing as an APRN in Florida, the APRN must establish a written protocol with an osteopathic or allopathic physician, or dentist, that must be maintained on site at the location where he or she practices,<sup>42</sup> unless the APRN is in autonomous practice. The osteopathic or allopathic physicians, or dentist, must maintain supervision for directing the specific course of medical care and treatment the APRN provides. An APRN, within the established framework of the written protocol, may:

- Prescribe, dispense, administer, or order any drug;<sup>43</sup>
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Order any medication for administration to a patient in a hospital or nursing home;
- Manage selected medical problems specified in the protocol;
- Order physical and occupational therapy;
- Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses;
- Monitor and manage patients with stable chronic diseases;
- Establish behavioral problems; and

<sup>38</sup> Section 464.012(1), F.S., and Fla. Admin. Code R. 64B9-4.002 (2021).

<sup>39</sup> Fla. Admin. Code R. 64B9-4.002(3) (2020).

<sup>40</sup> Section 456.048, F.S.

<sup>41</sup> Fla. Admin. Code R. 64B9-4.002 (2021). *Requirements for Licensure*. See Financial Responsibility, form number DH-MQA 1186, (Jan. 2009), incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-07539> (last visited Feb. 11, 2021).

<sup>42</sup> Section 464.012(3), F.S. The DOH may, by rule, also require that a copy of the protocol be filed with the DOH along with the notice required to be filed by physicians under s. 458.348, F.S.

<sup>43</sup> Section 464.012(3)(a), F.S., requires that for the APRN to prescribe or dispense controlled substance as defined in s. 893.03, F.S., he or she must have graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area.

- Medical diagnoses and treatment recommendations.<sup>44</sup>

An APRN who is also a certified nurse midwife<sup>45</sup> may, to the extent authorized by his or her established written protocol and approved by the medical staff of the health care facility he or she performs midwifery services, or the back-up physician when the delivery is performed at home, perform the following additional medical nursing functions:

- Superficial minor surgical procedures;
- Patient management during labor and delivery to include amniotomy, episiotomy, and repair;
- Ordering, initiating, and performing appropriate anesthetic procedures;
- Postpartum examination;
- Ordering appropriate medications;
- Providing family-planning services and well-woman care; and
- Managing the medical care of the normal obstetrical patient and the initial care of a newborn patient.

An APRN who is a clinical nurse specialist may perform any of the following additional medical nursing acts and functions within the framework of his or her established written protocol:

- The assessment of the health status of individuals and families using methods appropriate to the population and area of practice;
- The diagnosis of human responses to actual or potential health problems;
- Planning of health promotion, disease prevention, and therapeutic intervention in collaboration with the patient;
- Implementation of therapeutic interventions based on the nurse specialist's area of expertise and within the scope of the APRN's practice, including:
  - Direct nursing care;
  - Counseling;
  - Teaching;
  - Collaboration with other licensed health care providers;
  - Coordination of health care as necessary; and
  - Evaluation of the patient for the effectiveness of care.

An APRN psychiatric nurse,<sup>46</sup> within the framework of an established written protocol with a psychiatrist, may prescribe additional psychotropic controlled substances for the treatment of mental disorders.

When a physician enters into an established written protocol with an APRN, where the protocol calls for the APRN to perform general or specialized APRN medical acts and functions, the physician must submit a notice, within 30 days of entering into the protocol, to the BOM or Board of Osteopathic Medicine (BOOM), as appropriate; and must also notify the appropriate board within 30 days after the termination of the protocol. The notice must contain:

- The physician's name and license number;

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<sup>44</sup> Sections 464.012 and 464.003(2), F.S. In the case of multiple supervising physicians in the same group, an APRN must enter into a written supervisory protocol with at least one physician within the physician group practice.

<sup>45</sup> Section 467.003(2), F.S.

<sup>46</sup> Section 394.455(36), F.S.

- A statement that the physician has entered into a written protocol with \_\_\_\_ number of APRNs.<sup>47</sup>

There are no limits on the number of APRNs that a physician may have written protocol with or on the number of physicians an APRN may have a written protocols with.<sup>48</sup>

However, a physician who supervises APRNs in a medical office, other than the physician's primary practice location,<sup>49</sup> where the APRN is not under onsite or direct physician supervision, must comply with the following location limits:

- A physician who is engaged in "primary health care"<sup>50</sup> may not supervise more than four offices, in addition to his or her primary practice location;
- A physician who is engaged in "specialty health care"<sup>51</sup> may not supervise more than two offices, in addition to his or her primary practice location;
- A physician who is engaged in dermatologic or skin care services, include aesthetic skin care services other than plastic surgery, must:
  - Submit to the appropriate board the addresses of all locations, not his or her primary location, where he or she is supervising or has a written protocol with APRNs;
  - Be board certified or board eligible in dermatology or plastic surgery as recognized by the appropriate board.<sup>52</sup>
  - Arrange for all such locations, not the physician's primary practice, to be within 25 miles of the primary practice, or in a county that is contiguous to the county of the primary practice, but in no event may any of the locations be more than 75 miles from the primary practice; and
  - Supervise no more than one practice location other than his or her primary practice.<sup>53</sup>

### ***Certified Registered Nurse Anesthetists (CRNAs)***

An APRN who is also a CRNA may, to the extent authorized by his or her established written protocol with the supervising physician, at the facility in which he or she provides anesthetic services, perform any of the following:

- Determine patient health status as it relates to risk factors for anesthesia management;
- Determine the appropriate type of anesthesia;
- Order pre-anesthetic medication;
- Perform procedures used to render a patient insensible to pain during the performance of a surgical, obstetrical, therapeutic, or diagnostic procedure, including ordering and administering:

<sup>47</sup> Section 459.025(1), F.S.

<sup>48</sup> See ss. 464.012, 458.348, and 459.025, F.S.

<sup>49</sup> Sections 458.348(3) and 459.025(3), F.S. A physician's "primary practice location" is the physician's address reflected on his or her profile published pursuant to s. 456.041, F.S.

<sup>50</sup> Sections 458.348(3)(a) and 459.025(3)(a), F.S., "Primary health care" means health care services that are commonly provided to patients without referral from another practitioner, including obstetrical and gynecological services, and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

<sup>51</sup> Sections 458.348(3)(b) and 459.025(3)(b), F.S., "specialty health care" means health care services that are commonly provided to patients with a referral from another practitioner and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

<sup>52</sup> Sections 458.3312 and 459.0152, F.S.

<sup>53</sup> Sections 458.348(3)(c) and 459.025(3)(c), F.S.

- Regional anesthesia;
- Spinal anesthesia;
- General anesthesia;
- Inhalation agents;
- Intravenous agents; and
- Hypnosis techniques.
- Monitor procedures indicated as pertinent to the anesthetic health care management of the patient;
- Provide life support functions during anesthesia, including:
  - Induction;
  - Intubation;
  - The use of appropriate mechanical supportive devices; and
  - The management of fluid, electrolyte, and blood component balances.
- Recognize and provide corrective action for abnormal patient responses to anesthesia;
- Recognize and treat cardiac arrhythmias while the patient is under anesthetic care;
- Participate in the management of the patient while in the recovery area, including ordering the administration of fluids and drugs; and
- Place special peripheral and central venous and arterial lines for blood sampling and monitoring, as needed.

### ***Physician Supervision of CRNA's as a Condition of Participation in Medicare***

As a condition of a hospital's participation in the Medicare program, a CRNA who administers anesthesia must be under the supervision of an operating practitioner (a physician) or an anesthesiologist (a physician specialist) who is immediately available if needed, unless the CRNA is located in a state that has opted out of the supervision requirements.<sup>54</sup> Florida has not opted out.

An operating practitioner or an anesthesiologist is "immediately available" when he or she is physically located within the same area as the CRNA and is not otherwise occupied in a way that prevents an immediate hands-on intervention.<sup>55</sup>

As of February 1, 2021, 19 states and Guam have opted out of the federal physician supervision requirement, including Arizona, Oklahoma, Iowa, Nebraska, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, Montana, South Dakota, Wisconsin, California, Colorado, and Kentucky.<sup>56</sup> A state may opt out if the state's governor sends a letter to the federal Centers for Medicare & Medicaid Services requesting exemption from physician supervision of CRNAs. The governor's letter must attest that he or she has consulted with the state boards of medicine and nursing about issues relating to access to, and the quality of, anesthesia services in the state and has concluded that it is in the best interests of the

<sup>54</sup> 42 CFR s. 482.52.

<sup>55</sup> Centers for Medicare & Medicaid Services, Medicare Learning Network MLN Booklet, *Advanced practice Registered Nurses, Anesthesiologist Assistants, and Physician Assistants* (Apr. 2020) available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Medicare-Information-For-APRNs-AAAs-PAs-Text-Only.pdf> (last visited Feb. 14, 2021).

<sup>56</sup> American Association of Nurse Anesthetists, *Certified Registered Nurse Anesthetist Fact Sheet (Feb. 1, 2021)* available at <https://www.aana.com/membership/become-a-crna/crna-fact-sheet> (last visited Feb. 11, 2021).

state's citizens to opt-out of the federal physician supervision requirement. The opt-out must be consistent with state law.<sup>57</sup>

Beginning in March 2020, the federal Centers for Medicare and Medicaid began to waive the requirement that a CRNA is under the supervision of a physician in order to allow CRNAs to function to the fullest extent allowed by states and free up physicians to expand the capacity of both CRNAs and physicians throughout the public health emergency.<sup>58</sup>

### ***Physician Assistants***

Physician Assistants (PAs) are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the BOM for PAs licensed under ch. 458, F.S., or the BOOM for PAs licensed under ch. 459, F.S.<sup>59</sup>

The Council consists of five members, appointed as follows:<sup>60</sup>

- The chairperson of the BOM appoints one member who is a physician and member of the BOM who supervises a PA in his or her practice;
- The chairperson of the BOOM appoints one member who is a physician and member of the BOOM who supervises a PA in his or her practice; and
- The State Surgeon General, or his or her designee, appoints three PAs licensed under chs. 458 or 459, F.S.

The Council is responsible for:<sup>61</sup>

- Recommending PAs to the DOH for licensure;
- Developing rules for the boards' consideration<sup>62</sup> regulating the use of PAs by physicians;
- Developing rules to ensure the continuity of supervision in each practice setting;
- Making recommendations to the boards on matters relating to PAs;
- Addressing the concerns and problems of practicing PAs in order to improve safety in the clinical practices of PAs;<sup>63</sup> and
- Denying, restricting, or placing conditions on the license of a PA who fails to meet the licensing requirements.<sup>64</sup>

### ***Physician Assistant Licensure***

An applicant for a PA license must be at least 18 years of age. The DOH must issue a license to a person who has been certified by the Council as having met all of the following requirements:<sup>65</sup>

<sup>57</sup> 42 CFR s. 482.52(c).

<sup>58</sup> Centers for Medicare & Medicaid Services, Newsroom, *Trump Administration Makes Sweeping Regulatory Changes to Help U.S. Healthcare System Address Covid-19 Patient Surge* (Mar. 30, 2020) available at <https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19> (last visited Feb. 12, 2012).

<sup>59</sup> Sections 458.347 and 459. 022, F.S.

<sup>60</sup> Sections 458.347(9) and 459. 022(9), F.S. Members of the Board of Medicine and the Board of Osteopathic Medicine are appointed by the Governor and confirmed by the Senate. *See* ss. 458.307, F.S., and 459.004, F.S., respectively.

<sup>61</sup> *Id.*

<sup>62</sup> *See* ss. 458.347(9)(c)2. and 459.022(9)(c)2., F.S.

<sup>63</sup> *Id.*

<sup>64</sup> Sections 458.347(9)(d) and 459. 022(9)(d), F.S.

<sup>65</sup> Sections 458.347(7) and 459.022(7), F.S.

- Completed an approved PA training program;<sup>66</sup>
- Obtained a passing score on the National Commission on Certification of Physician Assistants (NCCPA) exam;
- Acknowledged any prior felony convictions;
- Submitted to a background screening and have no disqualifying offenses;<sup>67</sup>
- Acknowledged any previous revocation or denial of licensure in any state; and
- Provided a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

PAs must renew their licenses biennially. During each biennial renewal cycle, a PA must complete 100 hours of continuing medical education or must demonstrate current certification issued by the National Commission on Certification of Physician Assistants.<sup>68</sup> To maintain certification, a PA must earn at least 100 hours of continuing medical education biennially and must take a re-certification examination every 10 years.<sup>69</sup>

### ***Physician Assistant Scope of Practice and Physician Supervision***

A PA is licensed to perform only those medical services delegated to him or her by his or her supervising allopathic or osteopathic physician.<sup>70</sup> PAs may only practice under the direct or indirect supervision of an allopathic or osteopathic physician with whom they have a working relationship.<sup>71</sup> A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.<sup>72</sup> The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.<sup>73</sup>

Upon employment as a PA, a licensed PA must notify the DOH in writing within 30 days after such employment or after any subsequent changes of his or her supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of the supervising physician.<sup>74</sup>

Supervision of a PA requires the physician to exercise responsible supervision and control and, except in cases of emergency, requires the "easy availability" or physical presence of the physician for consultation and direction of the actions of the PA. "Easy availability" is defined in current law as the ability to communicate by way of telecommunication, and the law further directs the BOM and BOOM to establish rules as to what constitutes responsible supervision of a PA.<sup>75</sup>

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<sup>66</sup> See Fla. Admin. Code R. 64B8-30.012 and 64B15.004 (2020).

<sup>67</sup> Sections 456.0135, F.S.

<sup>68</sup> Sections 458.347(7)(c) and 459.022(7)(c), F.S.

<sup>69</sup> National Commission on Certification of Physician Assistants, *Maintaining Certification*, available at <https://www.nccpa.net/CertificationProcess> (last visited Feb. 15, 2021).

<sup>70</sup> Sections 458.347(4) and 459.022(4), F.S.

<sup>71</sup> Sections 458.347(2)(f) and 459.022(2)(f), F.S.

<sup>72</sup> Fla. Admin. Code R. 64B8-30.012 and 64B15-6.010 (2020).

<sup>73</sup> Sections 458.347(15) and 459.022(15), F.S.

<sup>74</sup> Sections 458.347(7) and 459.022(7), F.S.

<sup>75</sup> Sections 458.347(2)(f) and 459.022(2)(f), F.S.

The boards have established by rule that “responsible supervision” of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.<sup>76</sup>

A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect supervision based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.<sup>77</sup>

A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician’s scope of practice.<sup>78</sup> A supervising physician may delegate the authority for a PA to:

- Prescribe or dispense any medicinal drug used in the supervising physician’s practice unless such medication is listed in the negative formulary established by the Council<sup>79</sup> but only under the following circumstances:
  - The PA identifies himself or herself as a PA and advises of his or her right to see a physician before the prescription is written or dispensed;
  - The supervising physician must be registered as a dispensing practitioner<sup>80</sup> and have notified the DOH on an approved form of his or her intent to delegate prescriptive authority or to change prescriptive authority; and
  - The PA must have completed 10 hours of continuing medical education in the specialty practice in which the PA has prescriptive authority with each licensure renewal, and three of the 10 hours must be on the safe and effective prescribing of controlled substances.
- Order any medication for administration to the supervising physician’s patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.;<sup>81</sup> and

<sup>76</sup> Fla. Admin. Code R. 64B8-2.001, 64B8-30.001, and 64B15-6.001 (2020).

<sup>77</sup> See Sections 458.347(3) and 459.022(3), F.S.

<sup>78</sup> *Id.*

<sup>79</sup> Sections 458.347(4)(f) and 459.022(e), F.S., direct the Council to establish a negative formulary listing the medical drugs that a PA may not prescribe. The negative formulary in Florida Administrative Code Rule 64B8-30.008, and 64B15-6.0038, prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S.

<sup>80</sup> See s. 465.0276, F.S.

<sup>81</sup> Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.



- Perform any other service that is not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.<sup>82</sup>

## **Regulation of Pharmacy Establishments**

### ***Pharmacy Permitting***

The Florida Pharmacy Act regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.<sup>83</sup> The BOP is tasked with adopting rules to implement the provisions of the act and setting standards of practice within the state.<sup>84</sup> Any person who operates a pharmacy in Florida must have a permit. The DOH issues the following permits:

- Community pharmacy – A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.<sup>85</sup>
- Institutional pharmacy – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.<sup>86</sup>
- Nuclear pharmacy – A permit is required for 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.<sup>87</sup>
- Special pharmacy – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.<sup>88</sup>
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with, or obtain information from, consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.<sup>89</sup>
- Nonresident sterile compounding pharmacy – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.<sup>90</sup>
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.<sup>91</sup>

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<sup>82</sup> Sections 458.347(4) and 459.022(e), F.S.

<sup>83</sup> Chapter 465, F.S.

<sup>84</sup> Sections 465.005, 465.0155, and 465.022, F.S.

<sup>85</sup> Sections 465.003(11)(a)1. and 465.018, F.S.

<sup>86</sup> Sections 465.003(11)(a)2. and 465.019, F.S.

<sup>87</sup> Sections 465.003(11)(a)3. and 465.0193, F.S.

<sup>88</sup> Sections 465.003(11)(a)4. and 465.0196, F.S.

<sup>89</sup> Sections 465.003(11)(a)5. and 465.0197, F.S.

<sup>90</sup> Section 465.0158, F.S.

<sup>91</sup> Fla. Admin. Code R. 64B16-2.100 and 64B16-28.802 (2020). An outsourcing facility is considered a pharmacy and needs to hold a special sterile compounding permit if it engages in sterile compounding.

A pharmacy must pass an on-site inspection for a permit to be issued,<sup>92</sup> and the permit is valid only for the name and address to which it is issued.<sup>93</sup>

### ***Centralized Prescription Filling***

Section 465.003(16), F.S., defines the term “centralized prescription filling” as the filling (measuring the medicine and putting the right dosage into a bottle) of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

Pharmacies acting as the central-fill pharmacy must have the same owner as the originating pharmacy (where the prescription is initially presented) or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.<sup>94</sup>

### ***Prescription Department Managers<sup>95</sup>***

A prescription department manager is responsible for maintaining all drug records, providing for the security of the prescription department, and ensuring the pharmacy permittee’s compliance with all statutes and rules governing the practice of the profession of pharmacy. A pharmacist may only serve as the prescription department manager of one pharmacy location. However, the BOP may grant an exception based on circumstances, such as the proximity of the pharmacy locations and the workload of the pharmacist.

All community, internet, special parenteral and enteral, special closed system, nuclear and, if applicable, special sterile compounding pharmacy permittees must continuously maintain a designated prescription department manager who is a licensed pharmacist at all times the pharmacy is open and in operation.

## **Regulation of Pharmacists**

### ***Pharmacist Licensure Requirements***

To be licensed as a pharmacist in Florida, a person must:<sup>96</sup>

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>97</sup>

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<sup>92</sup> *Id.*

<sup>93</sup> Fla. Admin. Code R. 64B16-28.100 (2020).

<sup>94</sup> Fla. Admin. Code R. 64B16-28.450(2) (2020).

<sup>95</sup> Fla. Admin. Code R. 64B16-27.450 (2020).

<sup>96</sup> 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.

<sup>97</sup> If the applicant has graduated from a four-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 BOP-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.

- 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 licensure renewal period.<sup>98</sup> Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of their renewal.<sup>99</sup> Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for their renewal.<sup>100</sup>

### ***Pharmacist Scope of Practice***

In Florida, the practice of the profession of pharmacy includes:<sup>101</sup>

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of a medicinal drug;
- Consultation concerning therapeutic values and interactions of patented or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy;
- Reviewing, and making recommendations regarding the patient's drug therapy and health care status in communication with the patient's prescribing health care provider as authorized by the patient;
- Initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement;<sup>102</sup>
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;<sup>103</sup>
- Administering epinephrine injections;<sup>104</sup>
- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;<sup>105</sup>
- Administering antipsychotic medications by injection;<sup>106</sup>
- Ordering and dispensing over-the-counter drugs approved by the FDA;<sup>107</sup>
- Ordering and dispensing within his or her professional judgment, subject to specified conditions:<sup>108</sup>
  - Certain oral analgesics for mild to moderate pain;
  - Anti-nausea preparations;
  - Certain antihistamines and decongestants;

<sup>98</sup> Section 465.009, F.S.

<sup>99</sup> Section 465.009(6), F.S.

<sup>100</sup> Section 465.1893, F.S.

<sup>101</sup> Section 465.003(13), F.S.

<sup>102</sup> Section 465.1865, F.S.

<sup>103</sup> See s. 465.189, F.S.

<sup>104</sup> *Id.*

<sup>105</sup> A Class III institutional pharmacy are those pharmacies affiliated with a hospital. See s. 465.019(2)(d), F.S.

<sup>106</sup> Section 465.1893, F.S.

<sup>107</sup> Section 465.186, F.S.

<sup>108</sup> Fla. Admin. Code R. 64B16-27.220 (2020).

- Certain topical antifungal/antibacterial;
- Topical anti-inflammatory preparations containing an amount of hydrocortisone not exceeding 2.5 percent;
- Otic antifungal/antibacterial;
- Salicylic acid;
- Vitamins;
- Ophthalmics;
- Certain histamine H2 antagonists;
- Acne products; and
- Topical antivirals for herpes simplex infections of the lips.

Pharmacists are specifically prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine unless permitted by law.<sup>109</sup>

Only a pharmacist or registered pharmacy intern may:<sup>110</sup>

- Supervise or be responsible for the controlled substance inventory;
- Receive verbal prescriptions from a prescriber;
- Interpret and identify prescription contents;
- Engage in consultation with a health care practitioner regarding the interpretation of a prescription and date in a patient's profile record;
- Engage in professional communication with health care practitioners;
- Advise or consult with a patient, both as to the prescription and the patient profile record; and
- Perform certain duties related to the preparation of parenteral and bulk solutions.

Pharmacists must perform the final check of a completed prescription, thereby assuming complete responsibility for its preparation and accuracy.<sup>111</sup> A pharmacist must be personally available at the time of dispensing.<sup>112</sup> A prescription department is considered closed if a Florida-licensed pharmacist is not present and on duty unless the pharmacist leaves the prescription department to:<sup>113</sup>

- Consult, respond to inquiries, or provide assistance to customers or patients;
- Attend to personal hygiene needs; or
- Perform functions for which the pharmacist is responsible if such activities are performed in a manner that is consistent with the pharmacist's responsibility to provide pharmacy services.

### ***Pharmacists with a Broader Scope of Practice***

There are three categories of pharmacists that have broader scopes of practice than other pharmacists:

<sup>109</sup> Section 465.003(13), F.S.

<sup>110</sup> Fla. Admin. Code R. 64B16-27.1001(1)-(2) (2020). Section 465.003(12), F.S., defines a pharmacy intern as a person who is currently registered in, and attending, or is a graduate of a duly accredited college or school of pharmacy and is properly registered with DOH.

<sup>111</sup> Fla. Admin. Code R. 64B16-27.1001(3) (2020).

<sup>112</sup> Fla. Admin. Code R. 64B16-27.1001(4) (2020).

<sup>113</sup> Section 465.003(11)(b), F.S.

- The consultant pharmacist;<sup>114</sup>
- The pharmacist working under a collaborative pharmacy practice agreement with a physician to treat chronic health conditions;<sup>115</sup> and
- A pharmacist authorized to test or screen for and treat minor, nonchronic health conditions.<sup>116</sup>

### ***Consultant Pharmacists***

A consultant pharmacist works within the framework of a written collaborative practice agreement between the pharmacist and any of the following who are authorized to prescribe medicinal drugs:<sup>117</sup>

- A health care facility medical director;
- A medical, osteopathic, or podiatric physician; or
- A dentist.<sup>118</sup>

The consultant pharmacist may provide medication management services only in the following health care facilities:<sup>119</sup>

- Ambulatory surgical centers;
- Hospitals;
- Alcohol or chemical dependency treatment centers;
- Inpatient hospices;
- Nursing homes;
- Ambulatory care centers; or
- Nursing homes within a continuing care facility.

A consultant pharmacist may only provide medication management services, conduct patient assessments, and order and evaluate laboratory or clinical testing for patients of the health care practitioner with whom the consultant pharmacist has a written collaborative practice agreement.<sup>120</sup> The written collaborative practice agreement must outline the circumstances under which the consultant pharmacist may:

- Order and evaluate any laboratory or clinical tests to promote and evaluate patient health and wellness, and monitor drug therapy and treatment outcomes.
- Conduct patient assessments as appropriate to evaluate and monitor drug therapy.
- Modify or discontinue medicinal drugs as outlined in the agreed upon patient-specific order or preapproved treatment protocol under the direction of a physician. However, a consultant pharmacist may not modify or discontinue medicinal drugs prescribed by a health care practitioner who does not have a written collaborative practice agreement with the consultant pharmacist.
- Administer medicinal drugs.

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<sup>114</sup> Sections 465.003(3) and 465.0125, F.S.

<sup>115</sup> Section 465.1865, F.S.

<sup>116</sup> Section 465.1895, F.S.

<sup>117</sup> Section 465.0125, F.S.

<sup>118</sup> *Id.*

<sup>119</sup> Section 465.1865, F.S.

<sup>120</sup> Section 465.0125(1), F.S.

A consultant pharmacist must maintain drug, patient care, and quality assurance records and, with the collaborating practitioner, must maintain written collaborative practice agreements that must be available upon request from or upon inspection by the DOH. A consultant pharmacist is not authorized to diagnose any disease or condition.<sup>121</sup>

### ***Collaborative Pharmacy Practice for Chronic Health Conditions***

A collaborative pharmacy practice agreement is a written agreement between a pharmacist who is certified by the BOP and a medical or osteopathic physician in which the collaborating physician authorizes a pharmacist to provide specified patient care to the physician's patients named in the agreement. A chronic health condition is defined as:

- Arthritis;
- Asthma;
- Chronic obstructive pulmonary diseases;
- Type 2 diabetes;
- Human immunodeficiency virus or acquired immune deficiency syndrome;
- Obesity; or
- Any other chronic condition adopted in rule by the BOP in consultation with the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM).<sup>122</sup>

The terms and conditions of the collaborative pharmacy practice agreement must be appropriate to the pharmacist's training, and the services delegated to the pharmacist must be within the collaborating physician's scope of practice. A collaborative pharmacy practice agreement must include the following:

- The name(s) of the collaborating physician's patient or patients for whom a pharmacist may provide services;
- Each chronic health condition to be collaboratively managed;
- Specific medicinal drug or drugs to be managed by the pharmacist for each patient;
- Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests;
- Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur;
- Beginning and ending dates for the collaborative pharmacy practice agreement and termination procedures, including procedures for patient notification and medical records transfers; and
- A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.<sup>123</sup>

A pharmacist may not modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he or she does not have a collaborative pharmacy practice agreement. A physician may not delegate the authority to initiate or prescribe a controlled substance to a pharmacist.<sup>124</sup>

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<sup>121</sup> Section 465.0125(1)(c)-(d), F.S.

<sup>122</sup> Section 465.1865(1)(a)-(b), F.S.

<sup>123</sup> Section 465.1865(3)(a), F.S.

<sup>124</sup> Section 465.1865(4)-(5), F.S.

***Testing or Screening for and Treatment of Minor, Nonchronic Health Conditions***

The scope of practice for a pharmacist, within the framework of an established written protocol with a supervising medical or osteopathic physician, may also include the testing or screening for and treatment of minor, nonchronic health conditions, which are defined as short-term conditions that are generally managed with minimal treatment or self-care, and include:

- Influenza;
- Streptococcus;
- Lice;
- Skin conditions such as ring worm and athletes foot; and
- Minor, uncomplicated infections.<sup>125</sup>

The written protocol between a supervising physician and a pharmacist who has been certified by the BOP to provide the services listed above must include particular terms and conditions imposed by the supervising physician. The terms and conditions must be appropriate to the pharmacist's training. A pharmacist who enters into such a protocol with a supervising physician must submit the protocol to the BOP. At a minimum, the protocol must include:

- Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions.
- The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.
- The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results.
- A process and schedule for the physician to review the pharmacist's actions under the protocol.
- A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment.
- Any other requirements as established by the BOP in consultation with the BOM and the BOOM.<sup>126</sup>

A pharmacist authorized to test and screen for and treat minor, nonchronic conditions under a protocol must provide evidence of current certification by the BOP to his or her supervising physician. A supervising physician must review the pharmacist's actions in accordance with the protocol.<sup>127</sup>

***Pharmacist Supervision of Registered Pharmacy Interns***

A person seeking licensure as a pharmacist must submit proof that he or she has completed an internship program.<sup>128</sup> To become a registered pharmacy intern, a person must be certified by the BOP and enrolled in an intern program at an accredited school or college of pharmacy or as a

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<sup>125</sup> Section 465.1895(1), F.S.

<sup>126</sup> Section 465.1895(5)(a), F.S.

<sup>127</sup> Section 465.1895(5)(b), F.S.

<sup>128</sup> Section 465.007(1)(c), F.S.

graduate of an accredited school or college of pharmacy and not yet licensed as a pharmacist in Florida.<sup>129</sup>

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.<sup>130</sup> A registered intern may fill, compound, or dispense prescriptions or medicinal drugs only under the “direct and immediate personal supervision” of a licensed pharmacist.<sup>131</sup>

## **Regulation of Pharmacy Technicians**

### ***Pharmacy Technician Registration Requirements***

Pharmacy technicians assist pharmacists in dispensing medications and are accountable to a supervising pharmacist who is legally responsible for the care and safety of the patients served.<sup>132</sup> A person must register with the DOH to practice as a pharmacy technician. To register, an individual must:<sup>133</sup>

- Be at least 17 years of age;
- Submit an application and pay an application fee; and
- Complete a BOP-approved pharmacy technician training program.<sup>134</sup>

The pharmacy technician must renew the registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours.<sup>135</sup>

### ***Pharmacy Technician Training Programs***

The BOP has preapproved certain training programs that have been accredited by certain accreditation agencies or provided by a branch of the United States Armed Forces.<sup>136</sup> The BOP may review and approve other training programs that do not meet the criteria for pre-approval. Such programs must be licensed by the Commission for Independent Education or equivalent licensing authority or be within the public school system of this state and offer a course of study that includes:

- Introduction to pharmacy and health care systems;
- Confidentiality;
- Patient rights and the federal Health Insurance Portability and Accountability Act (HIPAA);
- Relevant state and federal law;
- Pharmaceutical topics, including medical terminology, abbreviations, and symbols; medication safety and error prevention; and prescriptions and medication orders;

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<sup>129</sup> Section 465.013, F.S. *See also* Fla. Admin. Code R. 64B16-26.2032 (2020) (U.S. pharmacy students/graduates); Fla. Admin. Code R. 64B16-26.2033 (2020) (foreign pharmacy graduates).

<sup>130</sup> Fla. Admin. Code R. 64B16-27.430 (2020).

<sup>131</sup> Sections 465.015(1)(b) and (2)(b), F.S.

<sup>132</sup> Section 465.014(1), F.S.

<sup>133</sup> Section 465.014(2), F.S.

<sup>134</sup> An individual is exempt from the training program if he or she was registered as a pharmacy technician before January 1, 2011, and either worked as a pharmacy technician at least 1,500 hours under a licensed pharmacist or received certification from an accredited pharmacy technician program.

<sup>135</sup> Section 465.014(6), F.S.

<sup>136</sup> Fla. Admin. Code R. 64B16-26.351(1)-(2) (2020).



- Records management and inventory control, including pharmaceutical supplies, medication labeling, medication packaging and storage, controlled substances, and adjudication and billing;
- Interpersonal relations and ethics, including diversity of communications, empathetic communications, ethics governing pharmacy practice, patient and caregiver communications; and
- Pharmaceutical calculations.<sup>137</sup>

The training program must provide the BOP with educational and professional background of its faculty.<sup>138</sup> A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.<sup>139</sup>

The BOP may also review and approve employer-based pharmacy technician training programs. An employer-based program must be offered by a Florida-permitted pharmacy or affiliated group of pharmacies under common ownership.<sup>140</sup> The program must include 160 hours of training over a period of no more than six months and may be provided only to the employees of that pharmacy.<sup>141</sup> The employer-based training program must:

- Meet the same qualifications as required for non-employment based pharmacy technician training programs as indicated above;
- Provide an opportunity for students to evaluate learning experiences, instructional methods, facilitates, and resources;
- Ensure that self-directed learning experience, such as home study or web-based courses, evaluate the participant's knowledge at the completion of the learning experience; and
- Designate a person to assume responsibility for the registered pharmacy technician-training program.<sup>142</sup>

### ***Pharmacy Technician Scope of Practice***

A registered pharmacy technician may not engage in the practice of the profession of pharmacy; however, a licensed pharmacist may delegate those duties, tasks, and functions that do not fall within the definition of the practice of professional pharmacy.<sup>143</sup> The BOP specifies, by rule, certain acts that registered pharmacy technicians are prohibited from performing, which include:

- Receiving new verbal prescriptions or any change in the medication, strength, or directions of an existing prescription;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Monitoring prescription drug usage;
- Transferring a prescription;
- Overriding clinical alerts without first notifying the pharmacist;

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<sup>137</sup> Fla. Admin. Code R. 64B16-26.351(3)(b) (2020).

<sup>138</sup> Fla. Admin. Code R. 64B16-26.351(3)(e) (2020).

<sup>139</sup> *Id.*

<sup>140</sup> Fla. Admin. Code R. 64B16-26.351(4) (2020).

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> Section 465.014(1), F.S.

- Preparing a copy of a prescription or reading a prescription to any person for the purpose of providing reference concerning treatment of the patient for whom the prescription was written;
- Engaging in patient counseling; or
- Engaging in any other act that requires the exercise of a pharmacist's professional judgment.<sup>144</sup>

A registered pharmacy technician must wear an identification badge with a designation as a "registered pharmacy technician" and identify herself or himself as a registered pharmacy technician in telephone or other forms of communication.<sup>145</sup>

### **Pharmacist Supervision of Pharmacy Technicians**

A licensed pharmacist must directly supervise the performance of a registered pharmacy technician<sup>146</sup> and is responsible for acts performed by persons under his or her supervision.<sup>147</sup> A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.<sup>148</sup>

Florida law prohibits a pharmacist from supervising more than one registered pharmacy technician, unless otherwise permitted by guidelines adopted by the BOP.<sup>149</sup> The guidelines include the following restrictions:<sup>150</sup>

- A pharmacist engaging in sterile compounding may supervise up to three registered pharmacy technicians.
- A pharmacist who is not engaged in sterile compounding may supervise up to six registered pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to eight registered pharmacy technicians, as long as the pharmacist or pharmacy is not involved in sterile compounding.
- In a pharmacy that dispenses medicinal drugs in a physically separate area<sup>151</sup> of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to eight registered pharmacy technicians.

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<sup>144</sup> Fla. Admin. Code R. 64B16-27.420(2) (2020).

<sup>145</sup> Fla. Admin. Code R. 64B16-27.100(2) (2020).

<sup>146</sup> Direct supervision means supervision by a pharmacist who is on the premises at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who is readily available to provide personal assistance, direction, and approval throughout the time the delegated tasks are being performed (Fla. Admin. Code R. 64B16-27.4001(2)(a)).

<sup>147</sup> Fla. Admin. Code R. 64B16-27.1001(7) (2020).

<sup>148</sup> Fla. Admin. Code R. 64B16-27.4001(2)(b) (2020).

<sup>149</sup> Section 465.014(1), F.S.

<sup>150</sup> Fla. Admin. Code R. 64B16-27.410 (2020).

<sup>151</sup> A "physically separate area" is a part of the pharmacy that is separated by a permanent wall or other barrier, which restricts access between the two areas.

## **Audiology**

One in eight people in the United States (13 percent, or 30 million) aged 12 years or older has hearing loss in both ears, based on standard hearing examinations.<sup>152</sup> About two or three out of every 1,000 children in the United States are born with a detectable level of hearing loss in one or both ears.<sup>153</sup>

### ***Audiologist Scope of Practice and Licensure Requirements***

An audiologist is licensed under part I of chapter 468, F.S., to practice audiology.<sup>154</sup> The practice of audiology includes the application of principles, methods, and procedures for the prevention, identification, evaluation, consultation, habilitation, rehabilitation, instruction, treatment, and research, relative to hearing and the disorders of hearing, and to related language and speech disorders.<sup>155</sup> A licensed audiologist may:

- Offer, render, plan, direct, conduct, consult, or supervise services to individuals or groups of individuals who have or are suspected of having disorders of hearing, including prevention, identification, evaluation, treatment, consultation, habilitation, rehabilitation, instruction, and research.
- Participate in hearing conservation, evaluation of noise environment, and noise control.
- Conduct and interpret tests of vestibular function and nystagmus, electrophysiologic auditory-evoked potentials, central auditory function, and calibration of measurement equipment used for such purposes.
- Habilitate and rehabilitate, including, but not limited to, hearing aid evaluation, prescription, preparation, fitting and dispensing, assistive listening device selection and orientation, auditory training, aural habilitation, aural rehabilitation, speech conservation, and speechreading.
- Fabricate earmolds.
- Evaluate tinnitus.
- Include speech and language screening, limited to a pass/fail determination for identifying individuals with disorders of communication.<sup>156</sup>

To become licensed as an audiologist, an applicant must:

- Have earned a doctoral degree in audiology or have completed the academic requirements of a doctoral degree program with a major emphasis on audiology at an institution that meets specified requirements.<sup>157</sup>
- Receive a passing score on a national examination;<sup>158</sup> and
- Demonstrate a minimum of 11 months of full-time professional employment or practice with a provisional license.<sup>159</sup>

<sup>152</sup> See National Institutes for Health, National Institute on Deafness and Other Communication Disorders (Dec. 15, 2016) available at <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing> (last visited Feb. 18, 2021).

<sup>153</sup> *Id.*

<sup>154</sup> Section 468.1125(1), F.S.

<sup>155</sup> Section 468.1125(6)(a), F.S.

<sup>156</sup> Section 468.1125(6)(b), F.S.

<sup>157</sup> Section 468.1155(3)(b), F.S.

<sup>158</sup> Section 468.1155(1)(a), F.S.

<sup>159</sup> *Id.*

An audiologist is required to perform a final fitting for a client to ensure the physical and operational comfort of the hearing aid “when indicated.”<sup>160</sup>

### ***Hearing Aid Specialist Scope of Practice and Licensure Requirements***

A hearing aid specialist is licensed under part II of chapter 485, F.S., to practice the dispensing of hearing aids.<sup>161</sup> To become a hearing aid specialist, an applicant must:

- Be a graduate from an accredited high school or its equivalent;
- Have completed a training program as established by the Board of Hearing Aid Specialists that is a minimum of six months in length, or be licensed or certified and have been actively practicing for at least 12 months as a licensed in another state; and
- Pass an examination as established by the Board of Hearing Aid Specialists.<sup>162</sup>

A hearing aid specialist is required to perform a final fitting for all clients to ensure the physical and operational comfort of the hearing aid.<sup>163</sup>

### ***Florida Telehealth in Relation to Audiology***

Both audiologists and hearing aid specialists are authorized to use telehealth to provide services to patients under s. 456.47, F.S. An out-of-state audiologist or a hearing aid specialist may register under that section to provide services to patients located in this state. Currently, selling or distributing hearing aids through the mail to the ultimate consumer constitutes a second degree misdemeanor.<sup>164</sup> Hearing aids sold in this state provide the buyer with a 30-day trial period and money-back guarantee.<sup>165</sup>

### **The Federal Health Insurance Portability and Accountability Act (HIPAA)<sup>166</sup>**

#### ***HIPAA Privacy Rule<sup>167</sup>***

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. The HIPAA Privacy Rule sets national standards for when protected health information (PHI) may be used and disclosed.

Only certain entities and their business associates are subject to HIPAA’s provisions. These “covered entities” include: health plans, health care providers; and health care clearinghouses.

The Privacy Rule gives individuals privacy and confidentiality rights with respect to their protected PHI, including rights to examine and obtain a copy of their health records in the form

<sup>160</sup> Section 468.1225(3), F.S.

<sup>161</sup> Section 484.041, F.S.

<sup>162</sup> Section 484.045, F.S.

<sup>163</sup> Section 484.0501(3), F.S.

<sup>164</sup> Sections 468.1265 and s. 484.054, F.S.

<sup>165</sup> Sections 468.1246 and s. 484.0512, F.S.

<sup>166</sup> Centers for Medicare & Medicaid Services, Medicare Learning Network Fact Sheet, HIPAA Basics for Providers: Privacy, Security, and Breach Notification Rules (Sept. 2018) available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurityTextOnly.pdf> (last visited Feb. 14, 2021).

<sup>167</sup> 45 C.F.R. Part 160 and Subparts A and E of Part 164.

and manner they request, and to ask for corrections to their information. Also, the Privacy Rule permits the use and disclosure of health information needed for patient care and other important purposes.

The Privacy Rule protects PHI held or transmitted by a covered entity or its business associate, in any form, whether electronic, paper, or verbal. PHI includes information that relates to any of the following:

- The individual's past, present, or future physical or mental health or condition;
- The provision of health care to the individual; or
- The past, present, or future payment for the provision of health care to the individual.

### ***HIPAA Security Rule<sup>168</sup>***

The HIPAA Security Rule specifies safeguards that covered entities and their business associates must implement to protect electronic PHI (ePHI) confidentiality, integrity, and availability.

Covered entities and business associates must develop and implement reasonable and appropriate security measures through policies and procedures to protect the security of ePHI they create, receive, maintain, or transmit. Each entity must analyze the risks to ePHI in its environment and create solutions appropriate for its own situation. What is reasonable and appropriate depends on the nature of the entity's business as well as its size, complexity, and resources.

Under the Security Rule, covered entities must:

- Ensure the confidentiality, integrity, and availability of all ePHI they create, receive, maintain, or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the ePHI;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by their workforce.

When developing and implementing Security Rule compliant safeguards, covered entities and their business associates may consider all of the following:

- Size, complexity, and capabilities;
- Technical, hardware, and software infrastructure;
- The costs of security measures; and
- The likelihood and possible impact of risks to ePHI.

Covered entities must review and modify security measures to continue protecting ePHI in a changing environment.

### ***HIPAA Breach Notification Rule<sup>169</sup>***

The HIPAA Breach Notification Rule requires covered entities to notify affected individuals; the federal HHS; and, in some cases, the media of a breach of unsecured PHI. Generally, a breach is an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of PHI.

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<sup>168</sup> 45 C.F.R. Part 160 and Subparts A and C of Part 164.

<sup>169</sup> 45 C.F.R. Subpart D.

The impermissible use or disclosure of PHI is presumed to be a breach unless the covered entity demonstrates a low probability that the PHI has been compromised based on a risk assessment of, at a minimum, the following factors:

- The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
- The unauthorized person who used the PHI or to whom the disclosure was made;
- Whether the PHI was actually acquired or viewed; and
- The extent to which the risk to the PHI has been mitigated.

Most notifications must be provided without unreasonable delay and no later than 60 days following the breach discovery. Notifications of smaller breaches affecting fewer than 500 individuals may be submitted to HHS annually. The Breach Notification Rule also requires business associates of covered entities to notify the covered entity of breaches at or by the business associate.

### ***Notification of Enforcement Discretion during Public Health Emergency***

Covered health care providers acting in good faith will not be subject to penalties for violations of the HIPAA Privacy Rule, the HIPAA Security Rule, or the HIPAA Breach Notification Rule that occur in the good faith provision of telehealth during the public health emergency.<sup>170</sup>

On March 17, 2020, the federal Department of Health & Human Services (HHS) Office for Civil Rights (OCR) issued a Notification of Enforcement of Discretion, meaning that the OCR may exercise its enforcement discretion and not pursue penalties for HIPAA violations against health care providers that serve patients through everyday communication technologies during the public health emergency.<sup>171</sup> If a provider follows the terms of the Notification and any applicable OCR guidance, it will not face HIPAA penalties if it experiences a hack that exposes protected health information from a telehealth session.<sup>172</sup>

### **Jurisdiction and Venue for Telehealth-related Actions<sup>173</sup>**

For purposes of s. 456.47, F.S., any act that constitutes the delivery of health care services is deemed to occur at the place where the patient is located at the time the act is performed or in the patient's county of residence. Venue for a civil or administrative action initiated by the DOH, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County.

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<sup>170</sup> U.S. Department for Health and Human Services Office for Civil Rights, *FAQs on Telehealth and HIPAA during the COVID-10 nationwide public health emergency* (Mar. 2020) available at <https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf> (Feb. 14, 2021).

<sup>171</sup> Press Release, U.S. Department of Health and Human Services, *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency* (Mar. 17, 2021) available at <https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html> (last visited Feb. 14, 2021).

<sup>172</sup> U.S. Department for Health and Human Services Office for Civil Rights, *FAQs on Telehealth and HIPAA during the COVID-10 nationwide public health emergency* (Mar. 2020) available at <https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf> (Feb. 14, 2021).

<sup>173</sup> Section 456.47(5), F.S.

### III. Effect of Proposed Changes:

**Section 1** amends s. 409.908, F.S., to require the AHCA to reimburse Medicaid providers for the use of telehealth, including services provided in real time, store-and-forward technologies, and remote patient monitoring services, subject to any limitations or directions provided in the General Appropriations Act. Currently, Medicaid health plans have broad flexibility in covering telemedicine services, including remote patient monitoring and store-and-forward services. Throughout the duration of the public health emergency, the AHCA has expanded services under the fee-for-service delivery system to cover store-and-forward and remote patient monitoring modalities rendered by licensed physicians, APRNs, and PAs functioning within their scope of practice.

The bill requires providers to ensure that such technologies are medically necessary and performed within a provider's scope of practice and within applicable supervision requirements. The bill requires providers to document the use of telehealth in the patient's medical record or progress notes. The AHCA already requires this of providers.

The bill authorizes out-of-state providers who are registered under s. 456.47(4), F.S., and enrolled in Florida Medicaid as an out-of-state provider to be reimbursed for telehealth services provided to recipients in this state.

The reimbursements required and authorized in Section 1 do not cover the purchase of telecommunications equipment used for the provision of telehealth, such as computers, tablets, or smartphones.

**Section 2** amends s. 456.47, F.S., to expand the definition of "telehealth" to include:

- A telehealth provider's supervision of health care services through the use of synchronous and asynchronous telecommunications technology.
- Telephone calls, emails, fax transmissions, and other nonpublic-facing telecommunications. Under current law, audio-only telephone calls, email messages, and fax transmissions are explicitly excluded from the definition of telehealth.

**Section 2** authorizes a telehealth provider,<sup>174</sup> acting within the scope of his or her practice, to prescribe controlled substances listed in Schedule III, Schedule IV, and Schedule V of s. 893.03, F.S. The telehealth provider must also comply with chapter 893 by consulting and reporting to the Prescription Drug Monitoring Program database. This change removes the prohibition on prescribing controlled substances via telehealth.<sup>175</sup>

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<sup>174</sup> Section 456.47(1)(b), F.S., defines the term "telehealth provider" as any individual who provides health care and related services using telehealth and who is licensed or certified under s. 393.17; part III of chapter 401; chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part III, part IV, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I or part II of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; who is licensed under a multistate health care licensure compact of which Florida is a member state; or who is registered under and complies with subsection (4).

<sup>175</sup> Section 456.47(2)(c), F.S.

**Section 2** authorizes a non-physician health care practitioner,<sup>176</sup> including, but not limited to, an APRN, a CRNA, or a PA, who is required to maintain a formal supervisory relationship with a physician, to satisfy that requirement through telehealth. This would authorize the synchronous and asynchronous remote supervision of non-physician health care practitioners by an in-state physician or by an out-of-state physician registered to provide telehealth services in Florida.

The bill does not specify whether the synchronous or asynchronous remote supervision of non-physician health care practitioners by an in-state or out-of-state physician would apply in the provision of services that require the “direct supervision” by or the “immediate availability” of the supervising physician. If the supervisory requirement is satisfied through telehealth, as provided in the bill, then it can be inferred that “direct supervision” requirements are included in that provision and may be satisfied through telehealth unless otherwise provided by law or rule.

CS/SB 700 does not indicate what constitutes a “formal” supervisory relationship. Certain supervisory relationships may be required by federal law or federal or state rules. Under the Florida Statutes, the following practitioners may also be affected in their practice or in the provision of specified services:

- Anesthesiologist Assistants (ss. 458.3475 and 459.023, F.S.);
- Emergency Medical Technicians (ss. 458.348 and 459.025, F.S.);
- Paramedics (ss. 458.348 and 459.025, F.S.);
- Any practitioner authorized to perform electrolysis (ss. 458.348 and 459.025, F.S.);
- Medical Assistants (s. 458.3485, F.S.);
- Certified Chiropractic Physician Assistants under supervision of a licensed chiropractic physician (s. 460.4165, F.S.);
- Certified Podiatric X-ray Assistants (ss. 461.0135 and 468.302, F.S.);
- Basic X-ray Machine Operator-podiatric Medicine (ss. 461.0135 and 468.302, F.S.);
- Retired Volunteer Nurses (s. 464.0205, F.S.);
- Midwives providing collaborative prenatal and postpartal care to pregnant women not at low risk in their pregnancy, labor, and delivery (s. 467.015, F.S.);
- Laryngectomized individuals rendering guidance and instruction to other laryngectomized individuals. (s. 468.1115, F.S.);
- Optician Apprentices (s. 484.007, F.S.); and
- Pharmacists (ch. 465, F.S. *See Present Situation of this analysis.*)

Under s. 456.47(4)(e), F.S., a registered out-of-state telehealth provider must maintain professional liability coverage or financial responsibility that includes coverage or responsibility for “telehealth services provided to patients” not located in the provider’s home state. Under the bill, it is unclear if such coverage or responsibility would extend to services provided to patients not located in the provider’s home state if those services were provided by a practitioner under the remote physician supervision of a registered-out-of-state telehealth provider.

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<sup>176</sup> Section 456.001(4), F.S., defines the term “health care practitioner” for purposes of ch. 456, as any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I or part II of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.



For purposes of s. 456.47, F.S., any act that constitutes the delivery of health care services is deemed to occur at the place where the patient is located at the time the act is performed or in the patient's county of residence. Venue for a civil or administrative action initiated by the DOH, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County. These provisions would apply to in-state and out-of-state physicians who remotely supervise health care practitioners in Florida.

The bill does not define the term "physician" as an allopathic physician or osteopathic physician, so the term would include chiropractic physicians and podiatric physicians.

**Sections 3 and 4** amend ss. 458.347 and 459.022, F.S., the practice acts for allopathic and osteopathic PAs, respectively, to revise the definitions of the terms "supervision" and "easy availability." In both sections, the bill replaces "telecommunication" with "telehealth as defined in s. 456.47(1), F.S.," to incorporate the definition of the term as amended by section 2 of this bill.

**Section 5** amends s. 465.003, F.S., to create a new type of pharmacy establishment. Section 5 expands the definition of "pharmacy" to include "remote-site pharmacies." The term "remote-site pharmacy" or "remote site" is defined as every location where medicinal drugs are compounded or dispensed by a registered pharmacy technician who is remotely supervised by an off-site pharmacist acting in the capacity of a prescription department manager.

**Section 5** also clarifies that an off-site pharmacist, acting in the capacity of a prescription department manager, is not prohibited from remotely supervising a registered pharmacy technician at a remote-site pharmacy.

**Section 6** amends s. 465.014, F.S., to authorize a registered pharmacy technician operating under the remote supervision of an off-site pharmacist under s. 456.0198, F.S., to compound and dispense medicinal drugs under such remote supervision.

**Section 6** also specifies that a licensed pharmacist may supervise more than one registered pharmacy technician as provided in s. 465.0198, F.S., as created in section 8 of this bill.

**Section 7** amends s. 465.015, F.S., to conform provisions to changes made by the act and make lawful the remote supervision of a registered pharmacy technician at a remote-site pharmacy.

**Section 8** creates s. 465.0198, F.S., and establishes the permitting of and regulation of remote-site pharmacies.

The term "supervising pharmacy" is defined as a pharmacy licensed in this state which employs a licensed pharmacist who remotely supervises a registered pharmacy technician at a remote-site pharmacy.

The bill requires a person desiring a permit to operate a remote-site pharmacy to apply to the DOH. If the BOP certifies that the application complies with the laws and rules of the BOP,<sup>177</sup> the DOH must issue the permit. To obtain a permit, a licensed pharmacist or a consultant pharmacist must be designated as the prescription department manager responsible for the oversight of the remote site. The permittee must notify the DOH within 10 days after any change of the prescription department manager.

Under the bill, a remote-site pharmacy must:

- Be jointly owned or operated under contract with a supervising pharmacy.
- Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 45 days.
- Display a sign visible to the public indicating that the location is a remote-site pharmacy and that the facility is under 24-hour video surveillance.
- Maintain a policies and procedures manual, which must be made available to the BOP or its agent upon request. The manual must contain, at a minimum, all of the following:
  - A description of how the pharmacy will comply with federal and state laws and rules;
  - The procedures for supervising the remote site and counseling its patients;
  - The procedures for reviewing the prescription drug inventory and drug records maintained by the remote site;
  - The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information;
  - The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote site's operation;
  - The procedures for use of the state prescription drug monitoring program by the prescription department manager before he or she may authorize the dispensing of any controlled substance;
  - The procedures for maintaining a perpetual inventory of the controlled substances listed in s. 893.03(2), F.S., and
  - The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote site.

The bill specifies that a remote-site pharmacy is not considered a pharmacy location for purposes of network access in managed care programs. The bill authorizes a remote-site pharmacy to store, hold, or dispense any medicinal drug, but prohibits centralized prescription filling. The bill requires a prescription department manager to visit the remote site, based on a schedule adopted by the BOP, to inspect the pharmacy, address personnel matters, and provide clinical services for patients. The BOP must adopt a rule that defines such a schedule.

A registered pharmacist may serve as the prescription department manager for up to three remote-site pharmacies that are under common control of the same supervising pharmacy.

**Section 9** amends s. 465.022, F.S., to conform to changes made by the bill and to make an exception for registered pharmacists to serve as the prescription department manager for more than one location (remote-site pharmacies) as authorized under s. 465.0198, F.S., as created by section 8 of this bill.

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<sup>177</sup> The BOP has rulemaking authority under s. 465.005, F.S., to implement the provisions of ch. 465.

**Section 10** amends s. 465.0265, F.S., to conform to changes made by the bill and clarify that provisions relating to centralized prescription filling do not apply to remote-site pharmacies. Under s. 456.0198(7), F.S., as created by section 8 of this bill, remote-site pharmacies are prohibited from performing centralized prescription filling.

**Section 11** amends s. 465.1893, F.S., to authorize a pharmacist who is authorized under current law to administer long-acting antipsychotic medication by injection, to also administer by injection an extended-release medication indicated to treat opioid use disorder, alcohol use disorder, or other substance use disorder or dependency, including but not limited to, buprenorphine, naltrexone, or other medications that have been approved by the United States Food and Drug Administration. The bill requires a pharmacist seeking to administer such medications to fulfill the eight-hour continuing education course requirement that applies to pharmacists seeking to administer long-acting antipsychotic medication. Under the bill, that course must also cover addiction medications.

**Section 12** amends s. 468.1225, F.S., to except an audiologist from minimal procedural and equipment requirements when fitting and selling a hearing aid for persons who are 18 years of age or older and who provide a medical clearance or a waiver of medical examination.

**Sections 13 and 15** amend ss. 468.1265 and 484.054, F.S., respectively, to make it lawful for a person to sell or distribute hearing aids through the mail to an ultimate consumer who is 18 years of age or older. Currently, selling or distributing hearing aids through the mail to an ultimate consumer of any age constitutes a second-degree misdemeanor.

**Section 14** amends s. 484.0501, F.S., to except a hearing aid specialist from minimal procedures and equipment requirements when fitting and selling a hearing aid for persons who are 18 years of age or older and who provide a medical clearance or a waiver of medical examination. The bill changes the requirement that a hearing aid specialist perform a final fitting, to ensure the physical and operational comfort of the hearing aid, so that it is only applicable to clients younger than 18 years of age. Under the bill, for clients 18 years of age or older, a final fitting by a hearing aid specialist is only required “when indicated.”

**Section 16** amends s. 893.05, F.S., to prohibit telehealth providers from prescribing Schedule I or Schedule II controlled substances through telehealth. Currently, telehealth providers may prescribe Schedule II drugs through telehealth only for the treatment of a psychiatric disorder, inpatient treatment at a hospital, the treatment of a patient receiving hospice services, or the treatment of a resident in a nursing home facility.<sup>178</sup> Under current law, no provider may prescribe a Schedule I drug under any circumstances.

**Section 17** provides an effective date of July 1, 2021.

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<sup>178</sup> Section 456.47(2)(c), F.S.

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

None.

**B. Public Records/Open Meetings Issues:**

None.

**C. Trust Funds Restrictions:**

None.

**D. State Tax or Fee Increases:**

Section 19, Article VII of the State Constitution requires a state tax or fee that is imposed or authorized by the Legislature to be “contained in a separate bill that contains no other subject.” The provisions of section 5 of the bill amending s. 465.033(11)(a), F.S., and of section 8 of the bill creating s. 465.0198, F.S., could result in the authorization of or imposition of the existing fees in s. 465.022(3),(7), and (14), F.S., on a new class of persons seeking a permit for a remote-site pharmacy. An amendment to this bill or a separate fee bill should be considered to address the applicable fees.

**E. Other Constitutional Issues:**

Section 6, Article III of the State Constitution requires every law to “embrace but one subject and matter properly connected therewith, and the subject shall be briefly expressed in the title.” The subject as expressed in the title circumscribes the one subject to which the act must relate. CS/SB 700 is titled “An act relating to telehealth,” but the following sections of the bill do not, or do not necessarily, relate to telehealth:

- Section 11 of the bill amends s. 465.1893, F.S., to authorize pharmacists to administer specified medications by injection, which can be done only in-person, not by telehealth.
- Sections 12 and 14 of the bill amend ss. 468.1225 and 484.0501, F.S., to change practice requirements for audiologists and hearing aid specialists, regardless of whether the services are performed in-person or via telehealth.

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

None.

**B. Private Sector Impact:**

The bill has an indeterminate fiscal impact on the private sector.

**C. Government Sector Impact:**

CS/SB 700 creates a new type of pharmacy establishment, a “remote-site pharmacy,” and requires the DOH to permit and regulate them. This would have a significant fiscal impact on the DOH, requiring 4.5 full-time equivalent (FTE) positions and 1 “Other Personal Services” (OPS) position. The projected total costs is \$338,363, with \$272,001 in recurring costs and \$66,362 in non-recurring costs.

*Appropriation Category Breakdown:*

Salary and Benefits:	\$217,832 (recurring)
Expenses:	\$83,085 (\$52,082 recurring / \$31,003 non-recurring)
OPS	\$35,359 (non-recurring)
HR Services	\$2,087 (recurring)

Two FTE are needed to manage the active and inactive licensure pool size, and 1.00 OPS is needed to handle the initial influx of applications. In addition, 2.5 FTE are needed to support the investigations and prosecution workload and one-half FTE is needed to manage the workload in the communication center.

The DOH will incur non-recurring costs associated with updating the Licensing and Enforcement Information Database System, the Online Service Portal, the License Verification Search Site, the board website to support remote site pharmacy permits and updates to existing data exchange services with the AHCA. In addition, DOH will incur costs for rulemaking but can absorb these costs within existing resources.

The AHCA does not expect this bill to have a fiscal impact on Medicaid. The bill is unlikely to increase the overall costs to the Medicaid program, as the majority of Medicaid recipients are already covered for the newly-required covered services under Medicaid health plans. Changes in the bill will pose operational impacts to the AHCA, including updating rules, amending the state plan, enrolling new providers, and programming the claims payment and enrollment systems. These actions are part of the AHCA’s routine business practices and do not require an appropriation.<sup>179</sup>

**VI. Technical Deficiencies:**

CS/SB 700 authorizes physicians to use telehealth to engage in formal supervisory relationships with nonphysician health care practitioners, but it does not indicate what constitutes a “formal” supervisory relationship.

“Formal supervisory relationships” are referenced twice in the Florida Statutes. Sections 458.348 and 459.025, F.S., directly mention the formal supervisory relationship between an emergency medical technician or a paramedic and medical or osteopathic physicians, respectively. In that situation, the physician must submit written notice of the relationship to the BOM or the BOOM, as applicable. The notice must contain the following statement:

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<sup>179</sup> Agency for Health Care Administration, *Senate Bill 700 Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy.)

“I, (name and professional license number of physician) , of (address of physician) have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with (number of persons) emergency medical technician(s), (number of persons) paramedic(s), or (number of persons) advanced practice registered nurse(s).”

Those sections suggest that a formal supervisory relationship is a relationship that exists in writing and is reported to the appropriate board. The bill should be amended to clarify what constitutes a formal supervisory relationship between a physician and a health care practitioner.

**Section 11** of the bill amends s. 465.1893, F.S., to authorize in-person pharmacists to administer specified medications. Lines 381-385 of the bill could be interpreted to authorize a pharmacist to administer a long-acting antipsychotic medication that has not been approved by the United States Food and Drug Administration. Such approval is required under current law. If this is not the intent, then those lines should be amended to provide clarification.

**Section 16** of the bill amends s. 893.05, F.S., to prohibit telehealth providers from prescribing through telehealth a Schedule I or Schedule II controlled substance. This prohibition should be relocated to subsection (2) of section 456.47, F.S., where the provision of health care services using telehealth is addressed.

## **VII. Related Issues:**

None.

## **VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 409.908, 456.47, 458.347, 459.022, 465.003, 465.014, 465.015, 465.022, 465.0265, and 893.05.

This bill creates section 465.0198 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 17, 2021:**

The CS:

- Deletes lines 164-166 from the underlying bill to remove a provision that would have prohibited physicians registered as out-of-state providers from remotely supervising nonphysician health care practitioners in the provision of a service that requires direct supervision under the laws and rules in this state.
- Deletes lines 159-164 from the underlying bill to remove duplicative language already authorized by lines 127 and 148-153.
- Adds provisions relating to pharmacist-administered medications. The CS amends s. 456.1893, F.S., to authorize a pharmacist, at the direction of a physician, to administer by injection an extended-release medication indicated to treat opioid use disorder, alcohol use disorder, or other substance use disorder or dependency,

including but not limited to, buprenorphine, naltrexone, or other medications that have been approved by the United States Food and Drug Administration. The CS requires a pharmacist seeking to administer such medications to complete an eight-hour continuing education course that must, under the CS, include education on addiction.

- Adds provisions relating to hearing aids:
  - The CS amends ss. 468.1225 and 484.0501, F.S., respectively, to create exceptions for audiologists and hearing aid specialists from procedural and equipment requirements when they are fitting and selling hearing aids to persons who are 18 years of age or older and who provide a medical clearance or a waiver. The amendments to s. 484.0501, F.S., change the requirement that a hearing aid specialist make a final fitting, to ensure the physical and operational comfort of the hearing aid, so that it applies to clients younger than 18 years of age in all cases. Under the CS, a final fitting by a hearing aid specialist is only required “when indicated” for clients 18 years of age or older.
  - The CS amends ss. 468.1265 and 484.054, F.S., respectively, to make it lawful for a person to sell or distribute hearing aids through the mail to an ultimate consumer who is 18 years of age or older. Under current law, selling or distributing hearing aids through the mail to the ultimate consumer of any age constitutes a second degree misdemeanor.

**B. Amendments:**

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/17/2021	.	
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The Committee on Health Policy (Rodriguez) recommended the following:

**Senate Amendment (with directory and title amendments)**

Delete lines 154 - 166.

===== D I R E C T O R Y   C L A U S E   A M E N D M E N T =====

And the directory clause is amended as follows:

Delete lines 116 - 122

and insert:

Section 2. Paragraph (a) of subsection (1) and paragraph (c) of subsection (2) of section 456.47, Florida Statutes, are





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11 amended, and paragraph (f) is added to subsection (2) of that  
12 section, to read:

13

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

15 And the title is amended as follows:

16       Delete lines 16 - 20

17 and insert:

18       requirement through telehealth; amending ss. 458.347

19       and



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
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The Committee on Health Policy (Rodriguez) recommended the following:

**Senate Amendment (with title amendment)**

Between lines 380 and 381  
insert:

Section 11. Section 465.1893, Florida Statutes, is amended  
to read

465.1893 Administration of long-acting ~~antipsychotic~~  
medication by injection.—

(1)(a) A pharmacist, at the direction of a physician  
licensed under chapter 458 or chapter 459, may administer a



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long-acting antipsychotic medication or an extended-release medication indicated to treat opioid use disorder, alcohol use disorder, or other substance use disorder or dependency, including, but not limited to, buprenorphine, naltrexone, or other medications that have been approved by the United States Food and Drug Administration by injection to a patient if the pharmacist:

1. Is authorized by and acting within the framework of an established protocol with the prescribing physician.

2. Practices at a facility that accommodates privacy for nondeltoid injections and conforms with state rules and regulations regarding the appropriate and safe disposal of medication and medical waste.

3. Has completed the course required under subsection (2).

(b) A separate prescription from a physician is required for each injection administered by a pharmacist under this subsection.

(2)(a) A pharmacist seeking to administer a ~~long-acting antipsychotic~~ medication described in paragraph (1)(a) ~~by injection~~ must complete an 8-hour continuing education course offered by:

1. A statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 Credit or the American Osteopathic Association (AOA) Category 1-A continuing medical education (CME) credit; and

2. A statewide association of pharmacists.

(b) The course may be offered in a distance learning format



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and must be included in the 30 hours of continuing professional pharmaceutical education required under s. 465.009(1). The course shall have a curriculum of instruction that concerns the safe and effective administration of behavioral health, addiction, and antipsychotic medications by injection, including, but not limited to, potential allergic reactions to such medications.

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

And the title is amended as follows:

Delete line 55

and insert:

F.S.; providing applicability; amending s. 465.1893,  
F.S.; providing additional long-acting medications  
pharmacists may administer under certain  
circumstances; revising requirements for a continuing  
education course such pharmacists must complete;  
amending s. 893.05,



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LEGISLATIVE ACTION

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

**Senate Amendment (with title amendment)**

Between lines 380 and 381  
insert:

Section 11. Subsections (1) through (4) of section  
468.1225, Florida Statutes, are amended to read:

468.1225 Procedures, equipment, and protocols.—

(1) The following minimal procedures must ~~shall~~ be used  
when a licensed audiologist fits and sells a hearing aid unless  
the client provides a medical clearance or a waiver of medical



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examination:

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

(b) Effective masking when indicated.

(c) Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit when indicated.

(2) The following equipment must ~~shall~~ be used unless the client provides a medical clearance or a waiver of medical examination:

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

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

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

(4) A licensed audiologist who fits and sells hearing aids must ~~shall~~ obtain the following medical clearance: If, upon inspection of the ear canal with an otoscope in the common procedure of fitting a hearing aid or ~~and~~ upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client must ~~shall~~ be instructed to see a physician, and a hearing aid may ~~shall~~ not be fitted until medical clearance is obtained for the condition noted. If, upon



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return, the condition noted is no longer observable and the client signs a medical waiver, a hearing aid may be fitted. Any person with a significant difference between bone conduction hearing and air conduction hearing must be informed of the possibility of medical or surgical correction.

Section 12. Subsections (1) through (4) of section 484.0501, Florida Statutes, are amended to read:

484.0501 Minimal procedures and equipment.—

(1) The following minimal procedures must ~~shall~~ be used in the fitting and selling of hearing aids unless the client provides a medical clearance or a waiver of medical examination:

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

(b) Effective masking when indicated.

(c) Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit.

(2) The following equipment must ~~shall~~ be used unless the client provides a medical clearance or a waiver of medical examination:

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

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

(3) A final fitting ensuring physical and operational



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69 comfort of the hearing aid must ~~shall~~ be made when indicated.

70 (4) The following medical clearance must ~~shall~~ be obtained:  
71 If, upon inspection of the ear canal with an otoscope in the  
72 common procedure of a hearing aid fitter or ~~and~~ upon  
73 interrogation of the client, there is any recent history of  
74 infection or any observable anomaly, the client must ~~shall~~ be  
75 instructed to see a physician, and a hearing aid may ~~shall~~ not  
76 be fitted until medical clearance is obtained for the condition  
77 noted. If, upon return, the condition noted is no longer  
78 observable and the client signs a medical waiver, a hearing aid  
79 may be fitted. Any person with a significant difference between  
80 bone conduction hearing and air conduction hearing must be  
81 informed of the possibility of medical correction.

82 Section 13. Sections 468.1265 and 484.054, Florida  
83 Statutes, are repealed.

84  
85 ===== T I T L E A M E N D M E N T =====

86 And the title is amended as follows:

87 Delete line 55

88 and insert:

89 F.S.; providing applicability; amending ss. 468.1225,  
90 and 484.0501, F.S.; revising minimum procedures and  
91 equipment requirements for fitting and selling hearing  
92 aids; repealing ss. 468.1265 and 484.054, F.S.,  
93 relating to the sale or distribution of hearing aids  
94 through mail; amending s. 893.05,





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LEGISLATIVE ACTION

Senate	.	House
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02/17/2021	.	
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The Committee on Health Policy (Bean) recommended the following:

**Senate Amendment to Amendment (302884) (with title amendment)**

Delete lines 10 - 83  
and insert:  
the client is 18 years of age or older and provides a medical clearance or a waiver of medical examination:

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

(b) Effective masking when indicated.



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(c) Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit when indicated.

(2) The following equipment must ~~shall~~ be used unless the client is 18 years of age or older and provides a medical clearance or a waiver of medical examination:

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

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

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

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



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Section 12. Section 468.1265, Florida Statutes, is amended to read:

468.1265 Sale or distribution of hearing aids through mail; penalty.—It is unlawful for any person to sell or distribute hearing aids through the mail to the ultimate consumer who is younger than 18 years of age. Any person who violates this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 13. Subsections (1) through (4) of section 484.0501, Florida Statutes, are amended to read:

484.0501 Minimal procedures and equipment.—

(1) The following minimal procedures must ~~shall~~ be used in the fitting and selling of hearing aids unless the client is 18 years of age or older and provides a medical clearance or a waiver of medical examination:

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

(b) Effective masking when indicated.

(c) Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit.

(2) The following equipment must ~~shall~~ be used unless the client is 18 years of age or older and provides a medical clearance or a waiver of medical examination:

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



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

(3) For clients younger than 18 years of age, a final fitting ensuring physical and operational comfort of the hearing aid must ~~shall~~ be made. For all other clients, such final fitting must be made when indicated.

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

Section 14. Section 484.054, Florida Statutes, is amended to read:

484.054 Sale or distribution of hearing aids through mail; penalty.—It is unlawful for any person to sell or distribute hearing aids through the mail to the ultimate consumer who is younger than 18 years of age. Any violation of this section constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

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



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And the title is amended as follows:

Delete lines 89 - 94

and insert:

F.S.; providing applicability; amending s. 468.1225,  
F.S.; revising minimum procedures and equipment  
requirements for fitting and selling hearing aids;  
amending s. 468.1265, F.S.; revising a prohibition on  
the sale or distribution of hearing aids through the  
mail; amending s. 484.0501, F.S.; revising minimum  
procedures and equipment requirements for fitting and  
selling hearing aids; amending s. 484.054, F.S.;  
revising a prohibition on the sale or distribution of  
hearing aids through the mail; amending s. 893.05,

By Senator Rodriguez

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1 A bill to be entitled  
 2 An act relating to telehealth; amending s. 409.908,  
 3 F.S.; requiring the Agency for Health Care  
 4 Administration to reimburse the use of telehealth  
 5 services under certain circumstances and subject to  
 6 certain limitations; requiring providers to include  
 7 certain documentation in patient records and notes;  
 8 authorizing certain out-of-state providers to receive  
 9 reimbursement for telehealth services; providing an  
 10 exception; amending s. 456.47, F.S.; revising the  
 11 definition of the term "telehealth"; authorizing  
 12 telehealth providers to prescribe specified controlled  
 13 substances through telehealth under certain  
 14 circumstances; authorizing nonphysician health care  
 15 practitioners to satisfy a certain supervision  
 16 requirement through telehealth; authorizing out-of-  
 17 state physician telehealth providers to engage in  
 18 formal supervisory relationships with certain  
 19 nonphysician health care practitioners in this state;  
 20 providing an exception; amending ss. 458.347 and  
 21 459.022, F.S.; revising the definition of the term  
 22 "supervision"; amending s. 465.003, F.S.; revising the  
 23 definition of the term "pharmacy"; revising  
 24 construction of the term "not present and on duty";  
 25 amending s. 465.014, F.S.; authorizing registered  
 26 pharmacy technicians to compound and dispense  
 27 medicinal drugs under certain circumstances; providing  
 28 an exception to certain supervision limitations;  
 29 amending s. 465.015, F.S.; providing applicability;

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

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30 exempting certain registered pharmacy technicians from  
 31 specified prohibitions; creating s. 465.0198, F.S.;  
 32 defining the term "supervising pharmacy"; providing  
 33 for the permitting of remote-site pharmacies;  
 34 requiring a licensed or consultant pharmacist to serve  
 35 as the prescription department manager of a remote  
 36 site; requiring remote-site pharmacies to notify the  
 37 Department of Health of a change in the pharmacy's  
 38 prescription department manager within a specified  
 39 timeframe; providing requirements for remote-site  
 40 pharmacies; providing that remote-site pharmacies are  
 41 not considered pharmacy locations for purposes of  
 42 network access in managed care programs; authorizing  
 43 remote-site pharmacies to store, hold, and dispense  
 44 medicinal drugs; prohibiting remote-site pharmacies  
 45 from performing centralized prescription filling;  
 46 requiring prescription department managers to visit  
 47 remote sites, based on a certain schedule, to perform  
 48 specified tasks; authorizing registered pharmacists to  
 49 serve as prescription department managers for up to  
 50 three remote-site pharmacies under certain  
 51 circumstances; amending s. 465.022, F.S.; exempting  
 52 registered pharmacists serving as prescription  
 53 department managers for remote-site pharmacies from  
 54 certain practice limitations; amending s. 465.0265,  
 55 F.S.; providing applicability; amending s. 893.05,  
 56 F.S.; prohibiting telehealth providers from  
 57 prescribing specified controlled substances through  
 58 telehealth; providing an effective date.

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

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

Section 1. Present subsections (22) through (26) of section 409.908, Florida Statutes, are redesignated as subsections (23) through (27), respectively, and a new subsection (22) is added to that section, to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent

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or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(22) Subject to any limitations or directions provided in the General Appropriations Act, the agency shall reimburse the use of telehealth as defined by s. 456.47, to include services provided in real time, services provided using store-and-forward technologies, and remote patient monitoring services to the extent that these technologies are available.

(a) Providers using any modality described in this subsection must ensure that treatment services are medically necessary and performed within a provider's scope of practice and any applicable supervision requirements.

(b) Providers must include documentation regarding the use of telehealth in the medical record or progress notes for each encounter with a recipient.

(c) Out-of-state providers who are registered under s. 456.47(4) and enrolled in Florida Medicaid as an out-of-state provider may be reimbursed for telehealth services provided to recipients in this state.

(d) Reimbursement under this subsection does not cover the purchase of any general telecommunications equipment that is not specific to or used solely for the provision of telehealth, including, but not limited to, computers, tablets, cell phones, smartphones, or any other similar equipment or device.

Section 2. Present paragraphs (h) and (i) of subsection (4)

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of section 456.47, Florida Statutes, are redesignated as paragraphs (i) and (j), respectively, a new paragraph (h) is added to that subsection, paragraph (f) is added to subsection (2) of that section, and paragraph (a) of subsection (1), paragraph (c) of subsection (2), and paragraph (c) of subsection (4) of that section are amended, to read:

456.47 Use of telehealth to provide services.—

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

(a) "Telehealth" means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide or supervise the provision of health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration. The term includes ~~does not include~~ audio-only telephone calls, personal e-mail messages, or facsimile transmissions, and any other nonpublic-facing telecommunications technology.

(2) PRACTICE STANDARDS.—

(c) A telehealth provider, acting within the scope of his or her practice and in accordance with chapter 893, may ~~not~~ use telehealth to prescribe a controlled substance listed in Schedule III, Schedule IV, or Schedule V of s. 893.03 ~~unless the controlled substance is prescribed for the following:~~

~~1. The treatment of a psychiatric disorder;~~

~~2. Inpatient treatment at a hospital licensed under chapter~~

~~395;~~

~~3. The treatment of a patient receiving hospice services as defined in s. 400.601; or~~

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~~4. The treatment of a resident of a nursing home facility as defined in s. 400.021.~~

(f) A nonphysician health care practitioner, including, but not limited to, an advanced practice registered nurse, a certified registered nurse anesthetist, or a physician assistant, who is required to maintain a formal supervisory relationship with a physician may satisfy such requirement through telehealth.

(4) REGISTRATION OF OUT-OF-STATE TELEHEALTH PROVIDERS.—

(c) The website of a telehealth provider registered under paragraph (b) must prominently display a hyperlink to the department's website containing information required under paragraph ~~(i)~~ ~~(h)~~.

(h) A physician registered under this subsection may use telehealth to engage in a formal supervisory relationship with a nonphysician health care practitioner in this state, including but not limited to, an advanced practice registered nurse, a certified registered nurse anesthetist, or a physician assistant. However, such supervision may not be for the provision of any health care service that requires direct supervision under the applicable laws and rules in this state.

Section 3. Paragraph (f) of subsection (2) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(2) DEFINITIONS.—As used in this section:

(f) "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician



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assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telehealth as defined in s. 456.47(1) telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.

Section 4. Paragraph (f) of subsection (2) of section 459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.—

(2) DEFINITIONS.—As used in this section:

(f) "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telehealth as defined in s. 456.47(1) telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.

Section 5. Subsection (11) of section 465.003, Florida Statutes, is amended to read:

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

(11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, ~~and~~ an Internet pharmacy, and a remote-site pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every

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location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. 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 chapter 395 or the nuclear medicine facilities of such hospitals.

4. 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.

5. 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. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

6. The term "remote-site pharmacy" or "remote site" includes every location where medicinal drugs are compounded or dispensed by a registered pharmacy technician who is remotely supervised by an off-site pharmacist acting in the capacity of a prescription department manager.

(b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not

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present and on duty. The term "not present and on duty" may  
~~shall~~ not be construed to prevent any of the following:

1. A pharmacist from exiting the prescription department  
 for the purposes of consulting or responding to inquiries or  
 providing assistance to patients or customers.

2. A pharmacist from, attending to personal hygiene needs.

3. A pharmacist from, ~~or~~ performing any other function for  
 which the pharmacist is responsible, provided that such  
 activities are conducted in a manner consistent with the  
 pharmacist's responsibility to provide pharmacy services.

4. An off-site pharmacist, acting in the capacity of a  
prescription department manager, from remotely supervising a  
registered pharmacy technician at a remote-site pharmacy.

Section 6. Subsection (1) of section 465.014, Florida  
 Statutes, is amended to read:

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy  
 intern may not engage in the practice of the profession of  
 pharmacy, except that a licensed pharmacist may delegate to  
 pharmacy technicians who are registered pursuant to this section  
 those duties, tasks, and functions that do not fall within the  
 purview of s. 465.003(13), and a registered pharmacy technician  
operating under remote supervision of an off-site pharmacist  
under s. 465.0198 may compound and dispense medicinal drugs  
under such supervision. All such delegated acts must be  
 performed under the direct supervision of a licensed pharmacist  
 who is responsible for all such acts performed by persons under  
 his or her supervision. A registered pharmacy technician, under  
 the supervision of a pharmacist, may initiate or receive

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communications with a practitioner or his or her agent, on  
 behalf of a patient, regarding refill authorization requests. A  
 licensed pharmacist may not supervise more than one registered  
 pharmacy technician, except as provided in s. 465.0198 or unless  
 otherwise permitted by the guidelines adopted by the board. The  
 board shall establish guidelines to be followed by licensees or  
 permittees in determining the circumstances under which a  
 licensed pharmacist may supervise more than one pharmacy  
 technician.

Section 7. Paragraph (b) of subsection (1) and paragraph  
 (b) of subsection (2) of section 465.015, Florida Statutes, are  
 amended to read:

465.015 Violations and penalties.—

(1) It is unlawful for any person to own, operate,  
 maintain, open, establish, conduct, or have charge of, either  
 alone or with another person or persons, a pharmacy:

(b) In which a person not licensed as a pharmacist in this  
 state or not registered as an intern in this state or in which  
 an intern who is not acting under the direct and immediate  
 personal supervision of a licensed pharmacist fills, compounds,  
 or dispenses any prescription or dispenses medicinal drugs. This  
paragraph does not apply to any person who owns, operates,  
maintains, opens, establishes, conducts, or has charge of a  
remote site pursuant to s. 465.0198.

(2) It is unlawful for any person:

(b) To fill, compound, or dispense prescriptions or to  
 dispense medicinal drugs if such person does not hold an active  
 license as a pharmacist in this state, is not registered as an  
 intern in this state, ~~or~~ is an intern not acting under the

39-00936A-21

2021700\_\_

direct and immediate personal supervision of a licensed pharmacist, or is not a registered pharmacy technician at a remote-site pharmacy acting under remote supervision of a licensed pharmacist pursuant to s. 465.0198.

Section 8. Section 465.0198, Florida Statutes, is created to read:

465.0198 Remote-site pharmacy permits.—

(1) As used in this section, the term “supervising pharmacy” means a pharmacy licensed in this state which employs a licensed pharmacist who remotely supervises a registered pharmacy technician at a remote-site pharmacy.

(2) Any person desiring a permit to operate a remote-site pharmacy must apply to the department. If the board certifies that the application complies with the laws and rules of the board, the department must issue the permit. A permit may not be issued unless a licensed pharmacist or consultant pharmacist is designated as the prescription department manager responsible for the oversight of the remote site. The permittee must notify the department within 10 days after any change of the prescription department manager.

(3) A remote-site pharmacy must comply with all of the following:

(a) Be jointly owned by or operated under a contract with a supervising pharmacy.

(b) Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 45 days.

(c) Display a sign visible to the public indicating that the location is a remote-site pharmacy and that the facility is

39-00936A-21

2021700\_\_

under 24-hour video surveillance.

(d) Maintain a policies and procedures manual, which must be made available to the board or its agent upon request, and must include, but need not be limited to, all of the following:

1. A description of how the pharmacy will comply with federal and state laws and rules.

2. The procedures for supervising the remote site and counseling its patients.

3. The procedures for reviewing the prescription drug inventory and drug records maintained by the remote site.

4. The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.

5. The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote site’s operation.

6. The procedures for use of the state prescription drug monitoring program by the prescription department manager before he or she may authorize the dispensing of any controlled substance.

7. The procedures for maintaining a perpetual inventory of the controlled substances listed in s. 893.03(2).

8. The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote site.

(4) A remote-site pharmacy is not considered a pharmacy location for purposes of network access in managed care programs.

(5) A remote-site pharmacy may store, hold, or dispense any

39-00936A-21

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349 medicinal drug.

350 (6) A remote-site pharmacy may not perform centralized  
 351 prescription filling as defined in s. 465.003(16).

352 (7) The prescription department manager must visit the  
 353 remote site, based on a schedule determined by the board, to  
 354 inspect the pharmacy, address personnel matters, and provide  
 355 clinical services for patients.

356 (8) A registered pharmacist may serve as the prescription  
 357 department manager for up to three remote-site pharmacies that  
 358 are under common control of the same supervising pharmacy.

359 Section 9. Paragraph (c) of subsection (11) of section  
 360 465.022, Florida Statutes, is amended to read:

361 465.022 Pharmacies; general requirements; fees.—

362 (11) A permittee must notify the department of the identity  
 363 of the prescription department manager within 10 days after  
 364 employment. The prescription department manager must comply with  
 365 the following requirements:

366 (c) A registered pharmacist may not serve as the  
 367 prescription department manager in more than one location,  
 368 except as authorized under s. 465.0198, unless approved by the  
 369 board.

370 Section 10. Subsection (1) of section 465.0265, Florida  
 371 Statutes, is amended to read:

372 465.0265 Centralized prescription filling.—

373 (1) A pharmacy licensed under this chapter may perform  
 374 centralized prescription filling for another pharmacy, provided  
 375 that the pharmacies have the same owner or have a written  
 376 contract specifying the services to be provided by each  
 377 pharmacy, the responsibilities of each pharmacy, and the manner

39-00936A-21

2021700\_\_

378 in which the pharmacies will comply with federal and state laws,  
 379 rules, and regulations. This subsection does not apply to a  
 380 remote-site pharmacy.

381 Section 11. Paragraph (e) is added to subsection (1) of  
 382 section 893.05, Florida Statutes, to read:

383 893.05 Practitioners and persons administering controlled  
 384 substances in their absence.—

385 (1)

386 (e) A telehealth provider as defined in s. 456.47 may not  
 387 prescribe through telehealth a controlled substance listed in  
 388 Schedule I or Schedule II of s. 893.03.

389 Section 12. This act shall take effect July 1, 2021.



The Florida Senate

## Committee Agenda Request

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

**Subject:** Committee Agenda Request

**Date:** February 2, 2021

---

I respectfully request that **Senate Bill #700**, relating to Telehealth, be placed on the:

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

A handwritten signature in black ink, appearing to read "Ana Maria Rodriguez".

---

Senator Ana Maria Rodriguez  
Florida Senate, District 39

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

2/17/21

Meeting Date

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

700

Bill Number (if applicable)

302884

Amendment Barcode (if applicable)

Topic SB 700 Amendment #302884

Name Steve Winn

Job Title Exec. Director

Address 2544 Blairston Pines Dr

Street

Tallahassee FL 32301

City

State

Zip

Phone 878-3056

Email winnsv2earthlink.net

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/17/21  
Meeting Date

700  
Bill Number (if applicable)

302884  
Amendment Barcode (if applicable)

Topic SB 700 Amendment # 302884

Name Steve Winn

Job Title Governmental Consultant

Address 2709 Killarney Way, Ste. 4  
Street

Phone 878-3056

Tallahassee FL 32309  
City State Zip

Email winnsr@earthlink.net

Speaking: ☐ For ☒ Against ☐ Information

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

Representing FL Society of Hearing Healthcare Professionals

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**

2/17/21  
Meeting Date

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

700  
Bill Number (if applicable)

Topic SB 700 - AA#286824 (Bean)

Amendment Barcode (if applicable)

Name Steve Winn

Job Title Exec Director / Gov't Consultant

Address 2544 Blairstone Pines Dr

Phone 878-3056

Street

Tallahassee

City

FL

State

32301

Zip

Email winnsv@earthlink.net

Speaking: ☒ For ☐ Against ☐ Information

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

Representing FOMIA & FL Society of Hearing

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)

2/14/21  
Meeting Date

700  
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Ron Watson

Job Title Lobbyist

Address 9114 Seafair Lane

Phone 850 567 1202

Street

City

Tallahassee

State

FL

Zip

32317

Email Watson.Strategies@comcast.net

Speaking: ☒ For ☐ Against ☒ Information

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

Representing myself

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**

2/17/2021

Meeting Date

700

Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Jake Farmer

Job Title Director of Government Affairs

Address 227 S Adams Street

Phone 352-359-6835

Street

Tallahassee

FL

32301

Email jake@frf.org

City

State

Zip

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

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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)

2/17/21  
Meeting Date

700  
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Phillip Suderman

Job Title Policy Director

Address \_\_\_\_\_ Phone \_\_\_\_\_  
Street

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_ Email \_\_\_\_\_

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Americans for Prosperity

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

2/17/21  
Meeting Date

700  
Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name Chris Noland

Job Title \_\_\_\_\_

Address 4427 Herschel St  
Street

Phone 904-233-3051

Jacksonville, FL 32210  
City State Zip

Email nolandlaw@aol.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Chapter, American College of Surgeons

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

2/17/21  
Meeting Date

700  
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Cesar Grajales

Job Title Policy Affairs Director

Address \_\_\_\_\_ Phone \_\_\_\_\_  
Street

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_ Email \_\_\_\_\_

Speaking: ☐ For ☐ Against ☐ Information

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

Representing LIBRE Initiative

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)

2/17/21

Meeting Date

700

Bill Number (if applicable)

Topic takehealth

Amendment Barcode (if applicable)

Name Eric Stevens

Job Title Director

Address 6800 Bay Dr  
Street

Phone 305 903 6106

Miami Beach FL 33141  
City State Zip

Email eric@floridaforcare.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida for Care

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)

16 Feb 21

Meeting Date

700

Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Barney Bishop III

Job Title Barney

Address 2215 Thomasville Rd

Phone 850.510.9922

Street

Tall

City

FL

State

32308

Zip

Email barney@barneybishop.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing SPAR - Small business Pharmacies Aligned for Reform

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)

FEB 17<sup>th</sup>

Meeting Date

SB 700

Bill Number (if applicable)

Topic

Telehealth

Amendment Barcode (if applicable)

Name

DAVID SARDAR

Job Title

STATESMAN

Address

66 WINTERGREEN DR

Phone 352 805 6597

Street

FRUITLAND PARK FL 34731

Email golferdave1955@gmail.com

City

State

Zip

Speaking:

☐

For

☐

Against

☒

Information

Waive Speaking:

☐

In Support

☐

Against

(The Chair will read this information into the record.)

Representing

Self & My Family SON MALZ NURSE  
ACUTE SPECIALIST

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)





# 2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

## BILL INFORMATION

BILL NUMBER:	SB 700
BILL TITLE:	Telehealth
BILL SPONSOR:	Senator Rodriguez
EFFECTIVE DATE:	July 1, 2021

## COMMITTEES OF REFERENCE

1) Health Policy (HP)
2) Appropriations Subcommittee on Health and Human Services (AHS)
3) Appropriations (AP)
4)
5)

## CURRENT COMMITTEE

--

## SIMILAR BILLS

BILL NUMBER:	
SPONSOR:	

## PREVIOUS LEGISLATION

BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

## IDENTICAL BILLS

BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?

Y \_\_\_ N \_X\_

## BILL ANALYSIS INFORMATION

DATE OF ANALYSIS:	February 15, 2021
LEAD AGENCY ANALYST:	Tim Buehner, Matt Brackett
ADDITIONAL ANALYST(S):	DD Pickle
LEGAL ANALYST:	
FISCAL ANALYST:	Maureen Castaño

## POLICY ANALYSIS

### 1. EXECUTIVE SUMMARY

Senate Bill (SB) 700 (Telehealth) amends sections 409.908 and 456.47, Florida Statutes (F.S.). These changes revise the state's definition of telehealth and add requirements for Florida Medicaid's reimbursement of telemedicine services. In addition, the bill makes changes to chapter 465, F.S., permitting telehealth providers acting within their scope of practice to prescribe certain controlled substances via telehealth and allowing physician supervisory arrangements of non-physician practitioners to take place via telehealth. Federal statutes do not allow the prescribing of controlled substances via telehealth. The bill also creates the term "remote-site pharmacy" and provides direction related to remote site pharmacy permits, operation, and oversight. SB 700's other changes align chapters 458, 459 and 893, F.S. with the amended language in section 409.908 and 456.47, F.S.

This bill poses operational impacts that are part of the agency's routine business practices and do not require an appropriation. This legislation is unlikely to increase overall costs to the Medicaid program, as the vast majority of Medicaid recipients are already covered for these services through the Medicaid health plans. This bill takes effect on July 1, 2021.

### 2. SUBSTANTIVE BILL ANALYSIS

#### 1. PRESENT SITUATION:

##### Florida Medicaid Program

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act. This authority includes establishing and maintaining a Medicaid state plan, approved by the Centers for Medicare and Medicaid Services (CMS).

##### Telemedicine under Florida Medicaid

By allowing patients to consult their practitioners remotely, telemedicine has the ability to improve health care access both nationally and at the state level. Telemedicine or telehealth has two primary categories, synchronous and asynchronous. The former involves the use of two-way, interactive audio-visual equipment to allow for real-time communication between a practitioner and patient, and the latter consists of practices such as store-and-forward that allows for the transmission of records or data for evaluation at a later time.

Florida Medicaid services are delivered to Medicaid recipients through either the fee-for-service delivery system or a managed care delivery system, with most Medicaid recipients receiving their services through a Medicaid managed care plan.

In the 2018 negotiations for the re-procurement of Medicaid health plan contracts, health plans agreed to cover additional telemedicine modalities. These modalities include asynchronous remote patient monitoring and store-and-forward services. In addition, Medicaid health plans are required to cover telemedicine services in "parity" with face-to-face services, meaning the health plan must cover services via telemedicine, where appropriate, in a manner no more restrictive than the health plan would cover the service face-to-face.

Currently, Florida Medicaid reimburses for services delivered via asynchronous telemedicine in the managed care delivery system, but not in the fee-for-service delivery system. To qualify for payment, practitioners must be in a location other than their patients and be using appropriate audio-visual equipment. Florida Medicaid currently does not reimburse for telehealth services such as chart reviews, telephone conversations, and email or fax transmissions. In response to the COVID-19 state of emergency, the Agency took multiple steps to expand telemedicine to prevent recipients from having lapses in treatment due to access issues. One of those changes was to allow audio-only telehealth services in both managed care and fee-for-service delivery systems.

##### Federal Telemedicine Requirements

CMS does not impose any significant requirements on how state Medicaid programs implement telemedicine, granting a high degree of flexibility provided that such service delivery is compliant with their state plan authorities. However, the U.S. Drug Enforcement Agency prohibits the prescription of controlled substances (e.g., opioids) via telemedicine consults, although it has made an exception to this policy during the COVID-19 pandemic.

## **2. EFFECT OF THE BILL:**

Senate Bill (SB) 700 (Telehealth) amends sections 409.908 and 456.47, Florida Statutes (F.S.). These changes revise the state's definition of telehealth and add requirements for Florida Medicaid's telemedicine services.

SB 700 amends the definition of telehealth in s. 456.47 to include audio-only telephone calls, personal email messages, facsimile transmission, and any other non-public facing telecommunications technology. SB 700 amends section 409.908, F.S. to require Florida Medicaid to reimburse telemedicine as defined in 456.47, including store-and-forward and remote patient monitoring. While Medicaid health plans cover remote patient monitoring and store and forward, this bill would mandate coverage for all Medicaid recipients, including those in the fee-for-service delivery system. The bill also permits out-of-state physicians who are registered with the Florida Department of Health as a telehealth provider to enroll in Florida Medicaid as an out-of-state provider for the purpose of providing telehealth services.

These changes pose operational impacts to update Medicaid Florida Administrative Code rules, seek federal approval for an amendment to the state plan, enroll new providers, and program the claims payment and enrollment systems. These actions are part of the Agency's routine business practices and do not require an appropriation. This legislation is unlikely to increase overall costs to the Medicaid program, as the vast majority of Medicaid recipients are already covered for these services through the Medicaid health plans. It has the potential increase utilization of telemedicine instead of face-to-face visits for diagnostic, preventive and treatment services.

SB 700 make additional changes that do not directly affect the Agency:

- Permits telehealth providers acting within their scope of practice to prescribe certain controlled substances via telehealth visit. This conflicts with federal regulations as stated above.
- Allows physician supervisory arrangements of non-physician practitioners (e.g., physician assistants and advanced practice registered nurses) to take place via telehealth
- Creates the term "remote site pharmacy" and provides direction related to remote site pharmacy permits, operation, and oversight.

This bill takes effect on July 1, 2021.

## **3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y \_\_\_ N \_X\_**

If yes, explain:	
Is the change consistent with the agency's core mission?	Y ___ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	

## **4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?**

Proponents and summary of position:	NA
Opponents and summary of position:	NA

**5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL?** Y \_\_\_ N x \_\_\_

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

**6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQUIRED BY THIS BILL?** Y \_\_\_ N x \_\_\_

Board:	
Board Purpose:	
Who Appointments:	
Appointee Term:	
Changes:	
Bill Section Number(s):	

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## FISCAL ANALYSIS

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**1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT?** Y \_\_\_ N X \_\_\_

Revenues:	N/A	
Expenditures:	N/A	
Does the legislation increase local taxes or fees? If yes, explain.	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 X \_\_\_ N \_\_\_

Revenues:	N/A	
Expenditures:	This legislation is unlikely to increase overall costs to the Medicaid program, as the vast majority of Medicaid recipients are already covered for these services through the Medicaid health plans.	

Does the legislation contain a State Government appropriation?	No	
If yes, was this appropriated last year?	N/A	

**3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y \_\_\_ N X\_\_\_**

Revenues:	N/A	
Expenditures:	N/A	
Other:	N/A	

**4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y \_\_\_ N X\_\_\_**

If yes, explain impact.	N/A	
Bill Section Number:	N/A	

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## TECHNOLOGY IMPACT

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**1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y x\_\_\_ N \_\_\_**

If yes, describe the anticipated impact to the agency including any fiscal impact.	Additional billing codes will need to be programmed. This is part of routine operations of the Agency.
--	--

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## FEDERAL IMPACT

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**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.	See comment on conflict with DEA prohibitions on prescribing controlled substances via telemedicine.
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## ADDITIONAL COMMENTS

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## LEGAL – GENERAL COUNSEL’S OFFICE REVIEW

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Issues/concerns/comments:	
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**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 866

INTRODUCER: Senator Hooper

SUBJECT: H. Lee Moffitt Cancer Center and Research Institute

DATE: February 16, 2021

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	<b>Favorable</b>
2.			FT	
3.			AP	

---

## I. Summary:

SB 866 increases the share of the cigarette tax<sup>1</sup> that is directed to the H. Lee Moffitt Cancer Center and Research Institute (Moffitt). Beginning on July 1, 2021, and continuing through June 30, 2024, the share of the tax directed to Moffitt is increased from 4.04 percent to 7 percent. Beginning on July 1, 2024, and continuing through June 20, 2054, the share of the tax directed to Moffitt is further increased to 10 percent.

The bill is effective upon becoming law.

## II. Present Situation:

### H. Lee Moffitt Cancer Center

Moffitt was established by the Legislature in 1981, began construction in 1983, and opened to patients on Oct. 27, 1986.<sup>2</sup> Moffitt began its research on cancer in 1993 and became a National Cancer Institute (NCI) designated cancer center in 1998. In 2001, Moffitt achieved NCI Comprehensive Cancer Center designation indicating that it is one of “the strongest institutions in the nation dedicated to scientific innovation and excellence; to interdisciplinary research, training and education; and to coordinated recognition and pursuit of new research opportunities.” Currently, Moffitt is the only NCI-designated Comprehensive Cancer Center based in Florida.<sup>3</sup>

Moffitt treats cancer patients and performs cancer research. Moffitt is Florida’s largest multi-disciplinary medical group practice that is dedicated to cancer care. The Moffitt Medical Group

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<sup>1</sup> Imposed by s. 210.02, F.S., less the 8 percent service charge provided for in s. 210.02, F.S., and less 0.9 percent of the amount, which is deposited in the Alcoholic Beverage and Tobacco Trust Fund.

<sup>2</sup> See <https://moffitt.org/about-moffitt/our-story/> (last visited Feb. 8, 2021).

<sup>3</sup> See <https://moffitt.org/about-moffitt/nci-designation/> (last visited Feb. 8, 2021).

(MMG), based at Moffitt Cancer Center, also provides services at other hospitals and clinics throughout the state of Florida and beyond. The MMG consists of 377 oncology specialists, including 221 board-certified physicians and 156 advanced practice professionals, as well as other staff who specialize in nearly 30 cancer programs and services.<sup>4</sup> Additionally, Moffitt employs about 800 research faculty scientists, career staff scientists, postdocs, graduate students, and support staff dedicated to cancer research.<sup>5</sup>

### ***Moffitt's Cigarette Tax Revenue***

As provided in s. 210.20(2)(b), F.S., the distribution of cigarette tax revenue to the H. Lee Moffitt Cancer Center is 4.04 percent of net cigarette tax collections each fiscal year, or 4.04 percent of net cigarette taxes that were collected in Fiscal Year 2001-2002, whichever is greater. This provision continues through June 30, 2053, under current law. For the purpose of determining the distribution amounts, net cigarette tax collections are defined as the cigarette tax imposed by s. 210.02, F.S., less the service charges provided for in s. 215.20, F.S., and less 0.9 percent of the amount derived from the cigarette tax imposed by s. 210.02, F.S.

Because cigarette tax collections today are substantially lower than they were in Fiscal Year 2001-2002, the Moffitt distribution amount is estimated to be \$15.6 million each fiscal year, which is equal to the amount Moffitt would have received in Fiscal Year 2001-2002. After all distributions from the cigarette tax are made, the remainder goes to the General Revenue Fund.<sup>6</sup>

### **III. Effect of Proposed Changes:**

SB 866 increases the percentage of cigarette tax revenue,<sup>7</sup> less the 8 percent service charge imposed by s. 215.20, F.S., and less 0.9 percent that is deposited into the Alcoholic Beverage and Tobacco Trust Fund, which is paid from month to month to Moffitt.

Beginning July 1, 2021, and continuing through June 30, 2024, the percentage is increased from the current percentage of 4.04 percent to 7 percent. Beginning July 1, 2024, the percentage is further increased to 10 percent.

The Revenue Estimating Impact Conference estimated on January 29, 2021, that SB 866 will increase the funds directed to Moffitt from \$15.6 million annually to \$26.9 million (an \$11.4 million increase over current year) from Fiscal Year 2021-2022 through Fiscal Year 2023-2024. Starting in Fiscal Year 2024-2025, the funds directed to Moffitt are estimated to be \$38.4 million annually (a \$22.9 million increase over current law). The amount of funds distributed to the state's General Revenue Fund from the cigarette tax is estimated to decrease by the corresponding amounts.<sup>8</sup>

The bill takes effect upon becoming law.

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<sup>4</sup> See <https://moffitt.org/about-moffitt/nci-designation/> (last visited Feb. 8, 2021).

<sup>5</sup> See <https://moffitt.org/about-moffitt/research/> (last visited Feb. 8, 2021).

<sup>6</sup> Revenue Estimating Conference report, Jan. 29, 2021, p. 19, available at <http://edr.state.fl.us/Content/conferences/revenueimpact/archives/2020/pdf/Impact1206.pdf> (last visited Feb. 8, 2021).

<sup>7</sup> *Supra* note 1.

<sup>8</sup> *Supra* note 6, at 20.



**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:

*See Section III of this analysis.*

## C. Government Sector Impact:

*See Section III of this analysis.*

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 210.20 of the Florida Statutes.

This bill reenacts section 210.205 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.

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

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By Senator Hooper

16-01127A-21

2021866\_\_

A bill to be entitled

An act relating to the H. Lee Moffitt Cancer Center and Research Institute; amending s. 210.20, F.S.; increasing, at specified timeframes, the percentage of cigarette tax proceeds paid to the Board of Directors of the H. Lee Moffitt Cancer Center and Research Institute for certain purposes; reenacting s. 210.205, F.S., relating to cigarette tax distribution reporting, to incorporate the amendment made to s. 210.20, F.S., in a reference thereto; providing an effective date.

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

Section 1. Paragraph (b) of subsection (2) of section 210.20, Florida Statutes, is amended to read:

210.20 Employees and assistants; distribution of funds.—

(2) As collections are received by the division from such cigarette taxes, it shall pay the same into a trust fund in the State Treasury designated "Cigarette Tax Collection Trust Fund" which shall be paid and distributed as follows:

(b) Beginning July 1, 2004, and continuing through June 30, 2013, the division shall from month to month certify to the Chief Financial Officer the amount derived from the cigarette tax imposed by s. 210.02, less the service charges provided for in s. 215.20 and less 0.9 percent of the amount derived from the cigarette tax imposed by s. 210.02, which shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund, specifying an amount equal to 1.47 percent of the net collections, and that

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

16-01127A-21

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amount shall be paid to the Board of Directors of the H. Lee Moffitt Cancer Center and Research Institute, established under s. 1004.43, by warrant drawn by the Chief Financial Officer. Beginning July 1, 2014, and continuing through June 30, 2021 ~~2053~~, the division shall from month to month certify to the Chief Financial Officer the amount derived from the cigarette tax imposed by s. 210.02, less the service charges provided for in s. 215.20 and less 0.9 percent of the amount derived from the cigarette tax imposed by s. 210.02, which shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund, specifying an amount equal to 4.04 percent of the net collections, and that amount shall be paid to the Board of Directors of the H. Lee Moffitt Cancer Center and Research Institute, established under s. 1004.43, by warrant drawn by the Chief Financial Officer. Beginning July 1, 2021, and continuing through June 30, 2024, the division shall from month to month certify to the Chief Financial Officer the amount derived from the cigarette tax imposed by s. 210.02, less the service charges provided for in s. 215.20 and less 0.9 percent of the amount derived from the cigarette tax imposed by s. 210.02, which shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund, specifying an amount equal to 7 percent of the net collections, and that amount shall be paid to the Board of Directors of the H. Lee Moffitt Cancer Center and Research Institute, established under s. 1004.43, by warrant drawn by the Chief Financial Officer. Beginning July 1, 2024, and continuing through June 30, 2054, the division shall from month to month certify to the Chief Financial Officer the amount derived from the cigarette tax imposed by s. 210.02, less the service charges provided for in

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s. 215.20 and less 0.9 percent of the amount derived from the cigarette tax imposed by s. 210.02, which shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund, specifying an amount equal to 10 percent of the net collections, and that amount shall be paid to the Board of Directors of the H. Lee Moffitt Cancer Center and Research Institute, established under s. 1004.43, by warrant drawn by the Chief Financial Officer. These funds are appropriated monthly out of the Cigarette Tax Collection Trust Fund, to be used for lawful purposes, including constructing, furnishing, equipping, financing, operating, and maintaining cancer research and clinical and related facilities; furnishing, equipping, operating, and maintaining other properties owned or leased by the H. Lee Moffitt Cancer Center and Research Institute; and paying costs incurred in connection with purchasing, financing, operating, and maintaining such equipment, facilities, and properties. In fiscal years 2004-2005 and thereafter, the appropriation to the H. Lee Moffitt Cancer Center and Research Institute authorized by this paragraph shall not be less than the amount that would have been paid to the H. Lee Moffitt Cancer Center and Research Institute in fiscal year 2001-2002, had this paragraph been in effect.

Section 2. For the purpose of incorporating the amendment made by this act to section 210.20, Florida Statutes, in a reference thereto, section 210.205, Florida Statutes, is reenacted to read:

210.205 Cigarette tax distribution reporting.—By March 15 of each year, each entity that received a distribution pursuant to s. 210.20(2)(b) in the preceding calendar year shall report to the Office of Economic and Demographic Research the following

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information:

(1) An itemized accounting of all expenditures of the funds distributed in the preceding calendar year, including amounts spent on debt service.

(2) A statement indicating what portion of the distributed funds have been pledged for debt service.

(3) The original principal amount and current debt service schedule of any bonds or other borrowing for which the distributed funds have been pledged for debt service.

Section 3. This act shall take effect upon becoming a law.

Page 4 of 4

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



The Florida Senate

## Committee Agenda Request

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

**Subject:** Committee Agenda Request

**Date:** February 4, 2021

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I respectfully request that **Senate Bill # 866**, relating to H. Lee Moffitt Cancer Center and Research Institute, be placed on the:

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

A handwritten signature in black ink, appearing to read "Ed Hooper", is written over a horizontal line.

Senator Ed Hooper  
Florida Senate, District 16

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

**THE FLORIDA SENATE**

**APPEARANCE RECORD**

2-17-2021

*Meeting Date*

866

*Bill Number (if applicable)*

Topic H. Lee Moffitt Cancer Center and Research Institute

*Amendment Barcode (if applicable)*

Name Merritt Martin

Job Title \_\_\_\_\_

Address 12902 Magnolia Drive

Phone 813-240-3454

*Street*

Tampa

FL

33612

Email Merritt.Martin@Moffitt.org

*City*

*State*

*Zip*

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Moffitt Cancer Center

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)

FEB 17<sup>th</sup> 2021  
Meeting Date

SB 866  
Bill Number (if applicable)

Topic Cigarette Tax increa

Amendment Barcode (if applicable)

Name David Sordani

Job Title STATES MAN SMOKER

Address 166 WINTERGREEN DR Phone 352 805 6597

Street

City

Fruitland

State

Zip

FL

34731

Email

golferdave1955@gmail.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing

Self

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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.)

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

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BILL: SB 780

INTRODUCER: Senator Gainer

SUBJECT: Health Care Licensure Requirements

DATE: February 16, 2021

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Brown	HP	<b>Favorable</b>
2.			MS	
3.			RC	

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## **I. Summary:**

SB 780 creates s. 456.0231, F.S., to require the Department of Health (DOH) to grant physicians, as defined under the bill, who are employees of the U.S. Department of Veterans Affairs (VA) an exemption from Florida's physician licensure requirements if such physicians submit proof of out-of-state licensure, proof of VA employment, and an attestation that they will only treat veterans in Florida-licensed hospitals or pursuant to their employment with the VA.

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

## **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<sup>1</sup> and four councils, licenses and regulates seven types of health care facilities, and more than 200 license types, in more than 40 health care professions.<sup>2</sup> Any person desiring to be a licensed health care professional in Florida must apply to the MQA in writing.<sup>3</sup> 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.<sup>4</sup>

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

<sup>2</sup> Florida Department of Health, Medical Quality Assurance, *Annual Report and Long Range Plan, 2019-2020*, available at <http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/documents/2019-2020-annual-report.pdf> (last visited Feb. 3, 2021).

<sup>3</sup> Section 456.013, F.S.

<sup>4</sup> See chs. 401, 456-468, 478, 480, 483, 484, 486, 490, and 491, F.S.



### ***Licensing of Florida Physicians***

Statutes regulating 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 respective board for each practice has the authority to establish, by rule, standards of practice and standards of care for particular settings.<sup>5</sup> 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.<sup>6</sup>

The current licensure application fee for a medical doctor<sup>7</sup> 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.<sup>8</sup>

For osteopathic physicians, the current application fee is a non-refundable \$200, and if approved, the initial licensure fee is \$305.<sup>9</sup> 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 seek Florida licensure by requesting the Board of Osteopathic Medicine (BOOM) to “endorse” the exam scores of the others state’s 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.<sup>10</sup>

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. Where the practice acts share the most similarities are the qualifications for licensure. Both the Board of Medicine (BOM) and the BOOM require their respective applicants to:

- 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.

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<sup>5</sup> Sections 458.331(1)(v) and 459.015(1)(z), F.S.

<sup>6</sup> *Id.*

<sup>7</sup> Medical doctors are also known as allopathic physicians.

<sup>8</sup> Florida Board of Medicine, *Medical Doctor Unrestricted – Process*, available at <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted> (last visited Feb. 3, 2021).

<sup>9</sup> 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. 3, 2021).

<sup>10</sup> Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure – Requirements*, available at <https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure> (last visited Feb. 3, 2021).

- 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.
- 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.<sup>11</sup>

<b>Statutory References for Practice Acts – Licensure of Medical Doctors and Osteopathic Physicians: Chapters 458 and 459, F.S.</b>		
<b>Issue</b>	<b>Medical Doctors</b>	<b>Osteopathic Physicians</b>
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 &amp; 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

<sup>11</sup> See ss. 458.311, F.S. and 459.0055, F.S.

<b>Statutory References for Practice Acts – Licensure of Medical Doctors and Osteopathic Physicians: Chapters 458 and 459, F.S.</b>		
<b>Issue</b>	<b>Medical Doctors</b>	<b>Osteopathic Physicians</b>
<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.

To practice medicine as an allopathic physician<sup>12</sup> in Florida, an individual must become a licensed medical doctor through licensure by examination<sup>13</sup> or licensure by endorsement.<sup>14</sup> Florida does not automatically recognize another state's medical license or provide licensure reciprocity. Licensure by endorsement requires the medical physician to meet one of the following requirements:

- Be a graduate of an allopathic United States medical school recognized and approved by the United States Department of Education and completed at least one year of residency training;
- Be a graduate of an allopathic international medical school 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 (5<sup>th</sup> 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.<sup>15</sup>

### ***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.<sup>16</sup> Physicians who

<sup>12</sup> *Supra*, note 7.

<sup>13</sup> Section 458.311, F.S.

<sup>14</sup> Section 458.313, F.S.

<sup>15</sup> Florida Board of Medicine, *Medical Doctor-Unrestricted; Licensure by Endorsement*, available at <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted> (last visited Feb. 3, 2021).

<sup>16</sup> Section 458.320, F.S.

perform surgeries in a certain setting or have hospital privileges must maintain professional liability insurance or other financial responsibility to cover an amount not less than \$250,000 per claim.<sup>17</sup> Physicians without hospital privileges must carry sufficient insurance or other financial responsibility in coverage amounts of not less than \$100,000 per claim.<sup>18</sup> Certain physicians who are exempt from the requirement to carry professional liability insurance or other financial responsibility must provide notice to their patients.<sup>19</sup>

Florida-licensed osteopathic physicians have similar financial responsibility requirements as allopathic physicians.<sup>20</sup> 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.<sup>21</sup>

### ***Disciplinary Process: Fines and Sanctions***

Chapter 456, F.S., contains the general regulatory provisions for health care professions and occupations under the MQA. 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.<sup>22</sup>

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.<sup>23</sup> The complainant is notified by letter as to the whether the complaint will be investigated and if any additional information is needed. Complaints that 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.<sup>24</sup> Authorization for the discipline of allopathic and osteopathic physicians can be found in state law and administrative rule.<sup>25</sup> If held liable for one of the offenses, the fines and sanctions by category and by offense are based on whether the offense is the physician's first, second, or third offense.<sup>26</sup> The boards may issue a written notice of noncompliance for the first

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<sup>17</sup> Section 458.320(2), F.S.

<sup>18</sup> Section 458.320(1), F.S.

<sup>19</sup> Section 458.320(5)(f) and (g), F.S.

<sup>20</sup> Section 459.0085, F.S.

<sup>21</sup> Sections 458.320(8) and 459.0085(9), F.S.

<sup>22</sup> 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. 3, 2021).

<sup>23</sup> 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. 3, 2021).

<sup>24</sup> See ss. 458.351(5) and 459.026(5), F.S.

<sup>25</sup> See ss. 458.307 and 459.004, F.S., for the regulatory boards, and Florida Admin. Code R. ss. 64B8-8 and 64B15-19, for administrative rules relating to disciplinary procedures.

<sup>26</sup> *Id.*

occurrence of a single minor violation.<sup>27</sup> 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 the physician should be disciplined for committing medical malpractice, gross medical malpractice, or repeated medical malpractice.<sup>28</sup>

### ***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:<sup>29</sup>

- The rendering of a handwriting sample to an agent of the DOH and waiver of any objections to its use as evidence;
- Waiver of confidentiality and authorizing 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
- Waiver of 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.<sup>30</sup>

### ***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.<sup>31</sup>

### ***Florida Background Checks***

Effective January 1, 2013, all applicants for initial physician licensure must undergo a Level 2 background screening<sup>32</sup> and use a Livescan provider<sup>33</sup> 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

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<sup>27</sup> Fla. Admin. Code R. ss. 64B8-8.011 and 64B15-19.0065. A minor violation is deemed to not endanger the public health, safety, and welfare and does not demonstrate a serious inability to practice.

<sup>28</sup> See ss. 458.3311 and 459.0151, F.S.

<sup>29</sup> See ss. 458.339 and 459.017, F.S.

<sup>30</sup> See ss. 458.343 and 459.019, F.S.

<sup>31</sup> See ss. 458.323 and 459.012, F.S.

<sup>32</sup> Sections 435.04 and 458.311(1)(g), F.S.

<sup>33</sup> Section 435.12, F.S.

search are returned to the Care Provider Background Screening Clearinghouse and made 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.<sup>34</sup>

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 provide it to the Livescan provider.<sup>35</sup>

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 valid for five years. Clearinghouse renewals can only be requested within a specific timeframe based on the retained print expiration date.

### **National Practitioner Data Bank**

Congress established the National Practitioner Data Bank (NPDB) in 1986. The NPDB is an Internet-based repository of reports on medical malpractice payments and certain adverse actions related to health care practitioners, providers, and suppliers. It is designed, in part, to prevent practitioners from moving from state to state without disclosure or discovery of previous damaging behavior.<sup>36</sup> The U.S. Department of Health and Human Services is responsible for administering the NPDB.

Federal regulations authorize eligible entities to report to or query the NPDB. Eligible entities are responsible for complying with all reporting or querying requirements that apply to them. Eligible entities include medical malpractice payers, hospitals and other health care entities, professional societies, health plans, peer review organizations, private accreditation organizations, quality improvement organizations, and certain federal and state agencies, including state licensing authorities such as the DOH.<sup>37</sup> The DOH is required to report to, and authorized to query, the NPDB.<sup>38</sup>

### **VA Practitioners in Florida**

Under federal law, health care practitioners who practice 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

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<sup>34</sup> Florida Board of Medicine, *Board of Medicine, Medical Doctor – Licensure Requirements*, available at <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted> (last visited Feb. 5, 2021).

<sup>35</sup> *Id.*

<sup>36</sup> National Practitioner Data Bank, *About Us*, available at <https://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp> (last visited Feb. 5, 2021).

<sup>37</sup> National Practitioner Data Bank, *The NPDB Guidebook*, available at <https://www.npdb.hrsa.gov/guidebook/APreface.jsp> (last visited Feb. 5, 2021).

<sup>38</sup> National Practitioner Data Bank, *What is an Eligible Entity?*, available at <https://www.npdb.hrsa.gov/guidebook/BWhatIsAnEligibleEntity.jsp> (last visited Feb. 5, 2021).

VA requires the practitioner to have an active, unrestricted license from any state.<sup>39</sup> 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 in Florida 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, which is supposed to include a background investigation process, for the purpose of determining their suitability for work. The NPDB is one information source the VA is supposed to use for the determination of whether health care practitioners applying for VA employment have been disciplined by a state licensing board or a health care facility.

The level of the VA's investigation into a prospective health care worker's background 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.<sup>40</sup>

### ***VA Inspector General Report***

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:<sup>41</sup>

- 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;<sup>42</sup>
- 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

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<sup>39</sup> U.S. Department of Veterans Affairs, *Navigating the Hiring Process*, available at <https://www.vacareers.va.gov/ApplicationProcess/NavigatingHiringProcess> (last visited Feb. 5, 2021).

<sup>40</sup> 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. 5, 2021).

<sup>41</sup> *Id.* pp. i-ii

<sup>42</sup> *Id.* p. 4



- 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.

### ***U.S. Government Accountability Office Report***

In February 2019, the U.S. Government Accountability Office (GAO)<sup>43</sup> published a report on the VA entitled, “Greater Focus on Credentialing Needed to Prevent Disqualified Providers from Delivering Patient Care.” The GAO’s investigation examined several aspects of the VA’s credentialing process, including how officials at VA medical facilities responded to adverse-action information received through the NPDB and how VA medical facilities adhered to policies regarding practitioners with adverse actions.<sup>44</sup> The GAO discovered that:

- In some cases, health care providers had adverse actions reported in the NPDB but VA medical facilities determined they could be hired anyway;
- VA medical facilities overlooked or were unaware of the disqualifying adverse-action information in the NPDB and, in such cases, the VA inappropriately hired health care providers;
- VA medical facilities did not consistently adhere to policies regarding health care providers with adverse actions, and some facility officials were not aware of VA employment policies;
- Officials in at least five VA medical facilities who were involved in verifying providers’ credentials and hiring them were unaware of the policy regarding hiring a provider whose license had been revoked or surrendered for professional misconduct, incompetence, or the delivery of substandard care. As a result, those five facilities hired or retained health care providers who were ineligible.

The GAO further reported that VA medical facilities provide mandatory, one-time training for certain VA staff but not for staff responsible for credentialing.

### **III. Effect of Proposed Changes:**

SB 780 creates s. 456.0231, F.S., requiring the DOH to grant physicians who are employees of the VA an exemption from Florida’s physician licensure requirements 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 under the bill from Florida licensure requirements pertaining to medical doctors under ch. 458, F.S., or osteopathic physicians under ch. 459, F.S., a VA physician must submit the following to the DOH:

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<sup>43</sup> The Government Accountability Office (previously called the Government Accounting Office) is an arm of the U.S. Congress and is responsible for determining whether the funds appropriated by Congress are spent for the purposes provided by Congress. The GAO conducts audits and investigations at the behest of congressional leadership. The GAO also evaluates federal programs and activities and provides analysis, options, and recommendations to assist Congress make oversight, policy, and funding decisions.

<sup>44</sup> U.S. Government Accountability Office, “Greater Focus on Credentialing Needed to Prevent Disqualified Providers from Delivering Patient Care,” (Feb. 28, 2019) available at <https://www.gao.gov/products/GAO-19-6> (last visited Feb. 5, 2021).



- Proof that he or she 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;
- 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 a physician within 15 business days after receipt of his or her proof and attestation as described above, that the physician is exempt.

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

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

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Hospitals will incur costs under the bill if VA-employed physicians who are exempt from Florida licensure provide medical treatment to veterans in those hospitals.

**C. Government Sector Impact:**

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

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

The bill requires the DOH to issue an exemption to a physician who submits the specified documentation. However, the bill provides no guidance regarding what is required of the physician to maintain the exemption, and it provides no monitoring or reporting mechanisms for the DOH to know what happens after an exemption is issued. To wit:

- The bill contains no provision for an exemption to expire, and exempt physicians are not required under the bill to notify the DOH about the status of their qualifications at any point after an exemption is issued.
- The bill provides no authority for the DOH to deny, suspend, or revoke an exemption for any reason.
- The DOH must issue an exemption based on the submission of documentation regarding a physician's point-in-time status and an attestation, which the bill does not require to be notarized. However, the bill does not make the exemption contingent on the continuation of VA employment, the maintenance of an active, unencumbered, out-of-state license as a physician, or the physician's faithfulness to the terms of the attestation.
- The bill does not require an exempt physician to notify the DOH regarding the hospital or hospitals in which he or she is treating veterans under the exemption.

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. The BOM and BOOM have authority to investigate and discipline Florida-licensed physicians only. Under the bill, the boards will have no authority or jurisdiction to discipline exempt physicians. If such physicians fail to meet Florida's standards of practice or cause patient harm in a Florida hospital, the state might not have the authority to impose discipline or prevent them from continuing to practice in those venues, 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 any one state or territory, he or she would be able to treat veterans in Florida hospitals, even if there were extensive disciplinary actions in other states where he or she is licensed. 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. Physicians exempted under the bill will not be subject to any of those provisions.

Physicians exempted under the bill will not have their criminal backgrounds checked by the DOH and will not be fingerprinted for those background checks, 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 criminal offense may still be able to practice in Florida hospitals under the bill.

As mentioned in Section V of this analysis, if veterans receive medical treatment in a Florida hospital under the bill, the hospital will incur ancillary costs. Presumably the VA will pay for the physician's services by virtue of his or her VA employment, but it is unclear whether hospitals will be reimbursed by the VA for ancillary costs relating to such treatment in their facilities.

#### **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.

By Senator Gainer

2-00969-21

2021780\_\_

1 A bill to be entitled  
 2 An act relating to health care licensure requirements;  
 3 creating s. 456.0231, F.S.; defining the term  
 4 "physician"; requiring certain physicians to submit  
 5 specified information to the Department of Health to  
 6 be exempt from specified licensure requirements;  
 7 requiring the department to notify such health care  
 8 practitioners of their exemption within a specified  
 9 timeframe; authorizing the department to adopt rules;  
 10 providing an effective date.  
 11  
 12 Be It Enacted by the Legislature of the State of Florida:  
 13  
 14 Section 1. Section 456.0231, Florida Statutes, is created  
 15 to read:  
 16 456.0231 Exemption from health care licensure requirements  
 17 for the treatment of veterans.—  
 18 (1) As used in this section, the term "physician" means a  
 19 person who holds an active, unencumbered license to practice  
 20 allopathic medicine or osteopathic medicine issued by another  
 21 state, the District of Columbia, or a possession, commonwealth,  
 22 or territory of the United States.  
 23 (2) A physician must submit to the department all of the  
 24 following to be exempt from the licensure requirements of  
 25 chapters 458 and 459:  
 26 (a) Proof that he or she holds an active, unencumbered  
 27 license to practice allopathic medicine or osteopathic medicine  
 28 issued by another state, the District of Columbia, or a  
 29 possession, commonwealth, or territory of the United States.

Page 1 of 2

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

2-00969-21

2021780\_\_

30 (b) Proof of current employment with the United States  
 31 Department of Veterans Affairs.  
 32 (c) An attestation that he or she will only provide medical  
 33 services:  
 34 1. To veterans.  
 35 2. Pursuant to his or her employment with the United States  
 36 Department of Veterans Affairs.  
 37 3. In hospitals licensed under chapter 395.  
 38 (3) The department shall notify the physician within 15  
 39 business days after receipt of the documentation required by  
 40 subsection (2) that the physician is exempt from the licensure  
 41 requirements of chapters 458 and 459.  
 42 (4) The department may adopt rules to administer this  
 43 section.  
 44 Section 2. This act shall take effect July 1, 2021.

Page 2 of 2

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



## THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

### COMMITTEES:

Appropriations Subcommittee on Transportation,  
Tourism, and Economic Development, *Chair*  
Appropriations  
Appropriations Subcommittee on Criminal  
and Civil Justice  
Criminal Justice  
Ethics and Elections  
Transportation

**SENATOR GEORGE B. GAINER**

2nd District

February 1, 2021

Re: SB 780

Dear Chair Diaz,

I am respectfully requesting Senate Bill 780, related to Health Care Licensing Requirements, be placed on the agenda for the next meeting of the Committee on Health Policy.

I appreciate your consideration of this bill. If there are any questions or concerns, please do not hesitate to call my office at (850) 487-5002.

Thank you,

A handwritten signature in cursive script, reading "George B. Gainer".

Senator George Gainer  
District 2

Cc: Allen Brown, Daniel Looke, Lynn Wells, Daniel Martinez, Claudia Farinas, Judith Ruiz

#### REPLY TO:

- ☐ 840 West 11th Street, Panama City, Florida 32401 (850) 747-5454
- ☐ Northwest Florida State College, 100 East College Boulevard, Building 330, Rooms 105 and 112, Niceville, Florida 32578 (850) 747-5454
- ☐ 408 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5002

Senate's Website: [www.flsenate.gov](http://www.flsenate.gov)

**WILTON SIMPSON**  
President of the Senate

**AARON BEAN**  
President Pro Tempore

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

**THE FLORIDA SENATE**

**APPEARANCE RECORD**

2/17/2021

*Meeting Date*

SB0780

*Bill Number (if applicable)*

Topic Health Care Licensure Requirements

*Amendment Barcode (if applicable)*

Name Roy L. Clark III

Job Title Legislative Affairs Director

Address 400 S. Monroe Street Ste 2105

Phone 850-487-1533

*Street*

Tallahassee

FL

32399

*City*

*State*

*Zip*

Email HartsellJ@FDVA.State.FL.US

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Department of Veterans' Affairs

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.)

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

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BILL: SB 768

INTRODUCER: Senator Baxley

SUBJECT: Immunizations

DATE: February 16, 2021

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto Van Winkle	Brown	HP	<b>Favorable</b>
2.	_____	_____	CF	_____
3.	_____	_____	RC	_____

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**I. Summary:**

SB 768 expands the scope of authority for certified pharmacists and pharmacy interns to administer vaccines within the framework of an established protocol with a supervising physician.

Under the bill, pharmacists and pharmacy interns are authorized to administer vaccines to persons six years of age or older, as opposed to current law which limits such administration to adults. To administer vaccines to children, the bill requires the pharmacist or intern to obtain a medical consent form for minors, with a notice that the parent or guardian may opt-out from the child's information being reported to the statewide immunization registry. The bill requires pharmacists and pharmacy interns to either report the child's vaccination data to the registry or send a completed opt-out form.

The bill authorizes pharmacists and pharmacy interns to administer to persons six years of age or older, under the protocol, any immunization or vaccine that is:

- Listed in the federal Centers for Disease Control and Prevention's (CDC) Adult Immunization Schedule, for adult patients;
- Listed in the CDC's Child and Adolescent Schedule, for patients who are children;
- Recommended by the CDC for international travel; or
- Approved by the Board of Pharmacy (BOP) in response to a state of emergency declared by the Governor.

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

## II. Present Situation:

### **Immunizations – U. S. Department of Health and Human Services**

The Office of Infectious Disease and HIV/AIDS Policy (Office), in the U. S. Department of Health and Human Services (HHS), oversees the National Vaccine Program, which provides strategic leadership for vaccine and immunization activities among federal agencies and to the states and other stakeholders, to help reduce the burden of preventable infectious diseases. The Office's services include the National Vaccine Strategic Plans (NVSP) and National Vaccine Advisory Committee (NVAC).<sup>1</sup> The NVSP for 2021-2025, released January 19, 2021, is the newest roadmap to coordinate vaccine development and use and is based on the NVAC's recommendations that revise the Standards for Adult Immunization Practices.<sup>2</sup>

### ***The Centers for Disease Control and Prevention's Immunization Recommendations***

The CDC, under the Secretary of HHS,<sup>3</sup> sets the adult and childhood immunization and vaccination schedules based on the recommendations from the Advisory Committee on Immunization Practices (ACIP).<sup>4</sup> The ACIP works with professional organizations, such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians, to develop annual childhood and adult immunization schedules.<sup>5</sup> The CDC reviews the ACIP's recommendations and, if approved, they are published as the CDC's official recommendations for immunizations for the population.<sup>6</sup> The current recommended immunization schedule for persons 18 years of age and older includes:<sup>7</sup>

- Influenza (annually) (IIV, RIV or LAIV);
- Measles, mumps, rubella (MMR) (if patient is born in 1957 or later);
- Zoster (ZVL) or (RZV);
- Pneumococcal polysaccharide (PPSV23);
- Haemophilus influenza Type B (Hib);
- Hepatitis B (HepB);
- Varicella (VAR) (if patient is born 1980 or later);
- Tetanus, diphtheria, pertussis (Tdap or Td) (booster every 10 years);
- Human papillomavirus (HPV);

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<sup>1</sup> U.S. Department of Health & Human Services, *Vaccines & Immunizations*, available at <https://www.hhs.gov/vaccines/index.html> (last visited Feb. 4, 2021).

<sup>2</sup> U.S. Department of Health & Human Services, *Vaccines National Strategic Plan*, available at <https://www.hhs.gov/vaccines/vaccines-national-strategic-plan/index.html> (last visited Feb. 4, 2021).

<sup>3</sup> U.S. Department of Health & Human Service, HHS Leadership, *Office of the Secretary Leaders*, available at <https://www.hhs.gov/about/leadership/index.html#opdiv> (last visited Feb. 4, 2021).

<sup>4</sup> Center for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations*, available at <https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html> (last visited Feb. 4, 2021).

<sup>5</sup> Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *ACIP Recommendations*, available at <https://www.cdc.gov/vaccines/acip/recommendations.html> (last visited Feb. 4, 2021).

<sup>6</sup> *Id.*

<sup>7</sup> Centers for Disease Control and Prevention, *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2020*, available at <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html> (last visited Feb. 4, 2021). The schedule provides the recommended age, as well as the administration intervals for vaccines that require multiple doses. Some vaccines are recommended only for populations with special situations that put those populations at higher risk.



- Pneumococcal conjugate (PCV13);
- Hepatitis A (HepA);
- Meningococcal A, C, W, Y (MenACWY); and
- Meningococcal B (MenB).

New vaccines are considered for addition to the schedule after being licensed by the Food and Drug Administration (FDA).<sup>8</sup> Not all newly licensed vaccines are added to the schedule. Some licensed vaccines are only recommended for people who are traveling to areas where certain vaccine-preventable diseases occur, such as yellow fever, cholera, dengue, Japanese encephalitis, plague, rabies, smallpox, and typhoid.<sup>9</sup>

### ***CDC Health Information for International Travel***

The CDC's *Health Information for International Travel*, commonly called the Yellow Book, is published biennially by the CDC as a reference to advise international travelers about health risks.<sup>10</sup> The Yellow Book includes the CDC's most current travel health guidelines, including pre-travel vaccine recommendations and destination-specific health advice. The Yellow Book is authored by subject-matter experts both within and outside the CDC and its guidelines are evidence-based and supported by best practices.<sup>11</sup>

Certain vaccinations are recommended by the CDC to protect international travelers from illness and prevent the importation of infectious diseases across international borders. The Yellow Book recommends that persons traveling internationally should be up to date on all CDC-recommended vaccines.<sup>12</sup> Additionally, the Yellow Book recommends additional vaccinations based on a traveler's destination and other factors.

### **Florida's Immunization Policy**

#### ***Communicable Disease Prevention and Control***

The Department of Health (DOH) is responsible for the state's public health system.<sup>13</sup> As part of fulfilling its public health mission, the DOH is responsible for conducting a communicable disease prevention and control program. A communicable disease is any disease caused by the transmission of a specific infectious agent, or its toxic products, from an infected person, animal, or the environment to a susceptible host, either directly or indirectly.<sup>14</sup>

The DOH communicable disease program includes, but need not be limited to, programs for the prevention and control of:

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<sup>8</sup> College of Physicians of Philadelphia, *The History of Vaccines: The Development of the Immunization Schedule*, available at <http://www.historyofvaccines.org/content/articles/development-immunization-schedule> (last visited Feb. 4, 2021).

<sup>9</sup> *Id.* For a complete list of FDA-licensed vaccines, see U.S. Food & Drug Administration, *Vaccines Licensed for Use in the United States*, (last rev. Apr. 24, 2020), available at <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states> (last visited Feb. 4, 2021).

<sup>10</sup> Centers for Disease Control and Prevention. *CDC Yellow Book 2020: Health Information for International Travel*, available at <https://wwwnc.cdc.gov/travel/page/yellowbook-home> (last visited Feb. 1, 2021).

<sup>11</sup> *Id.*

<sup>12</sup> *Supra*, note 10.

<sup>13</sup> Section 381.001, F.S.

<sup>14</sup> Section 381.003(1), F.S.

- Tuberculosis;
- Human immunodeficiency virus (HIV) infection;
- Acquired Immune Deficiency Syndrome (AIDS);
- Sexually transmissible diseases;
- Communicable diseases of public health significance; and
- Vaccine-preventable diseases,<sup>15</sup> including programs to immunize school children<sup>16</sup> and the development of an automated, electronic, and centralized database or registry for immunization records.<sup>17</sup>

The DOH may adopt rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for:<sup>18</sup>

- Investigating disease;
- Timeframes for reporting disease;
- Definitions;
- Procedures for managing specific diseases;
- Requirements for follow-up reports on disease exposure; and
- Procedures for providing access to confidential information necessary for disease investigations.

### ***Immunizations for Adults Recommended by the DOH***

The DOH recommends the following vaccines for adults:<sup>19</sup>

- Human Papillomavirus (HPV);
- Tetanus-diphtheria-pertussis (Tdap);
- Tetanus-diphtheria (Td) booster every ten years;
- Hepatitis A;
- Meningococcal;
- Measles-mumps-rubella (MMR);
- Varicella (chickenpox);
- Seasonal influenza;
- Zoster (shingles); and
- Pneumococcal.

### ***Required Immunizations for Children***

Each school district board and non-public school governing body is required to ensure that every child entering school in kindergarten through grade 12 must present or have on file a Florida

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<sup>15</sup> Measles, mumps, rubella, pertussis, diphtheria, tetanus, polio, varicella, pneumococcal disease, hepatitis A, hepatitis B, influenza, meningococcal and Haemophilus influenza type b (Hib) are all preventable by vaccine. See Department of Health, *Vaccine Preventable Diseases*, available at <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Feb. 1, 2021).

<sup>16</sup> See s. 1003.22(3)-(11), F.S.

<sup>17</sup> Section 381.003(1), F.S.

<sup>18</sup> Section 381.003(2), F.S.

<sup>19</sup> The Florida Department of Health, *Don't Miss Opportunities to Vaccinate!*, available at <http://www.floridahealth.gov/programs-and-services/immunization/publications/documents/opportunities-to-vaccinate-adult.pdf> (last visited Feb. 1, 2021).

Certificate of Immunization (FCI) before entering or enrolling in school.<sup>20</sup> Children entering, attending, or transferring to Florida public or non-public schools, kindergarten through grade 12, must have on file as part of their permanent school record<sup>21</sup> an FCI documenting that they have had the following immunizations:<sup>22</sup>

- Four or five doses of DTaP (Diphtheria-tetanus-acellular pertussis);
- Four or five doses of IPV (Inactivated polio vaccine);
- Two doses of MMR (Measles-mumps-rubella);
- Three doses of Hep B (Hepatitis B);
- One Tdap (Tetanus-diphtheria-acellular pertussis);
- Two doses of Varicella (unless there is a history of varicella disease documented by a health care provider); and
- If entering a public or non-public school in seventh grade or later, an additional dose of Tdap (Tetanus-diphtheria-acellular pertussis).

Private health care providers may grant a temporary medical exemption (TME), documented on the FCI form,<sup>23</sup> for those who are in the process of completing any necessary immunizations. The TME incorporates an expiration date after which the exemption is no longer valid, and the immunizations must be completed before or at that time. A permanent medical exemption may be granted if a child cannot be fully immunized due to medical reasons. In such case, the child's physician must state in writing the reasons for the exemption on the FCI form, based on valid clinical reasoning or evidence.<sup>24</sup>

A request for a religious exemption from immunizations requires the parent or guardian to provide the school or facility with a religious exemption immunization form.<sup>25</sup> The form is issued only by county health departments and only for children who are not immunized because of the family's religious tenets or practices. Exemptions for personal or philosophical reasons are not permitted under Florida law.<sup>26</sup>

### ***The DOH Immunization Registry (Florida SHOTS) for Children***

The DOH must ensure that all children are immunized against vaccine-preventable diseases and be included in the immunization registry, for the purpose of enhancing the DOH's immunization

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<sup>20</sup> Section 1003.22(4), F.S.

<sup>21</sup> *Id.*

<sup>22</sup> See also Department of Health, *School Immunization Requirements* (last modified Aug. 19, 2016), available at <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/school-immunization-requirements/index.html#childcare> (last visited Feb. 4, 2021).

<sup>23</sup> Department of Health, Form DH-680, *Florida Certification of Immunizations* (Jul. 2010) (on file with Senate Health Policy Committee).

<sup>24</sup> Department of Health, *Exemptions from Required Immunizations*, (last updated Sept. 18, 2019), available at <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/immunization-exemptions/index.html> (last visited Feb. 8, 2021).

<sup>25</sup> Department of Health, Form DH 681, *Religious Exemption From Immunization*, (Jul. 2008) puts a parent or guardian on notice that any child not immunized against a communicable disease that has been declared a communicable disease emergency will be temporarily excluded from school until such time as the county health department says the child can return. (on file with the Senate Health Policy Committee).

<sup>26</sup> Department of Health, Immunization Section, Bureau of Communicable Diseases, *Immunization Guidelines, Florida Schools, Childcare Facilities and Family Daycare Homes* (Mar. 2013), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/schoolguide.pdf> (last visited Feb. 5, 2021).

activities and improve immunization for all children. Florida's State Health Online Tracking System (SHOTS) is the free, statewide, centralized online immunization registry that assists healthcare providers, schools, and parents keep track of immunization records.<sup>27</sup> The program seeks to ensure a cause-and-effect response by monitoring immunization levels in vulnerable populations throughout the state, thereby contributing to strategies to attain and sustain high immunization levels.

The DOH immunization registry allows for immunization records to be electronically available to entities that are required by law to have such records, including schools and licensed child care facilities.<sup>28</sup>

Currently only allopathic and osteopathic physicians and nurses who administer vaccinations to children from birth to 18 years of age, or to college or university students who are 18 to 23 years of age at student health center or clinic, are required to report certain vaccination data to the immunization registry, unless the parents, guardian, or the college or university student opts-out.<sup>29</sup>

To be excluded from the registry, the parent or guardian of the child birth through age 17, must sign a DOH form, obtained from the DOH or the child's health care provider. The parent or guardian must provide the opt-out form to the health care practitioner at the time of the immunization. The health care practitioner must then submit the form to the DOH; or the parent or guardian may submit the opt-out form directly. Any records or identifying information pertaining to the child must be removed from the registry if the parent or guardian opts-out. In addition, each consent form for the immunizations of the child must contain a notice stating that the parent or guardian may refuse to have the child included in the immunization registry.<sup>30</sup>

A college or university student who is 18 to 23 years old, who obtains an immunization at a student health center or clinic, may also opt-out of the immunization registry by signing a form obtained from the DOH, health center, or clinic which indicates that he or she does not want to be included. The student must provide the opt-out form to the health center or clinic at the time of the immunization. The health center or clinic must submit the form to the DOH; or the student may submit the form directly. Any records or identifying information pertaining to the college or university student must be redacted from the registry if the student has opted-out of the immunization registry.<sup>31</sup>

Vaccination data for students in other age ranges may also be submitted to the immunization registry but only if the student consents to the data being included. The uploading of data from existing automated systems is an acceptable method for updating immunization information into

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<sup>27</sup> Department of Health, Providing Records to Patients, *Deliver Accurate, Timely Records*, available at <http://www.floridahealth.gov/programs-and-services/immunization/information-for-healthcare-providers/providing-records-to-patients/> (last visited Feb. 4, 2021).

<sup>28</sup> Section 381.003(1)(e)4., F.S.

<sup>29</sup> Section 381.003(1)(e)5., F.S.

<sup>30</sup> Section 381.003 (1)(e)2., F.S.

<sup>31</sup> Section 381.003(1)(e)3., F.S.

the immunization registry. The information submitted to the immunization registry must include:<sup>32</sup>

- The child's name;
- Date of birth;
- Address;
- Any unique identifier necessary to identify the child;
- The immunization record, including:
  - The date of the immunization;
  - Type of vaccine administered;
  - Vaccine lot number;
  - The presence or absence of any adverse reaction; and
  - Any contraindications noted to the immunization.

Information received by the DOH for the immunization registry is confidential medical information, and the DOH must maintain the confidentiality of that information. Health care practitioners who obtain information from the DOH immunization registry must also keep that information confidential.<sup>33</sup>

### **The Practice of Pharmacy**

The BOP, in conjunction with the DOH, regulates the practice of pharmacists and registered pharmacist interns pursuant to ch. 465, F.S.<sup>34</sup>

### ***Licensure***

To be licensed as a pharmacist in Florida, a person must:<sup>35</sup>

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>36</sup>
- 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 licensure renewal period.<sup>37</sup> Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections, as a part of their licensure renewal.<sup>38</sup>

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<sup>32</sup> *Id.*

<sup>33</sup> Sections 381.003(1)(e)5 and 456.057(9)(a), F.S.

<sup>34</sup> Sections 465.004 and 465.005, F.S.

<sup>35</sup> 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.

<sup>36</sup> If the applicant has graduated from a four-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 BOP-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.

<sup>37</sup> Section 465.009, F.S.

<sup>38</sup> Section 465.009(6), F.S.

### ***Scope of Pharmacy Practice***

In Florida, the practice of the profession of pharmacy includes:<sup>39</sup>

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of a medicinal drug;
- Consultation concerning therapeutic values and interactions of patented or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy;
- Reviewing, and making recommendations regarding the patient's drug therapy and health care status in communication with the patient's prescribing health care provider as authorized by the patient;
- Initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement;<sup>40</sup>
- Transmitting information from prescribers to their patients;
- Administering antipsychotropic medications by injection;<sup>41</sup>
- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;<sup>42</sup>
- Ordering and dispensing over-the-counter drugs approved by the FDA;<sup>43</sup>
- Ordering and dispensing within his or her professional judgment, subject to specified conditions:<sup>44</sup>
  - Certain oral analgesics for mild to moderate pain;
  - Anti-nausea preparations;
  - Certain antihistamines and decongestants;
  - Certain topical antifungal/antibacterial;
  - Topical anti-inflammatory preparations containing an amount of hydrocortisone not exceeding 2.5 percent;
  - Otic antifungal/antibacterial;
  - Salicylic acid;
  - Vitamins;
  - Ophthalmics;
  - Certain histamine H2 antagonists;
  - Acne products; and
  - Topical antivirals for herpes simplex infections of the lips.

### ***Pharmacist Authorization to Administer Immunizations and Epinephrine Auto-Injections***

A pharmacist may be authorized to administer immunizations to adults, according to CDC guidelines, and epinephrine auto-injections to address unforeseen allergic reactions, within the framework of an established protocol with a supervising physician. A pharmacist must become certified to administer immunizations and vaccines that are:

<sup>39</sup> Section 465.003(13), F.S.

<sup>40</sup> Section 465.1865, F.S.

<sup>41</sup> Section 465.1893, F.S.

<sup>42</sup> A Class III institutional pharmacy are those pharmacies affiliated with a hospital. *See* s. 465.019(2)(d), F.S.

<sup>43</sup> Section 465.186, F.S.

<sup>44</sup> Fla. Admin. Code R. 64B16-27.220 (2020).

- Listed in the CDC Adult Immunization Schedule as of February 1, 2015;
- Listed in the Adult Immunization Schedule after February 1, 2015, and authorized by BOP rule;
- Recommended by the CDC for international travel as of July 1, 2015;
- Recommended by the CDC for international travel after July 1, 2015, and authorized by BOP rule;<sup>45</sup> or
- Approved by the BOP in response to an emergency declared by the Governor.<sup>46</sup>

To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol with a supervising medical or osteopathic physician, and the protocol must:<sup>47</sup>
  - Specify the categories of patients and patient conditions for which the pharmacist may administer vaccines;
  - Be appropriate to the pharmacist's training and certification for administering the vaccine;
  - Outline the process and schedule for the review of the administration of vaccines by the pharmacist under 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;<sup>48</sup>
- Pass an examination and demonstrate vaccine administration technique;<sup>49</sup>
- Maintain and make available patient records using the same standards for confidentiality and retention of such records as required by s. 456.057, F.S., and maintain the records for at least five years;<sup>50</sup> and
- Maintain at least \$200,000 of professional liability insurance.<sup>51</sup>

A pharmacist may also administer epinephrine using an auto-injector delivery system within the framework of the established protocol under a supervising physician in order to address any unforeseen allergic reactions.<sup>52</sup>

A certified pharmacist is not authorized under Florida Statutes to administer immunizations to children.

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<sup>45</sup> Section 465.189(1)(b), F.S.

<sup>46</sup> Section 465.189, (1)(c), F.S.

<sup>47</sup> Section 465.189(7), F.S.

<sup>48</sup> Section 465.189(6), F.S., Fla. Admin. Code R. 64B16-26.1031 (2020), provides more detail regarding subject matter that must be included in the certification course.

<sup>49</sup> *Id.*

<sup>50</sup> 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.

<sup>51</sup> Section 465.189(3), F.S.

<sup>52</sup> Section 465.189(2), F.S. A certified registered pharmacy intern is not permitted to administer epinephrine auto-injections.

### ***Pharmacy Interns***

To become a pharmacy intern, a person must be certified by the BOP and enrolled in an intern program at an accredited school or college of pharmacy or as a graduate of an accredited school or college of pharmacy and not yet licensed as a pharmacist in Florida.<sup>53</sup> The BOP's rules outline the registration process for pharmacy interns and the internship program requirements for U.S. pharmacy students or graduates and foreign pharmacy graduates.<sup>54</sup>

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.<sup>55</sup>

To administer vaccines, a registered pharmacy intern must complete the same BOP-approved vaccine administration certification program as the pharmacist and also be supervised by a certified pharmacist, at a ratio of one pharmacist to one certified registered intern. Like pharmacists, pharmacy interns are not authorized under Florida Statutes to administer immunizations to children.<sup>56</sup>

### **Access to Vaccines During the COVID-19 Pandemic**

On March 9, 2020, Governor DeSantis issued Executive Order 20-52 declaring a state of emergency for the entire state of Florida as a result of COVID-19, allowing for the suspension of certain statutes and rules that prevent, hinder, or delay any necessary action in dealing with the state of emergency caused by COVID-19.<sup>57</sup>

### ***Federal Action to Authorize Pharmacists to Vaccinate Children***

On August 19, 2020, the HHS issued an amendment to the declaration published on March 17, 2020,<sup>58</sup> relating to the Public Readiness and Emergency Preparedness Act (PREP Act).<sup>59</sup> The amendment authorizes, effective August 24, 2020, state-licensed pharmacists (and pharmacy interns acting under their supervision) to order and administer vaccines to individuals ages three through 18 years, nationwide, subject to several requirements:<sup>60</sup>

- The vaccine must be authorized or approved by the FDA.

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<sup>53</sup> Section 465.013, F.S.

<sup>54</sup> Fla. Admin. Code R. 64B16-26.2032 (U.S. pharmacy students/graduates); Fla. Admin. Code R. 64B16-26.2033 (foreign pharmacy graduates).

<sup>55</sup> Fla. Admin. Code R. 64B16-27.430 (2020).

<sup>56</sup> Section 465.189(6), F.S.

<sup>57</sup> State of Florida, Office of the Governor, *Executive Order*, Number 20-52, available at [https://www.flgov.com/wp-content/uploads/orders/2020/EO\\_20-52.pdf](https://www.flgov.com/wp-content/uploads/orders/2020/EO_20-52.pdf) (last visited Feb. 10, 2021).

<sup>58</sup> 85 Fed. Reg. 15198 (2020).

<sup>59</sup> The PREP Act authorizes the Secretary of Health and Human Services the Secretary to issue a Declaration to provide liability immunity to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures Covered Countermeasures, except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant. The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2.

<sup>60</sup> 85 Fed. Reg. 136, 52136 - 52141 (2020). Also see <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html> (last visited Feb. 12, 2021).



- The vaccination must be ordered and administered according to the ACIP's standard immunization schedule.<sup>61</sup>
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE).
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE.
- The licensed pharmacist and licensed or registered pharmacy intern must have current certificates in basic cardiopulmonary resuscitation.

According to the announcement of the amendment, this federal action was for the purpose of increasing access to lifesaving childhood vaccines and decreasing the risk of vaccine-preventable disease outbreaks so children across the United States could return to daycare, preschool, and school.<sup>62</sup>

### ***State Emergency Action to Authorize Pharmacists to Vaccinate Children***

On October 1, 2020, the State Surgeon General issued an emergency order,<sup>63</sup> pursuant to authority granted by Executive Order No. 20-52, suspending the provision of s. 465.189(1), F.S., to the extent necessary to authorize a certified pharmacist, or a certified, registered pharmacy intern, to administer vaccines approved or licensed by the FDA to individuals under 18 years of age if the vaccine is approved for use in individuals under 18 years of age and upon receipt of a medical consent for the minor signed by a person who has the power to consent to the minor's medical care or treatment.

The Surgeon General's emergency order also authorized such practitioners to order and administer vaccines according to the CDC's ACIP immunization schedules and any vaccine approved by the FDA to immunize individuals against COVID-19.

This emergency order remains in effect until Executive Order No. 20-52, including any extensions, expires or is otherwise modified by order of the State Surgeon General.

### **III. Effect of Proposed Changes:**

SB 494 expands the scope of persons to whom certified pharmacists and pharmacy interns, under a protocol with a supervising physician, may administer CDC-listed and recommended

<sup>61</sup> Centers for Disease Control and Prevention, Immunization Schedules: *For Health Care Providers*, available at <https://www.cdc.gov/vaccines/schedules/hcp/index.html> (last visited Feb. 10, 2021). The immunization schedule recommends that certain vaccines be administered only to children of a certain age. For example, the second dose of both the measles, mumps, and rubella vaccine, as well as the varicella vaccine, should not be administered until a child is between four and six years old. See *Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger*, United States, 2020, CDC (Jan. 29, 2020), available at <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (last visited Feb. 10, 2021).

<sup>62</sup> U.S. Department of Health and Human Services, *HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic*, available at <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html> (last visited Feb. 12, 2021).

<sup>63</sup> State of Florida, Department of Health, State Surgeon General, *Emergency Order*, (Oct. 1, 2020) DOH No. 20-014, available at <https://floridahealthcovid19.gov/wp-content/uploads/2020/10/DOH-Emergency-Order-No-20-014.pdf> (last visited Feb. 10, 2021).

immunizations and vaccines. Under the bill, pharmacists and pharmacy interns may vaccinate a person six years of age or older, instead of being limited to adults as under current law.

The bill requires that a certified pharmacist or pharmacy intern who administers an immunization or vaccine to a child under 18 years of age, must:

- Obtain a medical consent form:
  - That contains an opt-out notice stating that a parent or guardian may opt-out of the DOH immunization registry; and
  - That is signed by a person who has the power to consent to medical care or treatment for the minor; which is defined as a natural or adoptive parent, legal custodian, or legal guardian; and, either
- Report vaccination data to the immunization registry; or
- Submit to DOH an opt-out immunization registry form that may be provided by the parent or guardian to the pharmacist or registered intern at the time the vaccine is administered.

The bill modifies the source list for immunizations and vaccines that certified pharmacists and pharmacy interns may administer. Currently, pharmacists and pharmacy interns, under a protocol with a supervising physician, are limited to administering vaccines to adults that are:

- Listed in the CDC's Adult Immunization Schedule as of February 1, 2015;
- Recommended by the CDC for international travel as of July 1, 2015;
- Authorized by BOP rule if listed or recommended, respectively, by the CDC after those dates; or
- Approved by the BOP in response to a state of emergency declared by the Governor.

The bill authorizes certified pharmacists and certified registered pharmacy interns, still under a protocol with a supervising physician, to administer vaccines and immunizations to persons six years of age or older that are:

- Listed in the CDC's Adult Immunization Schedule, without reference to the date they were listed, if the vaccine recipient is an adult;
- Listed in the CDC's Child and Adolescent Schedule, if the vaccine recipient is a child;
- Recommended by the CDC for international travel, without reference to the date they were recommended; or
- Approved by the BOP in response to a state of emergency declared by the Governor.

Under the bill, immunizations and vaccines added to the Adult Immunization Schedule after February 1, 2015, or recommended by the CDC for international travel after July 1, 2015, would no longer need authorization by BOP rule to be available for administration to adults by pharmacists and pharmacy interns. *See* Section IV.E. of this analysis for information concerning the removal of these dates from statute.

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

#### **IV. Constitutional Issues:**

##### **A. Municipality/County Mandates Restrictions:**

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Article II, Section 3, of the Florida Constitution has been interpreted by Florida courts to prohibit the Legislature from delegating its legislative power to others.<sup>64</sup> Under this non-delegation principle, Florida courts have held that the Legislature may enact laws that adopt federal statutes or other federal regulations in existence and in effect at the time the Legislature acts; however, if the Legislature incorporates into a Florida statute a *future* federal act or regulation, courts have held that such incorporation constitutes an unconstitutional delegation of legislative power.<sup>65</sup>

The bill incorporates CDC vaccination schedules and recommendations into Florida Statutes by reference and deletes the current statute's references to CDC schedules and recommendations that were in effect on certain dates in the past. The removal of those dates from statute could be viewed as opening-up authorization of vaccines that pharmacists and pharmacy interns may administer to include those currently listed or recommended by the CDC and those that may be listed or recommended by the CDC in the future.

However, when a statute incorporates a federal law or regulation by reference, in order to avoid holding the subject statute unconstitutional, Florida courts generally interpret the statute as incorporating only the federal law or regulation in effect on the date of the Legislature's action to enact the Florida law, reasoning that the Legislature is presumed to have intended to enact a valid and constitutional law.<sup>66</sup>

Under that premise, SB 768 may be interpreted by courts as authorizing pharmacists and pharmacy interns to administer vaccines that appear on the named CDC schedules or recommended by the CDC for international travel as of the date of the bill's passage or enactment, not vaccines that may be added to the CDC schedules or recommended by the CDC afterwards.

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<sup>64</sup>*Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, 15 So.3d 642 (Fla. 1d DCA 2009), citing *Gallagher v. Motors Ins. Corp.*, 605 So.2d 62, 71 (Fla. 1992).

<sup>65</sup>*State v. Rodriquez*, 365 So.2d 157, 160 (Fla.1978).

<sup>66</sup> *Id.*

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

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

By making childhood vaccinations available to Medicaid recipients through additional providers, the bill may result in additional childhood vaccinations being administered in the Medicaid program, which may increase the program's vaccination costs. The fiscal impact is indeterminate at this time.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 381.003, 465.189, and 465.003.

**IX. Additional Information:****A. Committee Substitute – Statement of Changes:**

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

None.

**B. Amendments:**

None.

By Senator Baxley

12-00562A-21

2021768\_\_

A bill to be entitled

An act relating to immunizations; amending s. 381.003, F.S.; requiring certain persons licensed to practice pharmacy to report specified vaccination data to the Department of Health's immunization registry, with exceptions; amending s. 465.189, F.S.; authorizing certain pharmacists and registered interns to administer specified immunizations and vaccines to children within a specified age range under certain circumstances; revising the specified immunizations or vaccines that such pharmacists and registered interns may administer; requiring authorized pharmacists and registered interns to obtain a certain medical consent form before administering a vaccine to a child younger than 18 years of age; specifying requirements for the consent form; requiring the parent or guardian of such child to provide a certain opt-out form to the pharmacist or registered intern to exclude the minor from the department's immunization registry; requiring the pharmacist or registered intern to submit the opt-out form to the department; requiring authorized pharmacists and registered interns to submit vaccination data to the department if an opt-out form is not provided; amending s. 465.003, F.S.; conforming a provision to changes made by the act; providing an effective date.

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

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

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Section 1. Paragraph (e) of subsection (1) of section 381.003, Florida Statutes, is amended to read:

381.003 Communicable disease and AIDS prevention and control.—

(1) The department shall conduct a communicable disease prevention and control program as part of fulfilling its public health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indirectly. The communicable disease program must include, but need not be limited to:

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 1003.22(3)-(11) and the development of an automated, electronic, and centralized database and registry of immunizations. The department shall ensure that all children in this state are immunized against vaccine-preventable diseases. The immunization registry must allow the department to enhance current immunization activities for the purpose of improving the immunization of all children in this state.

1. Except as provided in subparagraph 2., the department shall include all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics. The department shall add other children to the registry as immunization services are provided.

2. The parent or guardian of a child may refuse to have the child included in the immunization registry by signing a form obtained from the department, or from the health care

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practitioner or entity that provides the immunization, which indicates that the parent or guardian does not wish to have the child included in the immunization registry. Each consent to treatment form provided by a health care practitioner or by an entity that administers vaccinations or causes vaccinations to be administered to children from birth through 17 years of age must contain a notice stating that the parent or guardian of a child may refuse to have his or her child included in the immunization registry. The parent or guardian must provide such opt-out form to the health care practitioner or entity upon administration of the vaccination. Such health care practitioner or entity shall submit the form to the department. A parent or guardian may submit the opt-out form directly to the department. Any records or identifying information pertaining to the child shall be removed from the registry, if the parent or guardian has refused to have his or her child included in the immunization registry.

3. A college or university student, from 18 years of age to 23 years of age, who obtains a vaccination from a college or university student health center or clinic in the state may refuse to be included in the immunization registry by signing a form obtained from the department, health center, or clinic which indicates that the student does not wish to be included in the immunization registry. The student must provide such opt-out form to the health center or clinic upon administration of the vaccination. Such health center or clinic shall submit the form to the department. A student may submit the opt-out form directly to the department. Any records or identifying information pertaining to the student shall be removed from the

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registry if the student has refused to be included in the immunization registry.

4. The immunization registry shall allow for immunization records to be electronically available to entities that are required by law to have such records, including, but not limited to, schools and licensed child care facilities.

5. A health care practitioner licensed under chapter 458, chapter 459, ~~or~~ chapter 464, or chapter 465 in this state who administers vaccinations or causes vaccinations to be administered to children from birth through 17 years of age is required to report vaccination data to the immunization registry, unless a parent or guardian of a child has refused to have the child included in the immunization registry by meeting the requirements of subparagraph 2. A health care practitioner licensed under chapter 458, chapter 459, ~~or~~ chapter 464, or chapter 465 in this state who administers vaccinations or causes vaccinations to be administered to college or university students from 18 years of age to 23 years of age at a college or university student health center or clinic is required to report vaccination data to the immunization registry, unless the student has refused to be included in the immunization registry by meeting the requirements of subparagraph 3. Vaccination data for students in other age ranges may be submitted to the immunization registry only if the student consents to inclusion in the immunization registry. The upload of data from existing automated systems is an acceptable method for updating immunization information in the immunization registry. The information in the immunization registry must include the child's name, date of birth, address, and any other unique

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117 identifier necessary to correctly identify the child; the  
 118 immunization record, including the date, type of administered  
 119 vaccine, and vaccine lot number; and the presence or absence of  
 120 any adverse reaction or contraindication related to the  
 121 immunization. Information received by the department for the  
 122 immunization registry retains its status as confidential medical  
 123 information and the department must maintain the confidentiality  
 124 of that information as otherwise required by law. A health care  
 125 practitioner or other agency that obtains information from the  
 126 immunization registry must maintain the confidentiality of any  
 127 medical records in accordance with s. 456.057 or as otherwise  
 128 required by law.

129 Section 2. Present subsections (2) through (8) of section  
 130 465.189, Florida Statutes, are redesignated as subsections (3)  
 131 through (9), respectively, a new subsection (2) is added to that  
 132 section, and subsection (1) and present subsection (6) are  
 133 amended, to read:

134 465.189 Administration of vaccines and epinephrine  
 135 autoinjection.—

136 (1) In accordance with guidelines of the United States  
 137 Centers for Disease Control and Prevention for each recommended  
 138 immunization or vaccine, a pharmacist, or a registered intern  
 139 under the supervision of a pharmacist who is certified under  
 140 subsection (7)(6), may administer the following immunizations or  
 141 vaccines to a person 6 years of age or older an adult within the  
 142 framework of an established protocol under a supervising  
 143 physician licensed under chapter 458 or chapter 459:

144 (a) Immunizations or vaccines listed in the Adult  
 145 Immunization Schedule ~~as of February 1, 2015,~~ by the United

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146 States Centers for Disease Control and Prevention. ~~The board may~~  
 147 ~~authorize, by rule, additional immunizations or vaccines as they~~  
 148 ~~are added to the Adult Immunization Schedule.~~

149 (b) Immunizations or vaccines listed in the Child and  
 150 Adolescent Immunization Schedule by the United States Centers  
 151 for Disease Control and Prevention.

152 (c) Immunizations or vaccines recommended by the United  
 153 States Centers for Disease Control and Prevention for  
 154 international travel ~~as of July 1, 2015. The board may~~  
 155 ~~authorize, by rule, additional immunizations or vaccines as they~~  
 156 ~~are recommended by the United States Centers for Disease Control~~  
 157 ~~and Prevention for international travel.~~

158 (d) ~~(e)~~ Immunizations or vaccines approved by the board in  
 159 response to a state of emergency declared by the Governor  
 160 pursuant to s. 252.36.

161 A registered intern who administers an immunization or vaccine  
 162 under this subsection must be supervised by a certified  
 163 pharmacist at a ratio of one pharmacist to one registered  
 164 intern.

165 (2) To administer an immunization or vaccine to a child  
 166 younger than 18 years of age, a pharmacist or registered intern  
 167 certified under subsection (7) must first obtain a medical  
 168 consent form signed by a person who has the power to consent to  
 169 medical care or treatment on behalf of the child in accordance  
 170 with s. 743.0645. The medical consent form must contain a notice  
 171 stating that the parent or guardian of such child may refuse to  
 172 have the child included in the immunization registry under s.  
 173 381.003. If a parent or guardian does not want the child

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included in the immunization registry, he or she must provide to the pharmacist or registered intern a completed opt-out form approved by the department upon administration of the vaccine. The pharmacist or registered intern shall submit the opt-out form to the department. If a parent or guardian of a child younger than 18 years of age does not provide an opt-out form, the pharmacist or registered intern must report the vaccination data for such child to the department in accordance with s. 381.003.

(7)(6) Any pharmacist or registered intern seeking to administer vaccines ~~to adults~~ under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board and the registered intern complete at least 20 hours of coursework approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines, including, but not limited to, potential allergic reactions to such vaccines.

Section 3. Subsection (13) of section 465.003, Florida Statutes, is amended to read:

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

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or

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proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, the term "other pharmaceutical services" means monitoring the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes reviewing, and making recommendations regarding, the patient's drug therapy and health care status in communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or a similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient; and initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement. This subsection may not be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law or specifically authorized by s. 465.1865 or s. 465.1895. The term "practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of



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233 vaccines to persons 6 years of age or older ~~adults~~ pursuant to  
234 s. 465.189, the testing or screening for and treatment of minor,  
235 nonchronic health conditions pursuant to s. 465.1895, and the  
236 preparation of prepackaged drug products in facilities holding  
237 Class III institutional pharmacy permits. The term also includes  
238 the ordering and evaluating of any laboratory or clinical  
239 testing; conducting patient assessments; and modifying,  
240 discontinuing, or administering medicinal drugs pursuant to s.  
241 465.0125 by a consultant pharmacist.  
242       Section 4. This act shall take effect July 1, 2021.



## THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

**SENATOR DENNIS BAXLEY**  
12th District

**COMMITTEES:**

Ethics and Elections, *Chair*  
Appropriations Subcommittee on Criminal and Civil Justice  
Community Affairs  
Criminal Justice  
Health Policy  
Judiciary  
Rules

**JOINT COMMITTEE:**

Joint Legislative Auditing Committee, *Alternating Chair*

February 1, 2021

The Honorable Chair Manny Diaz  
306 Senate Office Building  
Tallahassee, Florida 32399

Dear Chair Diaz,

I would like to request that SB 768 Immunizations be heard in the next Health Policy Committee meeting.

This bill requires certain persons licensed to practice pharmacy to report specified vaccination data to the Department of Health's immunization registry, with exceptions. It also authorizes certain pharmacists and registered interns to administer specified immunizations and vaccines to children within a specified age range under certain circumstances.

Thank you for your favorable consideration.

Onward & Upward,

A handwritten signature in black ink, appearing to read "Dennis K. Baxley", written over a horizontal line.

Senator Dennis K. Baxley  
Senate District 12

DKB/dd

cc: Allen Brown, Staff Director

**REPLY TO:**

- 206 South Hwy 27/441, Lady Lake, Florida 32159 (352) 750-3133
- 315 SE 25th Avenue, Ocala, Florida 34471 (352) 789-6720
- 320 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5012

Senate's Website: [www.flsenate.gov](http://www.flsenate.gov)

Wilton Simpson  
President of the Senate

Aaron Bean  
President Pro Tempore





## FLORIDA CERTIFICATION OF IMMUNIZATION

Legal Authority: Sections 1003.22, 402.305, 402.313, Florida Statutes; Rule 64D-3.046, Florida Administrative Code

LAST NAME	FIRST NAME	MI	DOB (MM/DD/YY)
PARENT OR GUARDIAN	CHILD'S SS# (optional)	STATE IMMUNIZATION ID# (optional)	

### Directions:

- Enter all appropriate doses and dates below.
- Sign and date appropriate certificate (A, B, or C) on form.
- See DH Form 150-615, Immunization Guidelines - Florida Schools, Childcare Facilities and Family Daycare Homes (July 2010) for information and instructions on form completion. Guidelines are available at: [www.immunizeflorida.org/schoolguide.pdf](http://www.immunizeflorida.org/schoolguide.pdf).

VACCINE	DOE CODE	Dose 1 MM/DD/YY	Dose 2 MM/DD/YY	Dose 3 MM/DD/YY	Dose 4 MM/DD/YY	Dose 5 MM/DD/YY
DTaP/DTP	A					
DT	B					
Tdap	P					
Td	Q					
Polio	D					
Hib	E					
MMR (Combined)	F					
(Separate)	G, H					
	I	Measles (dose 1)	Measles (dose 2)	Mumps (dose 1)	Mumps (dose 2)	
		Rubella (dose 1)	Rubella (dose 2)			
Hepatitis B	J					
Varicella	K					
Varicella Disease	L					
		Year				
PneumoConju	N					

### Select appropriate box(es)

#### Certificate of Immunization for K-12

#### Part A-Complete

☐ DOE Code 1: Immunizations are complete K-12 (Excluding 7<sup>th</sup> grade/middle school requirements)

☐ DOE Code 8: Immunizations are complete for 7<sup>th</sup> grade

I have reviewed the records available, and to the best of my knowledge, the above named child has adequately been immunized for school attendance, as documented above.

#### Temporary Medical Exemption

Expiration date: \_\_\_\_\_

#### ☐ Part B-Temporary

**Part B** (For children in daycare, family daycare homes, preschool, kindergarten and grades 1 through 12 who are incomplete for immunizations in Part A) **Invalid without expiration date.** DOE Code 2

I certify that the above named child has received the immunizations documented above and has commenced a schedule to complete the required immunization. Additional immunizations are not medically indicated at this time.

#### Permanent Medical Exemption

#### ☐ Part C-Permanent

**Part C** (For medically contraindicated immunizations, list each vaccine and state valid clinical reasoning or evidence for exemption.)

DOE Code 3 \_\_\_\_\_

I certify the physical condition of this child is such that immunizations as indicated in Part C above are medically contraindicated.

Physician or Clinic Name: \_\_\_\_\_

Physician or

Authorized Signature: \_\_\_\_\_

Issued By: \_\_\_\_\_

Date: \_\_\_\_\_





**RELIGIOUS EXEMPTION FROM IMMUNIZATION**  
Exención Religiosa Para La Inmunización  
Eksepsyon Pou Kwayans Relijyon Pou Pa Nan Pran Piki Ak Vaksen

**Child's Name (printed)**

Nombre Del Niño (con letra de imprenta)

Non Timoun Nan (an gran karaktè)

**Date of Birth**

Fecha De Nacimiento  
Dat Li Te Fèt

**Child's SS# (optional)**

Número De Seguro Social  
Del Niño (opcional)  
Nimewo Sekirite Sosyal  
Timoun Nan (si ou vie)

**Name of Parent or Guardian**

Nombre Del Padre O Guardián

Non Paran Oubyen Moun Ki Reskonsab Li Ya

*(English)* I am the parent or legal guardian of the above-named child. Immunizations are in conflict with my religious tenets or practices. Therefore, I request that my child be enrolled in school, preschool, child day care facilities, or family day care homes without immunizations required by sections 1003.22, F.S., 402.305, F.S., and 402.313, F.S.

The presence of any of the communicable diseases for which immunization is required by the Department of Health in Florida schools, preschools, child day care facilities, or family day care homes shall permit the county health department director or administrator or the State Health Officer to declare a communicable disease emergency. Those children identified as not being immunized against the disease for which the emergency has been declared shall be temporarily excluded from the facility by the district school board or governing authority until such time as is specified by the county health department director or administrator.

*(Spanish)* Yo soy uno de los padres o el guardián legal del niño mencionado anteriormente. Las inmunizaciones están en conflicto con mis principios o prácticas religiosas. Por lo tanto, pido que mi hijo se matricule en el colegio, preescolar, guardería infantil o servicios de cuidado para familias sin las inmunizaciones requeridas por las secciones 1003.22, F.A., 402.305, F.S., y 402.313, F.S.

La presencia de cualquier enfermedad contagiosa para la cual el Departamento de Salud en los colegios, preescolares, guarderías infantiles o servicios de cuidado para familias de la Florida requiere inmunización permitirá que el director o el administrador del departamento de salud del condado o el oficial de salud estatal declare una emergencia de enfermedad contagiosa. Aquellos niños que sean identificados como no inmunizados contra la enfermedad para la cual se ha declarado la emergencia serán excluidos temporalmente de las instalaciones por parte de la junta del distrito escolar o las autoridades gobernantes hasta que el director o el administrador del departamento de salud del condado lo especifique necesario.

*(Creole)* Mwen menm se paran oubyen moun ki reskonsab devan lalwa timoun sa ke nou sot baw non li ya piwo wa. Sa yo ap fè nan san yo tankou piki, seròm ak vaksen pa mache ak prensip oubyen ak pratik ki gen nan legliz mwen yan. Poutèt sa, mwen mande ke timoun mwen yan enskri nan lekòl, lekòl matènèl, jaden danfan, oubyen kote yo fè gadri pou timoun, san ke yo pa bezwen pran vaksen yo jan atik 1003.22, F.S., 402.305, F.S., ak 402.313, F.S. yo mandel.

Prezans nenpòt ki maladi kontajye ki bezwen pou moun nan pran piki ak vaksen kan mèm dwe rekòmande pa Sèvis Sante ki nan lekòl yo ki anndan eta Florid la, lekòl matènèl, kote ke yo fasilite swen pou timoun, oubyen nan kay fanmi ki ap bay swen yo pou ka pèmèt direktè oubyen administratè Sante zòn nan oubyen ofisye sante eta deklare ke ou genyen you maladi kontajye ki gen ijans. Timoun sa yo ke yo idanfifye ki pa te pran piki, seròm ak lòt bagay nan san kont maladi kontajye ke yo deklare ki gen ijans lan nou pral mete yo deyò pou you ti tan jiskaske direktè ya oubyen administratè sante zòn nan deklare ke lè ya rive pou yo tounen.

**Electronic Signature of Parent or Guardian**

Firma del Padre o Guardián  
Siyati Paran Oubyen Moun Ki Reskonsab Li

**Date**

Fecha  
Dat

**Electronic Signature of Director/Administrator**

**Date**

**County Health Department**

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

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

2/17/21

Meeting Date

768

Bill Number (if applicable)

Topic Immunizations

Amendment Barcode (if applicable)

Name Doug Bell

Job Title \_\_\_\_\_

Address 119 S. Monroe St

Street

Phone 205-7000

TLH

City

State

Zip

Email doug.bell@whtf.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing FCAP - Pediatricians

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

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

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

February 17, 2021

Meeting Date

768

Bill Number (if applicable)

Topic Immunizations

Amendment Barcode (if applicable)

Name Barney Bishop III

Job Title Chair

Address 2215 Thomasville Road

Phone 850.510.9922

Street

Tallahassee

FL

32308

City

State

Zip

Email Barney@BarneyBishop.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing SPAR - Small business Pharmacies Aligned for Reform

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

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

THE FLORIDA SENATE

APPEARANCE RECORD

2/17/2021

Meeting Date

768

Bill Number (if applicable)

Topic Immunizations

Amendment Barcode (if applicable)

Name Jake Farmer

Job Title Director of Government Affairs

Address 227 S Adams Street

Phone 352-359-6835

Street

Tallahassee

FL

32301

Email jake@frf.org

City

State

Zip

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.

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

FEB 17<sup>th</sup> 2021  
Meeting Date

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

SB 768  
Bill Number (if applicable)

Topic Immunizations/Lic. Person's/exceptions  
Name David Sardon  
Job Title STATES MAN SENATOR  
Address 16 Wintergreen Dr  
City Fruitland Park State FL Zip 34731  
Phone 352 805 6597  
Email goldendave1955@gmail.com

Amendment Barcode (if applicable)  
Family male  
family with wife  
Hospital

Speaking: ☐ For ☐ Against ☒ Information

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

Representing SELF

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)



# CourtSmart Tag Report

**Room:** KN 412

**Case No.:**

**Type:**

**Caption:** Senate Health Policy Committee

**Judge:**

**Started:** 2/17/2021 9:02:59 AM

**Ends:** 2/17/2021 10:09:45 AM

**Length:** 01:06:47

9:02:57 AM Meeting called to order by Chair Diaz  
9:03:02 AM Roll call by CAA Lynn Wells  
9:03:12 AM Quorum present  
9:03:21 AM Comments from Chair Diaz  
9:03:39 AM Introduction of Tab 1, SB 362 by Chair Diaz  
9:04:16 AM Explanation of SB 362, Pediatric Cardiac Care by Senator Harrell  
9:09:08 AM Introduction of Amendment Barcode 695626 by Chair Diaz  
9:09:18 AM Explanation of Amendment by Senator Harrell  
9:09:42 AM Comments from Chair Diaz  
9:09:55 AM Amendment adopted  
9:09:58 AM Introduction of Amendment Barcode 915466 by Chair Diaz  
9:10:07 AM Explanation of Amendment by Senator Harrell  
9:10:22 AM Comments from Chair Diaz  
9:10:28 AM Amendment adopted  
9:10:31 AM Introduction of Amendment Barcode 265666 by Chair Diaz  
9:10:44 AM Explanation of Amendment by Senator Harrell  
9:11:02 AM Comments from Chair Diaz  
9:11:07 AM Amendment adopted  
9:11:15 AM Comments from Chair Diaz  
9:11:30 AM Chris Nuland, Florida Society of Theracic and Cardiovascular Surgeons waives in support  
9:11:43 AM Doug Bell, Florida Chapter of American Academy of Pediatrics waives in support  
9:11:48 AM Marnie George, Florida Chapter AM College of Cardiology waives in support  
9:11:55 AM Comments from Chair Diaz  
9:12:07 AM Closure by Senator Harrell  
9:12:19 AM Roll call by CAA  
9:12:37 AM CS/SB 362 reported favorably  
9:12:49 AM Introduction of Tab 4, SB 780 by Chair Diaz  
9:13:46 AM Explanation of SB 780, Health Care Licensure Requirements by Senator Gainer  
9:14:11 AM Comments from Chair Diaz  
9:14:17 AM Question from Senator Cruz  
9:14:24 AM Response from Senator Gainer  
9:15:22 AM Roy Clark, Florida Department of Veterans' Affairs waives in support  
9:15:32 AM Comments from Chair Diaz  
9:15:41 AM Closure waived  
9:15:43 AM Roll call by CAA  
9:15:49 AM SB 780 reported favorably  
9:16:04 AM Introduction of Tab 3, SB 866 by Chair Diaz  
9:16:33 AM Explanation of SB 866, H. Lee Moffitt Cancer Center and Research Institute by Senator Hooper  
9:18:25 AM Comments from Chair Diaz  
9:18:35 AM Merritt Martin, Moffitt Cancer Center waives in support  
9:18:57 AM Comments from Chair Diaz  
9:19:04 AM Senator Baxley in debate  
9:19:43 AM Senator Cruz in debate  
9:20:41 AM Comments from Chair Diaz  
9:20:47 AM Senator Hooper in closure  
9:20:53 AM Roll call by CAA  
9:21:16 AM SB 866 reported favorably  
9:21:28 AM Introduction of Tab 2, SB 700 by Chair Diaz  
9:21:49 AM Explanation of SB 700, Telehealth by Senator Rodriguez  
9:23:05 AM Introduction of Amendment Barcode 970352 by Chair Diaz  
9:23:17 AM Explanation of Amendment by Senator Rodriguez  
9:24:08 AM Comments from Chair Diaz

9:24:17 AM Question from Senator Baxley  
9:24:27 AM Response from Senator Rodriguez  
9:24:39 AM Comments from Chair Diaz  
9:24:45 AM Closure waived  
9:24:48 AM Amendment adopted  
9:24:53 AM Introduction of Amendment Barcode 882802 by Chair Diaz  
9:25:07 AM Explanation of Amendment by Senator Rodriguez  
9:25:22 AM Comments from Chair Diaz  
9:25:40 AM Closure waived  
9:25:43 AM Amendment adopted  
9:25:51 AM Introduction of Amendment Barcode 302884 by Chair Diaz  
9:26:16 AM Explanation of Amendment by Senator Rodriguez  
9:26:20 AM Comments from Chair Diaz  
9:26:27 AM Question from Senator Baxley  
9:27:10 AM Response from Senator Rodriguez  
9:28:35 AM Comments from Chair Diaz  
9:28:42 AM Introduction of Late-filed Amendment Barcode 286824 to AM 302884 by Chair Diaz  
9:29:00 AM Explanation of Late-filed Amendment by Senator Bean  
9:30:05 AM Comments from Chair Diaz  
9:30:18 AM Speaker Steve Winn, Florida Osteopathic Medical Association (FOMA) and Florida Society of Hearing Healthcare Professionals in opposition  
9:33:29 AM Comments from Chair Diaz  
9:33:37 AM Senator Rodriguez on Amendment  
9:33:47 AM Closure waived  
9:33:52 AM Amendment barcode 286824 to AM 302884 adopted  
9:33:59 AM Chair Diaz on AM 302884 as amended by Senator Rodriguez  
9:34:26 AM Steve Winn, FOMA, Florida Society of Hearing in opposition  
9:36:40 AM Comments from Chair Diaz  
9:36:40 AM Amendment barcode 302884 adopted  
9:36:51 AM Back on the bill as amended  
9:37:07 AM Speaker Ron Watson in support  
9:38:36 AM Speaker Jake Farmer, Florida Retail Federation in support  
9:39:02 AM Speaker Phillip Suderman, Americans for Prosperity in support  
9:40:54 AM Speaker Chris Nuland, Florida Chapter, American College of Florida Physicians in support  
9:41:56 AM Cesar Grajales, LIBRE Initiative waives in support  
9:42:52 AM Speaker Barney Bishop, SPAR - Small Business Pharmacies Aligned for Reform in opposition  
9:44:10 AM Speaker Eric Stevens, Florida for Care in support  
9:45:14 AM Speaker David Serdar  
9:47:02 AM Comments from Chair Diaz  
9:47:05 AM Senator Baxley in debate  
9:48:19 AM Senator Cruz in debate  
9:51:25 AM Senator Farmer in debate  
9:52:25 AM Chair Diaz in debate  
9:53:35 AM Senator Rodriguez in closure  
9:53:40 AM Roll call by CAA  
9:54:10 AM CS/SB 700 reported favorably  
9:54:27 AM Introduction of Tab 5, SB 768 by Chair Diaz  
9:54:42 AM Explanation of SB 768, Immunizations by Senator Baxley  
9:55:48 AM Comments from Chair Diaz  
9:56:01 AM Speaker Doug Bell, FCAAP - Pediatricians in opposition  
9:59:44 AM Speaker Barney Bishop, SPAR - Small Business Pharmacies Aligned for Reform in support  
10:00:48 AM Jake Farmer, Florida Retail Federation waives in support  
10:01:28 AM Speaker David Serdar  
10:02:57 AM Comments from Chair Diaz  
10:03:12 AM Senator Book in debate  
10:03:58 AM Senator Cruz in debate  
10:05:03 AM Senator Jones in debate  
10:05:55 AM Chair Diaz in debate  
10:06:06 AM Senator Baxley in closure  
10:07:46 AM Roll call by CAA  
10:08:48 AM SB 768 reported favorably  
10:09:22 AM Comments from Chair Diaz

**10:09:27 AM** Senator Bean moves to adjourn

**10:09:35 AM** Meeting adjourned