

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

**HEALTH POLICY**  
**Senator Harrell, Chair**  
**Senator Berman, Vice Chair**

**MEETING DATE:** Tuesday, February 19, 2019  
**TIME:** 10:00—11:30 a.m.  
**PLACE:** Pat Thomas Committee Room, 412 Knott Building

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

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	<b>SB 302</b> Brandes (Similar H 411)	Nonemergency Medical Transportation Services; Authorizing Medicaid nonemergency transportation services to be provided to a Medicaid recipient by certain transportation network companies or transportation brokers, subject to compliance with certain requirements; requiring the Agency for Health Care Administration to update the Non-Emergency Transportation Services Coverage Policy by a specified date, etc.  HP 02/11/2019 Not Considered HP 02/19/2019 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
2	<b>SB 592</b> Albritton (Similar H 375)	Prescription Drug Monitoring Program; Expanding the exceptions to a requirement that a prescriber or dispenser must consult the program to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance for a patient of a certain age, etc.  HP 02/19/2019 Favorable AHS AP	Favorable Yeas 10 Nays 0
3	<b>SB 354</b> Montford (Similar H 213)	Immunization Registry; Revising provisions relating to the communicable disease prevention and control programs under the Department of Health; establishing that a certain student who obtains a vaccination from a Florida college or university student health center may refuse to be included in the immunization registry; revising school-entry health requirements to require students to have a certificate of immunization on file with the department's immunization registry, etc.  HP 02/19/2019 Favorable ED RC	Favorable Yeas 10 Nays 0

**COMMITTEE MEETING EXPANDED AGENDA**

Health Policy

Tuesday, February 19, 2019, 10:00—11:30 a.m.

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TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	<b>SB 366</b> Braynon (Similar H 171)	Infectious Disease Elimination Programs; Citing this act as the "Infectious Disease Elimination Act (IDEA)"; authorizing certain eligible entities to establish sterile needle and syringe exchange programs, rather than a single program established in Miami-Dade County; exempting certain persons affiliated with a program from prosecution for possession of a needle or syringe under certain circumstances, etc.  HP 02/19/2019 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
5	<b>SB 434</b> Harrell	Ambulatory Surgical Centers; Revising the definition of the term "ambulatory surgical center"; requiring the Agency for Health Care Administration, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules that establish requirements for practitioners and facilities related to the delivery of surgical care to children in ambulatory surgical centers, in accordance with specified standards, etc.  HP 02/19/2019 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
6	Discussion on Certificate of Need:  Molly McKinstry, Deputy Secretary Agency for Health Care Administration		Discussed
Other Related Meeting Documents			

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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 302

INTRODUCER: Health Policy Committee and Senator Brandes

SUBJECT: Nonemergency Medical Transportation Services

DATE: February 21, 2019

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Williams</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	_____	_____	<u>AHS</u>	_____
3.	_____	_____	<u>AP</u>	_____

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

COMMITTEE SUBSTITUTE - Substantial Changes

**I. Summary:**

CS/SB 302 authorizes a transportation network company under contract with a Medicaid managed care plan, a transportation broker under contract with a Medicaid managed care plan, a transportation broker under direct contract with the Agency for Health Care Administration (AHCA), or a transportation network company that receives referrals from a transportation broker contracting with Medicaid managed care plans or the AHCA to provide Medicaid nonemergency transportation services to a Medicaid recipient, subject to compliance with state and federal Medicaid requirements.

The bill directs the AHCA to update any regulations, policies, and other guidance, including the Non-Emergency Transportation Services Coverage Policy handbook, as necessary, to reflect this authorization by October 1, 2019.

The bill stipulates that requirements for transportation network companies (TNCs) and transportation network company drivers may not exceed those requirements for transportation network companies imposed under s. 627.748, F.S., under which TNCs are regulated, except as necessary to conform to federal Medicaid transportation requirements administered by the AHCA.

The bill stipulates that its provisions may not be construed to expand or limit the existing transportation benefit provided to Medicaid recipients or to require a Medicaid managed care plan to contract with a transportation network company or a transportation broker.

CS/SB 302 amends s. 401.25, F.S., relating to Department of Health Emergency Medical Services licensure of basic life support providers and advanced life support providers. The bill creates a new subsection (8) of that section to authorize a Medicaid managed care plan that administers nonemergency Medicaid transportation benefits, a plan's subcontracted transportation broker, or a transportation broker that administers the nonemergency Medicaid transportation benefit under contract with the AHCA, to engage a licensed basic life support or a licensed advanced life support ambulance for the provision of nonemergency Medicaid transportation in permitted ambulances in any county without first obtaining a Certificate of Public Convenience and Necessity, as would otherwise be required under paragraph (2)(d) of that section.

The bill has no fiscal impact on state or local governments.

The effective date of the bill is July 1, 2019.

## **II. Present Situation:**

### **Non-Emergency Medical Transportation (NEMT) Services**

Non-emergency medical transportation (NEMT) includes transportation services offered to health care consumers who face barriers getting to their medical appointments. Those barriers can include not having a valid driver's license, not having a working vehicle in the household, being unable to travel or wait for services alone, or having a physical, cognitive, mental, or developmental limitation.

NEMT services are usually intended for medical appointments or other forms of non-emergent care. NEMT is widely known to serve Medicaid beneficiaries. Transportation services were established by the federal government as required Medicaid benefits when the Medicaid program was established at the national level in 1966.<sup>1</sup>

### **Florida Medicaid Program**

The Florida Medicaid program is a partnership between the federal and state governments. Each state operates its own Medicaid program under a state plan approved by the federal Centers for Medicare & Medicaid Services (CMS). The state plan outlines Medicaid eligibility standards, policies, and reimbursement methodologies.

Florida Medicaid is administered by the Agency for Health Care Administration (AHCA) and financed with federal and state funds. Just under four million Floridians are currently enrolled in Medicaid, and the program's estimated expenditures for the 2019-2020 state fiscal year are \$28.2 billion.<sup>2</sup>

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<sup>1</sup> What Is Non-Emergency Medical Transportation, Patient Access?: *available at* <https://patientengagementhit.com/news/what-is-non-emergency-medical-transportation-patient-access> (last visited Feb. 5, 2019).

<sup>2</sup> Social Services Estimating Conference, Medicaid Caseloads and Expenditures, November 19, 2018 and December 10 2018, Executive Summary <http://edr.state.fl.us/Content/conferences/medicaid/execsummary.pdf> (last visited Feb. 5, 2019).

Eligibility for Florida Medicaid is based on several factors, including age, household or individual income, and assets. State Medicaid payment guidelines are provided in s. 409.903, F.S. (Mandatory Payments for Eligible Persons) and s. 409.904, F.S. (Optional Payments for Eligible Persons). Minimum coverage thresholds are established in federal law for certain population groups, such as children or pregnant women.

Services are not eligible for federal matching funds under Medicaid unless they are authorized by the federal government. Section 409.905, F.S., specifies mandatory Medicaid services, which are required by the federal government, while s. 409.906, F.S., specifies optional services that the state has chosen to cover in its Medicaid program. Among the mandatory services included in s. 409.905, F.S., are Medicaid transportation services. Subsection (12) of this section reads:

The agency shall ensure that appropriate transportation services are available for a Medicaid recipient in need of transport to a qualified Medicaid provider for medically necessary and Medicaid-compensable services, provided a client's ability to choose a specific transportation provider shall be limited to those options resulting from policies established by the agency to meet the fiscal limitations of the General Appropriations Act. The agency may pay for transportation and other related travel expenses as necessary only if these services are not otherwise available.

Under the coverage policies (also known as handbooks) separately adopted in rule by the AHCA, both emergency transportation services<sup>3</sup> and non-emergency transportation (NET) services<sup>4</sup> are covered when they meet specified criteria. Each of the handbooks consistently addresses: introductory details relating to service description, legal authority, definitions; recipient and provider eligibility; coverage information; exclusions; required documentation; authorization requirements; and reimbursement guidance.

As part of the implementation of Statewide Medicaid Managed Care (SMMC) in 2011, the Florida Medicaid program incorporated into managed care contracts the provision of NET services. As specified in s. 409.973, F.S., "transportation to access covered services" is one of the benefits managed care plans are required to provide under SMMC.

Approximately 80 percent of the enrollees in Florida Medicaid have their NET services provided as part of their managed care service coverage. The remainder of the Medicaid enrollees receive NET services that are paid for by the AHCA on a fee-for-service basis.

The AHCA has a federal waiver that allows for selective contracting with transportation brokers to provide NET services to Medicaid recipients not enrolled in managed care plans. To provide this benefit to such recipients, the AHCA has contracted with two transportation brokers.<sup>5</sup>

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<sup>3</sup> Medicaid Emergency Transportation Services Coverage Policy (October 2016), *available at* [http://www.fdhc.state.fl.us/medicaid/review/Specific/59G4.015\\_Emergency\\_Transportation\\_Coverage\\_Policy\\_Adoption.pdf](http://www.fdhc.state.fl.us/medicaid/review/Specific/59G4.015_Emergency_Transportation_Coverage_Policy_Adoption.pdf) (last visited Feb. 5, 2019).

<sup>4</sup> Medicaid NET Coverage Policy, *available at* [http://www.fdhc.state.fl.us/medicaid/review/Specific/59G-4.330\\_NET\\_Coverage\\_Policy\\_Adoption.pdf](http://www.fdhc.state.fl.us/medicaid/review/Specific/59G-4.330_NET_Coverage_Policy_Adoption.pdf) (last accessed Feb. 5, 2019.)

<sup>5</sup> Agency for Health Care Administration, *Senate Bill 302 Analysis* (Jan. 23, 2019) (on file with the Senate Committee on Health Policy).

The AHCA published a notice in the Florida Administrative Register (FAR) for a rule change for Rule 59G-4.330 specific to NET services, on June 6, 2018, with a workshop held on June 22, 2018, and a deadline for submission of any comments on June 25, 2018.<sup>6</sup> The proposed amendment would update the policy to specify that transportation network companies are eligible to render Medicaid non-emergency transportation services. To date, no follow-up information has appeared in the FAR.

### **Transportation Brokers**

Currently, the AHCA and managed care plans participating in the SMMC program contract directly with transportation brokers to coordinate and reimburse for NET services. A transportation broker is a company that subcontracts with NET providers throughout the state to schedule, monitor, and pay for transportation services. The Medicaid transportation brokers ensure that drivers have completed background screening and drug screening requirements and that they meet all other state and federal Medicaid requirements related to transportation services. They also ensure that vehicles meet all requirements and that each recipient receives the appropriate mode of transportation.<sup>7</sup>

### **Nonemergency Medical Transportation Services**

Section 316.87, F.S., created in 2016, is specific to nonemergency medical transportation services. The provision prohibits a county that has licensed or issued a permit to a provider of nonemergency medical transportation services from requiring the provider to use a vehicle larger than needed to transport the number of passengers or that is inconsistent with the medical condition of the individuals receiving the service. This section is not applicable to procurement, contracting, or provision of paratransit services, directly or indirectly, by a county or an authority, pursuant to the Americans with Disabilities Act of 1990, as amended.

### **Transportation Network Companies**

Transportation network companies (TNCs) are regulated under s. 627.748, F.S. Transportation network companies use smartphone technology to connect individuals who want to ride with private drivers for a fee.<sup>8</sup>

In addition to definitions of relevant terms, s. 627.748, F.S., contains provisions regarding exclusions, a requirement for agent designation, fare transparency, identification requirements for vehicles and drivers, electronic receipts, insurance requirements specific to the company and drivers, including related disclosures and exclusions, limitations on TNCs, zero tolerance for driver drug or alcohol use, specific driver requirements, prohibited driver and company conduct, nondiscrimination and accessibility requirements, recordkeeping, and a prohibition on local preemption.

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<sup>6</sup> Medicaid NET Coverage Policy FAR notice, available at <https://www.flrules.org/gateway/ruleNo.asp?id=59G-4.330> (last visited Feb. 5, 2019).

<sup>7</sup> *Supra* note 5

<sup>8</sup> Primary examples of TNCs are the companies Lyft and Uber.

## **Emergency Medical Services (EMS) and Certificates of Public Convenience and Necessity (COPCN)**

Chapter 401, F.S., relates to medical telecommunications and transportation. Part III of ch. 401, F.S., consisting of ss. 401.2101-401.465, F.S., is specific to medical transportation services and provides for the regulation of emergency medical services by the Department of Health (DOH), including the licensure of EMS service entities, the certification of the staff employed by those services, and the permitting of vehicles used by the staff in those services—whether for Basic Life Support (BLS), Advanced Life Support (ALS), and Air Ambulance Services (AAS). As indicated on the DOH website, at present, the department is responsible for the licensure and oversight of over 60,000 Emergency Medical technicians and paramedics, 270+ advanced and basic life support agencies, and over 4,500 EMS vehicles.<sup>9</sup>

In addition to the state requirements for licensure of EMS services, the statute provides that county governments also have a responsibility in the licensure of EMS service entities. Section 401.25, F.S., relating to licensure as a BLS or an ALS EMS service, includes, among other standards, the requirement for the issuance of a Certificate of Public Convenience and Necessity by the county in which the service will operate. Section 401.25(2)(d), F.S., requires the department to issue a license to any applicant which has obtained a certificate of public convenience and necessity from each county in which the applicant will operate.

Section 401.25(6), F.S., authorizes counties to adopt ordinances that provide reasonable standards for certificates of public convenience and necessity for basic or advanced life support services and air ambulance services, and, in so doing, to consider state guidelines, recommendations of the local or regional trauma agency created under chapter 395, F.S., and the recommendations of municipalities within its jurisdiction.

Similar to s. 401.25, F.S., specific to ALS and BLS EMS entities, s. 401.251, F.S., is specific to those entities seeking to provide air ambulance services. Among the licensure requirements, paragraph (4)(b) stipulates that an air ambulance service that uses rotary-winged aircraft in conjunction with another emergency medical service, the air ambulance service must meet the provisions of s. 401.251, F.S., and must separate basic life support and advanced life support requirements unique to air ambulance operations as is required by rules of the department. Section 401.251, F.S., also subjects to air ambulance service to the provisions of s. 401.25, F.S., relating to a certificate of public convenience and necessity. However, an air ambulance service may operate in any county under the terms of mutual aid agreements.

In addition to the applicable statutory provisions, the DOH has adopted and enforces rules under ch. 64J-1, Florida Administrative Code (F.A.C.), specific to EMS regulation. Rule 64J-1.001, F.A.C., defines a “certificate of public convenience and necessity” as “a written statement or document, issued by the governing board of a county, granting permission for an applicant or licensee to provide services authorized by a license issued under chapter 401, part III, F.S., for the benefit of the population of that county or the benefit of the population of some geographic

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<sup>9</sup> Department of Health Emergency Medical Services System website, found at: <http://www.floridahealth.gov/licensing-and-regulation/ems-system/index.html> (last visited Feb. 7, 2019).

area of that county. No COPCN from one county may interfere with the prerogatives asserted by another county regarding COPCN.”

### III. Effect of Proposed Changes:

**Section 1** of the bill amends s. 316.87, F.S., relating to nonemergency transportation services. A new subsection (2) is added to this section of statute to authorize a transportation network company under contract with a Medicaid managed care plan, a transportation broker under contract with a Medicaid managed care plan, a transportation broker under direct contract with the AHCA, or a transportation network company that receives referrals from a transportation broker contracting with Medicaid managed care plans or the AHCA to provide Medicaid nonemergency transportation services to a Medicaid recipient, subject to compliance with state and federal Medicaid requirements.

The bill directs the AHCA to update any regulations, policies, and other guidance, including the Non-Emergency Transportation Services Coverage Policy handbook, as necessary to reflect this authorization by October 1, 2019.

The bill stipulates that requirements for transportation network companies and transportation network company drivers may not exceed requirements for transportation network companies imposed under s. 627.748, F.S., except as necessary to conform to federal Medicaid transportation requirements administered by the AHCA. The AHCA indicates that the only additional requirement that it would impose beyond what is specified in s. 627.748, F.S., would be to require that TNC drivers undergo FDLE Level I background screening requirements, as this is required for Medicaid providers per s. 409.907, F.S.<sup>10</sup>

The bill stipulates that its provisions may not be construed to expand or limit the existing transportation benefit provided to Medicaid recipients or to require a Medicaid managed care plan to contract with a transportation network company or a transportation broker.

**Section 2** of the bill amends s. 401.25, F.S., relating to Department of Health Emergency Medical Services licensure of basic life support providers and advanced life support providers, to create a new subsection (8) of that section to authorize a Medicaid managed care plan that administers nonemergency Medicaid transportation benefits, a plan’s subcontracted transportation broker, or a transportation broker that administers the nonemergency Medicaid transportation benefit under contract with the AHCA, to engage a licensed basic life support or a licensed advanced life support ambulance for the provision of nonemergency Medicaid transportation in permitted ambulances in any county without first obtaining a Certificate of Public Convenience and Necessity, as would otherwise be required under paragraph (2)(d) of that section

**Section 3** of the bill provides for a July 1, 2019, effective date.

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<sup>10</sup> *Supra* note 5



**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:

Affected transportation service providers may benefit financially from potential flexibility provided under CS/SB 302 for Medicaid managed care plans to contract with such providers. Individuals in need of Medicaid nonemergency transportation services may benefit from having additional options of providers for those services. Transportation network companies would have the opportunity to compete with existing transportation providers such as taxis to provide services to Medicaid recipients.

## C. Government Sector Impact:

The bill has no fiscal impact on state or local governments.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

The Agency for Health Care Administration might have difficulty meeting the time constraints of the requirement on lines 50-53 of the bill to update its existing regulations, policies, and other

guidance, including the nonemergency transportation services policy handbook, by October 1, 2019.

The AHCA indicates that it is not aware of any other state Medicaid programs that reimburse NET services provided by TNCs.<sup>11</sup>

### **VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 316.87 and 401.25.

### **IX. Additional Information:**

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

##### **CS by Health Policy on February 19, 2019:**

The CS:

- Adds to the list of those entities that may provide nonemergency transportation services a transportation network company that receives referrals from a transportation broker contracting with Medicaid managed care plans or the Agency for Health Care Administration (AHCA);
- Directs the AHCA to update any regulations, policies, and other guidance necessary, not just the Non-emergency Transportation Services Coverage Policy as was required by the underlying bill; and
- Amends s. 401.25, F.S., relating to Department of Health Emergency Medical Services licensure of basic life support providers and advanced life support providers and creates a new subsection (8) of that section to authorize a Medicaid managed care plan that administers nonemergency Medicaid transportation benefits, a plan's subcontracted transportation broker, or a transportation broker that administers the nonemergency Medicaid transportation benefit under contract with the AHCA, to engage a licensed basic life support or a licensed advanced life support ambulance for the provision of nonemergency Medicaid transportation in permitted ambulances in any county without first obtaining a Certificate of Public Convenience and Necessity, as would otherwise be required under paragraph (2)(d) of that section.

#### **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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<sup>11</sup> *Supra* note 5



388104

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/19/2019	.	
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The Committee on Health Policy (Brandes) recommended the following:

**Senate Amendment (with title amendment)**

Delete lines 36 - 55

and insert:

(2) (a) Subject to compliance with any applicable state and federal Medicaid requirements, a transportation network company under contract with a Medicaid managed care plan, a transportation broker under contract with a Medicaid managed care plan, a transportation broker under direct contract with the Agency for Health Care Administration, or a transportation



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11 network company that receives referrals from a transportation  
12 broker contracting with Medicaid managed care plans or the  
13 Agency for Health Care Administration may provide Medicaid  
14 nonemergency transportation services to a Medicaid recipient.  
15 The Agency for Health Care Administration shall update any  
16 regulations, policies, or other guidance, including the Non-  
17 Emergency Transportation Services Coverage Policy, as necessary  
18 to reflect this authorization by October 1, 2019. Requirements  
19 for transportation network companies and transportation network  
20 company drivers may not exceed those imposed under s. 627.748,  
21 except as necessary to conform to federal Medicaid  
22 transportation requirements administered by the Agency for  
23 Health Care Administration.

24 (b) This subsection may not be construed to expand or limit  
25 the existing transportation benefit provided to Medicaid  
26 recipients or to require a Medicaid managed care plan to  
27 contract with a transportation network company or a  
28 transportation broker.

29 Section 2. Subsection (8) is added to section 401.25,  
30 Florida Statutes, to read:

31 401.25 Licensure as a basic life support or an advanced  
32 life support service.—

33 (8) At the request of an eligible plan as defined in s.  
34 409.962 which administers the nonemergency Medicaid  
35 transportation benefit, the plan's subcontracted transportation  
36 broker, or a transportation broker that administers the  
37 nonemergency Medicaid transportation benefit for the Agency for  
38 Health Care Administration, a licensed basic life support or  
39 licensed advanced life support ambulance service may provide



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40 nonemergency Medicaid transportation in permitted ambulances in  
41 any county without obtaining a certificate of public convenience  
42 and necessity as required in paragraph (2)(d).

43  
44 ===== T I T L E A M E N D M E N T =====

45 And the title is amended as follows:

46 Delete lines 8 - 17

47 and insert:

48 requirements; requiring the Agency for Health Care  
49 Administration to update certain regulations,  
50 policies, or other guidance by a specified date;  
51 providing that the requirements for transportation  
52 network companies and transportation network company  
53 drivers may not exceed specified requirements, except  
54 as necessary to conform to federal Medicaid  
55 transportation requirements administered by the  
56 agency; providing construction; amending s. 401.25,  
57 F.S.; authorizing a licensed basic life support or  
58 licensed advanced life support ambulance service to  
59 provide nonemergency Medicaid transportation in  
60 permitted ambulances in any county at the request of a  
61 certain eligible plan; providing an effective date.

By Senator Brandes

24-00630-19

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1                                   A bill to be entitled  
 2           An act relating to nonemergency medical transportation  
 3           services; amending s. 316.87, F.S.; authorizing  
 4           Medicaid nonemergency transportation services to be  
 5           provided to a Medicaid recipient by certain  
 6           transportation network companies or transportation  
 7           brokers, subject to compliance with certain  
 8           requirements; requiring the Agency for Health Care  
 9           Administration to update the Non-Emergency  
 10          Transportation Services Coverage Policy by a specified  
 11          date; providing that the requirements for  
 12          transportation network companies and transportation  
 13          network company drivers may not exceed specified  
 14          requirements, except as necessary to conform to  
 15          federal Medicaid transportation requirements  
 16          administered by the agency; providing for  
 17          construction; providing an effective date.

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

20  
 21           Section 1. Section 316.87, Florida Statutes, is amended to  
 22           read:

23           316.87 Nonemergency medical transportation services.—

24           (1) To ensure the availability of nonemergency medical  
 25           transportation services throughout the state, a provider  
 26           licensed by the county or operating under a permit issued by the  
 27           county may not be required to use a vehicle that is larger than  
 28           needed to transport the number of persons being transported or  
 29           that is inconsistent with the medical condition of the

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2019302\_\_

30 individuals receiving the nonemergency medical transportation  
31 services. This subsection ~~section~~ does not apply to the  
32 procurement, contracting, or provision of paratransit  
33 transportation services, directly or indirectly, by a county or  
34 an authority, pursuant to the Americans with Disabilities Act of  
35 1990, as amended.

36 (2) (a) Subject to compliance with state and federal  
37 Medicaid requirements, a transportation network company under  
38 contract with a Medicaid managed care plan, a transportation  
39 broker under contract with a Medicaid managed care plan, or a  
40 transportation broker under direct contract with the Agency for  
41 Health Care Administration may provide Medicaid nonemergency  
42 transportation services to a Medicaid recipient. The Agency for  
43 Health Care Administration shall update the Non-Emergency  
44 Transportation Services Coverage Policy to reflect this  
45 authorization by October 1, 2019. Requirements for  
46 transportation network companies and transportation network  
47 company drivers may not exceed those imposed under s. 627.748,  
48 except as necessary to conform to federal Medicaid  
49 transportation requirements administered by the Agency for  
50 Health Care Administration.

51 (b) This subsection may not be construed to expand or limit  
52 the existing transportation benefit provided to Medicaid  
53 recipients or to require a Medicaid managed care plan to  
54 contract with a transportation network company or a  
55 transportation broker.

56 Section 2. This act shall take effect July 1, 2019.



# 2019 AGENCY LEGISLATIVE BILL ANALYSIS

**AGENCY:** Agency for Health Care Administration

## BILL INFORMATION

<b>BILL NUMBER:</b>	SB 302
<b>BILL TITLE:</b>	Nonemergency Medical Transportation
<b>BILL SPONSOR:</b>	Senator Brandes
<b>EFFECTIVE DATE:</b>	July 1, 2019

## COMMITTEES OF REFERENCE

1) N/A
2)
3)
4)

## CURRENT COMMITTEE

N/A

## SIMILAR BILLS

**BILL NUMBER:** HB 411

## PREVIOUS LEGISLATION

<b>BILL NUMBER:</b>	N/A
<b>SPONSOR:</b>	
<b>YEAR:</b>	
<b>LAST ACTION:</b>	

## IDENTICAL BILLS

**BILL NUMBER:** N/A

**SPONSOR:**

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

Y \_\_\_ N x

## BILL ANALYSIS INFORMATION

<b>DATE OF ANALYSIS:</b>	January 23, 2019
<b>LEAD AGENCY ANALYST:</b>	Matt Brackett, Division of Medicaid and Brittney Moulton, Division of Medicaid
<b>ADDITIONAL ANALYST(S):</b>	Christina Vracar, Division of Medicaid
<b>LEGAL ANALYST:</b>	
<b>FISCAL ANALYST:</b>	



## POLICY ANALYSIS

### **1. EXECUTIVE SUMMARY**

Senate Bill (SB) 302 amends section 316.87, Florida Statutes (F.S.) to allow transportation network companies (TNCs) to deliver transportation services to Florida Medicaid recipients. In addition, SB 302 amends the statute to permit the Agency for Health Care Administration (Agency) and health plans participating in the Statewide Medicaid Managed Care (SMMC) program to either contract directly with TNCs or with transportation brokers who contract with TNCs. The language does not require either the Agency or health plans to allow TNCs to provide transportation services to Medicaid recipients. The bill further specifies that the Agency cannot impose stricter requirements on TNCs than what is stated in section 627.748, F.S. except when necessary to comply with federal Medicaid transportation regulations, which the Agency may need to do, particularly for background screenings. Currently, the screening requirements specified in section 627.748, F.S. do not align with Medicaid background screening requirements contained in section 409.907, F.S., which requires all Medicaid providers undergo a Florida Department of Law Enforcement (FDLE) Level I background screening (in accordance with Chapter 435, F.S.).

SB 302 also directs the Agency to update the Medicaid Non-Emergency Transportation Services Coverage Policy by October 1, 2019 to reflect the changes specified in the bill.

The bill has an effective date of July 1, 2019.

### **2. SUBSTANTIVE BILL ANALYSIS**

#### **1. PRESENT SITUATION:**

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act (SSA). This authority includes establishing and maintaining a Medicaid state plan, approved by the Centers for Medicare and Medicaid Services. A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid program. It establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements.

The state Medicaid program may request a formal waiver of the requirements codified in the SSA. Federal waivers give state flexibility not afforded through the Medicaid state plan. Florida has several waivers authorized that facilitate implementation of certain statutory requirements.

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted on a regional basis with the Agency under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has three components: the integrated Managed Medical Assistance (MMA) component, Long-term Care (LTC) component and Dental component. Florida's SMMC program benefits are authorized through federal waivers and are specifically required by the Florida Legislature in sections 409.973 and 409.98, F.S. The SMMC benefits are a robust health care package covering medical, behavioral health, long-term care, and dental services.

Medicaid covers transportation services for medical emergencies and to all Medicaid services through the MMA and LTC programs.

The Agency has a federal waiver that allows for selective contracting with transportation brokers to provide non-emergency transportation (NET) services to recipients in the fee-for-service (FFS) delivery system. To provide this benefit to the FFS population, the Agency has contracted with two transportation brokers.

#### **Non-Emergency Transportation Services**

As a benefit specified in the state plan, Florida Medicaid provides NET services to eligible recipients of all ages for the purpose of accessing Medicaid-covered services. Depending on the recipient's individual needs, NET services can range from city buses to air ambulances equipped for advanced life support. The services transport recipients to and from appointments, hospitals, and other medically necessary services. NET services are also available to transport recipients to receive services outside of their region or state.

Vehicles utilized for NET services vary greatly. Recipients who are either wheelchair bound or bedridden require special vans, while those who require medical management or assistance need air or ground ambulances. Recipients who do not need special assistance may use public transportation or taxis. Florida Medicaid allows for the following vehicle types under the NET benefit:

- Public transportation
- Taxis and private vehicles
- Multi-load passenger vans
- Wheelchair and stretcher vans
- Ground ambulances
- Air ambulances
- Commercial airlines

Aside from reimbursing for recipients' transportation, the NET benefit also covers transporting an escort (e.g., parent, guardian, or authorized representative) and lodging expenses for trips out-of-state or region. NET is applicable to any Medicaid covered service, and the number of trips is not restricted.

Florida Medicaid requires that vehicles and drivers must meet certain requirements to be eligible to transport Medicaid recipients. These include completing background screening requirements, maintaining clean interiors, ensuring regular engine maintenance, and having adequate storage space and seating. Drivers must complete a Florida Department of Law Enforcement Level I background screening, but do not need to undergo a Level II background screening like other Medicaid providers. This is due to their classification as a non-traditional provider under the federal Health Insurance Portability and Accountability Act. The Agency has authority to require background screenings under Title 42 Code of Federal Regulations section 455.434 and section 409.907, F.S.

### **Transportation Brokers**

Currently, the Agency and health plans participating in the SMMC program contract directly with transportation brokers to coordinate and reimburse for NET services. A transportation broker is a company that subcontracts with NET providers throughout the state to schedule, monitor, and pay for transportation services. The Medicaid transportation brokers ensure that drivers have completed background screening and drug screening requirements and that they meet all other state and federal Medicaid requirements related to transportation services. They also ensure that vehicles meet all requirements and that each recipient receives the appropriate mode of transportation.

### **Transportation Network Companies**

Based on a system of independent contractors, Transportation Network Companies (TNCs) such as Uber and Lyft function by using a digital platform to connect riders with transportation in their respective areas. Utilizing a smartphone application, riders can schedule, select, and track the location of their drivers while awaiting pick up. The drivers have the ability to select which transportation requests to fulfill based on their schedule and proximity to location. Because they function independently, TNC drivers can set their own hours and schedules. In addition, rates for TNCs tend to fluctuate depending on peak demand times.

Effective July 1, 2017, TNCs operating in Florida had to conform to section 627.748, F.S. Under this law, drivers wanting to contract with TNCs must pass a local and national criminal background check that includes a search of Multi-State/Multi-Jurisdiction Criminal Records Locator or similar commercial nationwide database, a search of the United States Department of Justice National Sex Offender Public website, a driving history report, and meet specific insurance liability requirements. These requirements are not identical to the Level I background check requirements defined in section 435.03, F.S. In addition, TNCs have the option of subcontracting with third parties to complete the required screenings.

Aside from insurance and background requirements, TNCs do not have to follow uniform vehicle inspection standards, as this is not specified in statute. However, nationwide TNCs have similar requirements including passing an all-points inspection, having four doors, and being free from dents and interior damage. Additionally, these TNCs also have customer ratings standards that drivers must meet in order to remain contracted.

The Agency is not aware of any other state Medicaid programs that reimburse NET services provided by TNCs.

**2. EFFECT OF THE BILL:**

Senate Bill (SB) 302 amends section 316.87, F.S. by adding language that allows for transportation network companies (TNCs) as defined in section 627.748, F.S. to provide non-emergency transportation (NET) services to Florida Medicaid recipients. If passed, TNCs may contract directly with health plans participating in the Statewide Medicaid Managed Care program or through transportation brokers that are either contracted with the Agency or the health plans. The bill does not mandate that the Agency or health plans use TNCs for non-emergency transportation services.

The bill requires the Agency to update its Medicaid NET coverage policy by October 1, 2019 to reflect this change. Updating the Medicaid coverage policies is part of the Agency's routine business practices and poses an insignificant operational impact. Updates to the coverage policy will be subject to the administrative procedures act requirements, outlined in Chapter 120, F.S., which may take up to nine months. This may mean that the rule may not be finalized and adopted by October 1, 2019.

The bill specifies that the Agency may not impose stricter requirements on TNCs beyond what is specified in section 627.748, F.S. unless it is necessary to comply with federal and state regulations. The only additional requirement that the Agency would implement beyond what is specified in s. 627.748, F.S., would be to require that drivers undergo FDLE Level I background screening requirements, as this is required for Medicaid providers per s. 409.907, F.S.

The changes in this bill do not pose a fiscal impact to the Agency.

SB 302 takes effect on July 1, 2019.

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

If yes, explain:	Existing rules will need to be amended to comply with the bill.
Is the change consistent with the agency's core mission?	Y_X__ N__
Rule(s) impacted (provide references to F.A.C., etc.):	59G-4.330 – Nonemergency Transportation Services Coverage Policy

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

Proponents and summary of position:	Transportation Network Companies and Transportation Brokers
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Opponents and summary of position:	Unknown
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**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:	N/A
Board Purpose:	N/A
Who Appointments:	N/A
Appointee Term:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

## FISCAL ANALYSIS

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

Revenues:	Unknown
Expenditures:	Unknown
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

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

Revenues:	Unknown
Expenditures:	Unknown
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**

Revenues:	Unknown
Expenditures:	Unknown
Other:	Transportation Network Companies would have the opportunity to compete with existing transportation providers such as taxis to provide services to Medicaid recipients.

**4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y  N**

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  N**

If yes, describe the anticipated impact to the agency including any fiscal impact.	Routine operational procedures and business functions to update Florida Medicaid to include transportation network companies and transportation brokers as provider types to enroll in Florida Medicaid.
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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.	N/A
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**ADDITIONAL COMMENTS**

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N/A
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**LEGAL – GENERAL COUNSEL’S OFFICE REVIEW**

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Issues/concerns/comments:	
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THE FLORIDA SENATE

APPEARANCE RECORD

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

2/19/19 Meeting Date

302 Bill Number (if applicable)

Topic Non Emergency Medicaid Transportation Amendment Barcode (if applicable) 388104

Name Cari Roth

Job Title

Address 215 S. Monroe St Suite 815 Phone 850 999 4100
Street City State Zip Jacksonville FL 32301 Email croth@deanmed.com

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

Representing Fl. Ambulance Assoc, Lee, Manatee + Charlotte Counties

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.

# APPEARANCE RECORD

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

2/19/2019

Meeting Date

302

Bill Number (if applicable)

388104

Amendment Barcode (if applicable)

Topic Non Emergency <sup>Medical</sup> Transportation

Name Jorge Chamizo

Job Title Attorney

Address 108 South Monroe Street

Street

Tallahassee FL 32301

City

State

Zip

Phone (850) 681-0029

Email jorge@flapartners.com

Speaking:  For  Against  Information

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

Representing Uber Technologies

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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

2-19-19

Meeting Date

302

Bill Number (if applicable)

388104

Amendment Barcode (if applicable)

Topic \_\_\_\_\_

Name Audrey Brown

Job Title CEO

Address 200 West College

Street

Phone 386-2904

Tall FL 32301

City

State

Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

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

Representing FL Assoc of Healthplans

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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THE FLORIDA SENATE

APPEARANCE RECORD

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

2/19/19

Meeting Date

SB 302

Bill Number (if applicable)

Topic Non emergency Medical Transportation

Amendment Barcode (if applicable)

Name Ron Watson

Job Title Lobbyist

Address 3738 Murdan Way

Phone 850 567-1202

Street

Tallahassee

FL

32309

City

State

Zip

Email waton.strategies@comcast.net

Speaking: [ ] For [ ] Against [ ] Information

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

Representing Florida Renal Coalition

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

Lobbyist registered with Legislature: [ ] Yes [ ] No

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

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S-001 (10/14/14)

412-K

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

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

2/19/2019

*Meeting Date*

302

*Bill Number (if applicable)*

Topic Nonemergency Medical Transportation Services

*Amendment Barcode (if applicable)*

Name Christian R. Camara -- Institute for Justice

Job Title Legislative Fellow

Address 901 N Glebe Road, Suite 900

Phone 305.721.1600

*Street*

Arlington

VA

22203

Email Christian@ChamberConsultantsFL.com

*City*

*State*

*Zip*

Speaking:  For  Against  Information

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

Representing Institute for Justice

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)

2/19/19  
Meeting Date

302  
Bill Number (if applicable)

Topic Non Emergency Medicaid Transportation

Amendment Barcode (if applicable)

Name Cari Roth

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

Address 215 S. Monroe St Suite 815

Phone 850/999-4100

Tallahassee FL 32301  
City State Zip

Email croth@deanmead.com

Speaking:  For  Against  Information

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

Representing Fl. Ambulance Assoc., Lee, Manatee + Charlotte Counties

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**  
**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 592

INTRODUCER: Senator Albritton

SUBJECT: Prescription Drug Monitoring Program

DATE: February 18, 2019

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

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	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Brown</u>	<u>HP</u>	<b>Favorable</b>
2.	_____	_____	<u>AHS</u>	_____
3.	_____	_____	<u>AP</u>	_____

---

**I. Summary:**

SB 592 amends s. 893.055, F.S., to exempt prescribers and dispensers from the requirement to check the prescription drug monitoring program database (PDMP) before prescribing or dispensing controlled substances:

- To a patient for the alleviation of pain related to a terminal condition; or
- To a patient receiving palliative care for the relief of symptoms related to an incurable, progressive illness or injury.

**II. Present Situation:**

**Florida's Prescription Drug Monitoring Program**

Chapter 2009-197, Laws of Florida, established the PDMP in s. 893.055, F.S. The PDMP uses a comprehensive electronic database to monitor the prescribing and dispensing of certain controlled substances.<sup>1</sup> The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.<sup>2</sup> Health care practitioners began accessing the PDMP on October 17, 2011.<sup>3</sup>

Section 893.055, F.S., requires that for each controlled substance<sup>4</sup> dispensed to a patient in Florida, the dispensing practitioner must report specified information<sup>5</sup> by the close of the next

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<sup>1</sup> Section 893.055(2)(a), F.S.

<sup>2</sup> Florida Dept. of Health, *2012-2013 Prescription Drug Monitoring Program Annual Report* (Dec. 1, 2013), available at <http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf> (last visited on Jan. 7, 2018).

<sup>3</sup> Id.

<sup>4</sup> Section 893.055, F.S., defines "controlled substance" as "a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 or 21 U.S.C. s. 812." Prior to the passage of HB 21 in 2018 controlled substances listed in Schedule V were exempt from reporting. See ch. 2018-13, Laws of Fla.

<sup>5</sup> For the information required to be reported, see 893.055(3)(a)1.-8., F.S.

business day. All acts of administration, the dispensing of a controlled substance to a person under the age of 16, and the dispensing of a controlled substance in a health care system of the Department of Corrections are exempt from the requirement to report. During the 2017-2018 reporting period, there were approximately 33 million controlled substances prescribed to Florida patients. This is a decline of 4.64 percent over the previous reporting period.<sup>6</sup>

Prior to the enactment of HB 21<sup>7</sup> in 2018, a dispensing or prescribing health care practitioner was authorized, but not required, to check the PDMP prior to dispensing or prescribing a controlled substance. HB 21 created a new requirement that all prescribing<sup>8</sup> and dispensing<sup>9</sup> practitioners, or a designee of the prescriber or dispenser, must consult the PDMP to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance to the patient. This requirement does not apply when prescribing or dispensing to a patient under the age of 16, when prescribing or dispensing a non-opioid Schedule V controlled substance, or when the PDMP is not operational or cannot be accessed due to a technological or electrical failure. Between 2017 and 2018, the number of PDMP queries by health care practitioners increased by 26.6 percent from approximately 35.8 million to approximately 45 million.<sup>10</sup>

### III. Effect of Proposed Changes:

SB 592 amends s. 893.055, F.S. to exempt prescribers and dispensers from the requirement to check the prescription drug monitoring program database (PDMP) before prescribing or dispensing a controlled substances to:

- A patient for the alleviation of pain related to a terminal condition; or
- A patient receiving palliative care for the relief of symptoms related to an incurable, progressive illness or injury.

The bill provides an effective date of July 1, 2019.

### IV. Constitutional Issues:

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

None.

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

None.

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<sup>6</sup> Florida Dept. of Health, *2017-2018 Prescription Drug Monitoring Program Annual Report* (Dec. 1, 2018), available at [http://www.floridahealth.gov/statistics-and-data/e-forcse/health\\_care\\_practitioners/documents/2018-pdmp-annual-report.pdf](http://www.floridahealth.gov/statistics-and-data/e-forcse/health_care_practitioners/documents/2018-pdmp-annual-report.pdf) (last visited on Feb. 13, 2018).

<sup>7</sup> Chapter 2018-13, Laws of Fla.

<sup>8</sup> "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner authorized by the laws of this state to order controlled substances. (see s. 893.055(j), F.S.)

<sup>9</sup> "Dispenser" means a dispensing health care practitioner, pharmacy, or pharmacist licensed to dispense controlled substances in or into this state. (see s. 893.055(e), F.S.)

<sup>10</sup> *Supra* note 7

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 592 may have a positive fiscal impact, accompanied by a reduction in workload, for health care providers who treat terminally ill patients and who are providing palliative care as such practitioners will no longer be required to check the PDMP for such patients.

C. Government Sector Impact:

None.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 893.055 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 Albritton

26-00832-19

2019592\_\_

1                   A bill to be entitled  
2       An act relating to the prescription drug monitoring  
3       program; amending s. 893.055, F.S.; expanding the  
4       exceptions to a requirement that a prescriber or  
5       dispenser must consult the program to review a  
6       patient's controlled substance dispensing history  
7       before prescribing or dispensing a controlled  
8       substance for a patient of a certain age; providing an  
9       effective date.

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

12  
13       Section 1. Subsection (8) of section 893.055, Florida  
14       Statutes, is amended to read:

15       893.055 Prescription drug monitoring program.—

16       (8) A prescriber or dispenser or a designee of a prescriber  
17       or dispenser must consult the system to review a patient's  
18       controlled substance dispensing history before prescribing or  
19       dispensing a controlled substance for a patient age 16 or older.  
20       This requirement does not apply when prescribing or dispensing a  
21       controlled substance to a patient for the alleviation of pain  
22       related to a terminal condition, as defined in s.  
23       456.44(1)(a)2., when prescribing or dispensing a controlled  
24       substance to a patient receiving palliative care for the relief  
25       of symptoms related to an incurable, progressive illness or  
26       injury, or when prescribing or dispensing a nonopioid controlled  
27       substance listed in Schedule V of s. 893.03 or 21 U.S.C. 812.  
28       For purposes of this subsection, a "nonopioid controlled  
29       substance" is a controlled substance that does not contain any

26-00832-19

2019592\_\_

30 amount of a substance listed as an opioid in s. 893.03 or 21  
31 U.S.C. 812.

32 (a) The duty to consult the system does not apply when the  
33 system:

- 34 1. Is determined by the department to be nonoperational; or
- 35 2. Cannot be accessed by the prescriber or dispenser or a  
36 designee of the prescriber or dispenser because of a temporary  
37 technological or electrical failure.

38 (b) A prescriber or dispenser or designee of a prescriber  
39 or dispenser who does not consult the system under this  
40 subsection shall document the reason he or she did not consult  
41 the system in the patient's medical record or prescription  
42 record and shall not prescribe or dispense greater than a 3-day  
43 supply of a controlled substance to the patient.

44 (c) The department shall issue a nondisciplinary citation  
45 to any prescriber or dispenser who fails to consult the system  
46 as required by this subsection for an initial offense. Each  
47 subsequent offense is subject to disciplinary action pursuant to  
48 s. 456.073.

49 Section 2. This act shall take effect July 1, 2019.



The Florida Senate

## Committee Agenda Request

**To:** Senator Gayle Harrell, Chair  
Committee on Health Policy

**Subject:** Committee Agenda Request

**Date:** February 8, 2019

---

I respectfully request that **SB 592**, relating to Prescription Drug Monitoring Program, be placed on the:

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

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

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

2/19/2019

SB 592

*Meeting Date*

*Bill Number (if applicable)*

Topic Prescription Drug Monitoring Program

*Amendment Barcode (if applicable)*

Name Zayne Smith

Job Title Associate State Director

Address 200 W. College Ave

Phone 850-228-4243

*Street*

Tallahassee

FL

32301

Email zsmith@aarp.org

*City*

*State*

*Zip*

Speaking:  For  Against  Information

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

Representing AARP Florida

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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

S-001 (10/14/14)

412 K - 10am

THE FLORIDA SENATE

APPEARANCE RECORD

2/19/19

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

Meeting Date

592

Bill Number (if applicable)

Topic PDMP

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Dr

Phone 878-3056

Street

Tallahassee

FL

32301

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 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.

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# APPEARANCE RECORD

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

2/19/19

Meeting Date

592

Bill Number (if applicable)

Topic PDMP

Amendment Barcode (if applicable)

Name Mary Thomas

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

Address 1430 Piedmont Dr E

Phone 850 224 6496

TLH FL 32308

City

State

Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

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

Representing Florida Medical Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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# APPEARANCE RECORD

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

2/19/19

Meeting Date

592

Bill Number (if applicable)

n/a

Amendment Barcode (if applicable)

Topic Albritten - PDMP

Name Paul Ledford

Job Title Executive Director, FL Hospice + Palliative Care ASSOC.

Address 1616 D Metropolitan Circle

Street

Phone 850 878-2632

Tallahassee, FL 32308

City

State

Zip

Email paul@floridahospice.org

Speaking:  For  Against  Information

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

Representing FL Hospice + Palliative Care Assoc.

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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

**The Florida Senate**  
**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 354

INTRODUCER: Senator Montford

SUBJECT: Immunization Registry

DATE: February 18, 2019

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	<b>Favorable</b>
2.	_____	_____	ED	_____
3.	_____	_____	RC	_____

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**I. Summary:**

SB 354 directs certain health care practitioners to report vaccination administration data to the Department of Health (DOH) immunization registry when vaccinating children up to 18 years of age or college or university students at a college or university health center who are 19 to 23 years of age. The bill permits a parent or guardian of a child up to 18 years of age or a college or university student 19 to 23 years of age to refuse to be included in the immunization registry. Such a decision not to participate in the immunization registry must be noted in the registry. The reporting of the vaccination data to the registry for other persons is permitted but not mandated.

The bill also directs school boards and private school governing bodies to establish and enforce a policy requiring that before a child may attend a public or private school, the child must have on file a Florida Certification of Immunization (FCI) with the DOH immunization registry. Any child who does not participate in the immunization registry must present or have on file with the school an FCI form, which will be a part of the student's permanent record and be transferred with the student if the student transfers.

The bill also provides that school boards and private school governing bodies must establish and enforce a policy requiring appropriate scoliosis screening at the proper age.

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



## II. Present Situation:

### Communicable Disease Prevention and Control

The DOH is responsible for the state's public health system, which must promote, protect, and improve the health of all people in the state.<sup>1</sup> As part of fulfilling this 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>2</sup>

The DOH communicable disease program includes, but need not be limited to, programs for the prevention and control of:

- Tuberculosis;
- Human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS);
- Sexually transmissible diseases;
- Communicable diseases of public health significance; and
- Vaccine-preventable diseases<sup>3</sup>, including programs to immunize school children<sup>4</sup> and the development of an automated, electronic, and centralized database or registry for immunization records.<sup>5</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:

- 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.<sup>6</sup>

### The DOH Immunization Registry (Florida SHOTS)

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 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

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<sup>1</sup> Section 381.001, F.S.

<sup>2</sup> Section 381.003(1), F.S.

<sup>3</sup> Measles, mumps, 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*, <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Jan. 18, 2019).

<sup>4</sup> See s. 1003.22(3)-(11), F.S.

<sup>5</sup> Section 381.003(1), F.S.

<sup>6</sup> Section 381.003(2), F.S.

healthcare providers, schools, and parents keep track of immunization records.<sup>7</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. This has the effect of lowering vaccine-preventable disease rates.<sup>8</sup>

The DOH may make rules for the immunization registry, to include:

- Procedures for a health care practitioner to obtain authorization to use the registry;
- Methods for a parent or guardian to elect not to participate in the registry; and
- Procedures for health care practitioners licensed under chs. 458, 459, or 464, F.S., to access and share electronic immunization records with other entities allowed by law to have access to the records.<sup>9</sup>

The DOH includes all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics and then adds other children to the registry as immunizations are given. The DOH documents in the registry the child's:

- Name;
- Date of birth;
- Address;
- Other unique information to identify the child; and
- The immunization(s) administered, including:
  - Type of vaccine administered;
  - The date the vaccine was administered;
  - The vaccine lot number; and
  - The presence or absence of any adverse reaction or contraindication to the immunization.<sup>10</sup>

A parent or guardian may refuse to have a child included in the immunization registry. In such case, a parent or guardian must sign a DOH-approved form which indicates that the parent or guardian does not wish to have the child's immunization history included in the immunization registry. The decision to not participate in the registry must be noted in the registry.<sup>11</sup>

The DOH immunization registry allows for immunization records to be electronically transferred to entities that are required by law to have such records, including schools, licensed child care facilities, and any other entities required by law to obtain proof of a child's immunizations. Any health care practitioner licensed under chs. 458, 459, or 464, F.S., who complies with the DOH rules to access the immunization registry, may:

- Directly access a child's immunization records;
- Update a child's immunization history; or

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<sup>7</sup> Department of Health, Providing Records to Patients, *Deliver Accurate, Timely Records*, <http://www.floridahealth.gov/programs-and-services/immunization/information-for-healthcare-providers/providing-records-to-patients/index.html> (last visited Jan. 18, 2019).

<sup>8</sup> See Department of Health, *Vaccine Preventable Diseases*, <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Jan. 18, 2019).

<sup>9</sup> Section 381.003(1)(e), F.S.

<sup>10</sup> Section 381.003(1)(e)4., F.S.

<sup>11</sup> Section 381.003 (1)(e)2., F.S.

- Exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.<sup>12</sup>

The SHOTS also helps prevent needless revaccinations for entry into daycare and schools because of lost or unavailable paper records. Currently over 15,000 health care practitioners licensed under chs. 458, 459, or 464, F.S., voluntarily provide data to the registry; but because reporting is currently voluntary, some individuals' immunization records in the data base have been incomplete. As a result, the immunization program has received many complaints with respect to incomplete records. This has resulted in unnecessary revaccinations and difficulty for parents and schools to obtain a paper record.<sup>13</sup>

The information included in the DOH immunization registry retains its status as confidential medical information; and the DOH must maintain the confidentiality of that information as required by law. A health care practitioner or other agency that obtains information from the immunization registry must also maintain the confidentiality of the records as required by law.<sup>14</sup>

### **Required Immunizations**

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 Certificate of Immunization (FCI) before entering or enrolling in school.<sup>15</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>16</sup> an FCI documenting that they have had the following immunizations:

- 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).<sup>17</sup>

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<sup>12</sup> Section 381.003(1)(e), F.S.

<sup>13</sup> Department of Health, *Florida Shots, keeping shots in check*. available at <http://flshotsusers.com/parents-guardians>, (last visited Feb. 14, 2019).

<sup>14</sup> Section 381.003(1)(e)4., F.S.

<sup>15</sup> Section 1003.22(4), F.S.

<sup>16</sup> *Id.*

<sup>17</sup> See also Department of Health, *School Immunization Requirements* (last modified Aug. 19, 2016), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/children-and-adolescents/school-immunization-requirements/index.html#childcare> (last visited Jan. 18, 2019). See also the Dep't of Health, Form DH-680, Form for Florida Certification of Immunizations (Jul. 2010), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/documents/dh-680-sample.pdf> (last visited Jan. 18, 2019).

Private health care providers may grant a temporary medical exemption (TME), documented on the FCI form,<sup>18</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 based on valid clinical reasoning or evidence on the FCI form.<sup>19</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>20</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>21</sup>

### **Scoliosis Screening**

The term "scoliosis" indicates lateral curvature and rotation of the spine. Although it can span all age groups, the deformity is most frequently seen in normal, rapidly-growing, preadolescent or adolescent children. Because most of the serious consequences of scoliosis can be prevented, it is particularly responsive to early diagnosis and proper treatment.<sup>22</sup>

Currently, the DOH School Health Services Program, a component of the public health system, provides basic health services to all public school students, including scoliosis screening. Scoliosis screening is required by the DOH, at a minimum, for all sixth grade students.<sup>23</sup> In addition, all 67 counties provide additional basic services through the DOH School Health Services Program, including:

- Health appraisals;
- Nursing assessments;
- Child-specific training;
- Preventative dental screenings and services;
- Vision, hearing, scoliosis, and growth and development screenings;

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<sup>18</sup> Dep't of Health, Form DH-680, Form for Florida Certification of Immunizations (Jul. 2010), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/documents/dh-680-sample.pdf> (last visited Jan. 18, 2019).

<sup>19</sup> Department of Health, *Exemptions from Immunizations*, <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/immunization-exemptions/index.html> (last visited Jan. 18, 2019).

<sup>20</sup> Department of Health, Form DH-681, *Form for Religious Exemption From Immunization*, <http://www.floridahealth.gov/%5C/programs-and-services/immunization/documents/dh-681-sample.pdf> (last visited Jan. 18, 2019). The DH 681 Form, *Religious Exemption From Immunization* form, puts a parent or guardian on notice that any child not immunized against a communicable disease that has been declared a communicable disease emergency.

<sup>21</sup> Department of Health, Immunization Section, Bureau of Communicable Diseases, *Immunization Guidelines, Florida Schools, Childcare Facilities and Family Daycare Homes* (March 2013), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/schoolguide.pdf> (last visited Jan. 18, 2019).

<sup>22</sup> Barbara H. Dunn, Michael W. Hakala, & Mary E. McGee, PEDIATRICS: *Scoliosis Screening* (May 1978, VOLUME 61 / ISSUE 5 available at [http://pediatrics.aappublications.org/content/61/5/794?sso=1&sso\\_redirect\\_count=1&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token](http://pediatrics.aappublications.org/content/61/5/794?sso=1&sso_redirect_count=1&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token)

<sup>23</sup>Rule 64F-003, F.A.C.

- Health counseling;
- Referral and follow-up of suspected or confirmed health problems;
- First aid and emergency health services;
- Assistance with medication administration; and
- Health care procedures for students with chronic or acute health conditions.

The goal of the School Health Services Program is to ensure that students are healthy, in school, and ready to learn.<sup>24,25</sup> In cooperation with the Department of Education (DOE), the School Health Services Program provides funding for the services mandated by statute.<sup>26</sup>

A non-public school may request to participate in the School Health Services Program. A non-public school that voluntarily participates must:

- Cooperate with the county health department and district school board in the development of the cooperative health services plan;
- Make available adequate physical facilities for health services;
- Provide in-service health training to school personnel;
- Cooperate with public health personnel in the implementation of the school health services plan;
- Be subject to health service program reviews by the DOH and the DOE;
- At the beginning of each school year, provide parents and guardians with information concerning ways they can help their children to be physically active and to eat healthful foods; and
- At the beginning of each school year, inform parents or guardians in writing that their children who are students in the school will receive specified health services as provided for in the district health services plan. A student will be exempt out of these services if his or her parent or guardian requests such exemption in writing.<sup>27</sup>

### III. Effect of Proposed Changes:

The bill directs health care practitioners licensed under chs. 458, 459, or 464, F.S., who administer vaccinations, or cause vaccinations to be administered, to children up to 18 years of age, or to college or university students at a college or university student health center who are 19 to 23 years of age, to report the following patient vaccination administration information to the DOH immunization registry (SHOTS):

- Patient's name;
- Date of birth;
- Address;
- Other unique information to identify the child; and
- The immunization(s) administered, including:

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<sup>24</sup> The Department of Health, School Health Services program, *School Health Services*, available at: <http://www.floridahealth.gov/programs-and-services/childrens-health/school-health/index.html> (last visited Feb. 14, 2019).

<sup>25</sup> Philip, Celeste, M.D., M.P.H., State Surgeon General and Secretary, the Department of Health, School Health Administrative Resource Manual (revised 2017) at p. 8, available at <http://www.floridahealth.gov/programs-and-services/childrens-health/school-health/documents/2017-school-health-resource-manual1.pdf>

<sup>26</sup> See ss. 381.0056, 381.0057, and 402.3026, F.S.

<sup>27</sup> Section 381.0056(5), F.S.

- Type of vaccine administered;
- The date the vaccine was administered;
- The vaccine lot number; and
- The presence or absence of any adverse reaction or contraindication to the immunization.

The bill permits a parent or guardian of a child up to 18 years of age or a college or university student 19 to 23 years of age to refuse to be included in the immunization registry. The decision not to participate in the immunization registry must be noted in the registry.

The bill directs school boards and private school governing bodies to establish and enforce a policy requiring that before a child may attend a public or non-public school, the child must have on file a Florida Certificate of Immunization (FCI) with the DOH immunization registry. Any child who does not participate in the immunization registry must present or have on file with the school an FCI form, which will be a part of the student's permanent record and be transferred with the student if the student transfers.

The bill also directs school boards and private school governing bodies to establish and enforce a policy requiring appropriate scoliosis screening at the proper age.

The bill specifies that the reporting of the vaccination administration data to the DOH immunization registry for other persons is permitted but not required. Health care practitioners may use an existing automated data system for updating immunization information in the immunization registry.

The bill directs that the immunization registry must make electronically available the immunization records to entities required by law to have such records, including, but not limited to, schools and licensed child care facilities.

The bill directs that detailed rulemaking authority relating to the DOH's responsibilities to conduct a communicable disease prevention and control program be condensed into a general granting of rulemaking authority.

The bill takes effect January 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:

Housing vaccination data in the registry may allow individuals to avoid the cost of needless revaccinations.

The bill may create a negative fiscal impact on private school governing bodies to cover the costs associated with establishing and enforcing a policy requiring appropriate scoliosis screening at the proper age.

C. Government Sector Impact:

None.

**VI. Technical Deficiencies:**

The title of the bill is “An act relating to immunization registry.” That title could be interpreted as failing to address the bill’s requirements relating to public and private school scoliosis screening.

**VII. Related Issues:**

The DOH, in cooperation with the DOE, already has responsibility for the administration, supervision, and periodic review of the School Health Services Program, which includes mandatory scoliosis screening in public schools and in non-public schools that request to participate in the School Health Services Program.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 381.003, and 1003.22.

**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 Montford

3-00364-19

2019354\_\_

1                                   A bill to be entitled  
2       An act relating to immunization registry; amending s.  
3       381.003, F.S.; revising provisions relating to the  
4       communicable disease prevention and control programs  
5       under the Department of Health; establishing that a  
6       certain student who obtains a vaccination from a  
7       Florida college or university student health center  
8       may refuse to be included in the immunization  
9       registry; providing requirements for electronic  
10      availability of, rather than transfer of, immunization  
11      records; requiring certain health care practitioners  
12      to report data to the immunization registry;  
13      authorizing the department to adopt rules; amending s.  
14      1003.22, F.S.; revising school-entry health  
15      requirements to require students to have a certificate  
16      of immunization on file with the department's  
17      immunization registry; providing an effective date.

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

20  
21       Section 1. Section 381.003, Florida Statutes, is amended to  
22       read:

23       381.003 Communicable disease and AIDS prevention and  
24       control.—

25       (1) The department shall conduct a communicable disease  
26       prevention and control program as part of fulfilling its public  
27       health mission. A communicable disease is any disease caused by  
28       transmission of a specific infectious agent, or its toxic  
29       products, from an infected person, an infected animal, or the

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30 environment to a susceptible host, either directly or  
31 indirectly. The communicable disease program must include, but  
32 need not be limited to:

33 (a) Programs for the prevention and control of tuberculosis  
34 in accordance with chapter 392.

35 (b) Programs for the prevention and control of human  
36 immunodeficiency virus infection and acquired immune deficiency  
37 syndrome in accordance with chapter 384 and this chapter.

38 (c) Programs for the prevention and control of sexually  
39 transmissible diseases in accordance with chapter 384.

40 (d) Programs for the prevention, control, and reporting of  
41 communicable diseases of public health significance as provided  
42 for in this chapter.

43 (e) Programs for the prevention and control of vaccine-  
44 preventable diseases, including programs to immunize school  
45 children as required by s. 1003.22(3)-(11) and the development  
46 of an automated, electronic, and centralized database and ~~or~~  
47 registry of immunizations. The department shall ensure that all  
48 children in this state are immunized against vaccine-preventable  
49 diseases. The immunization registry must ~~shall~~ allow the  
50 department to enhance current immunization activities for the  
51 purpose of improving the immunization of all children in this  
52 state.

53 1. Except as provided in subparagraph 2., the department  
54 shall include all children born in this state in the  
55 immunization registry by using the birth records from the Office  
56 of Vital Statistics. The department shall add other children to  
57 the registry as immunization services are provided.

58 2. The parent or guardian of a child may refuse to have the

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59 child included in the immunization registry by signing a form  
60 obtained from the department, or from the health care  
61 practitioner or entity that provides the immunization, which  
62 indicates that the parent or guardian does not wish to have the  
63 child included in the immunization registry. The decision not to  
64 ~~not~~ participate in the immunization registry must be noted in  
65 the registry.

66 3. A college or university student, from 19 years of age to  
67 23 years of age, who obtains a vaccination from a Florida  
68 college or university student health center may refuse to be  
69 included in the immunization registry by signing a form obtained  
70 from the department, or from a Florida college or university  
71 student health center, which indicates that the student does not  
72 wish to be included in the immunization registry. The decision  
73 not to participate in the immunization registry must be noted in  
74 the registry.

75 4.3. The immunization registry shall allow for immunization  
76 records to be electronically available ~~transferred~~ to entities  
77 that are required by law to have such records, including, but  
78 not limited to, schools and ~~7~~ licensed child care facilities, ~~and~~  
79 ~~any other entity that is required by law to obtain proof of a~~  
80 ~~child's immunizations.~~

81 5.4. A ~~Any~~ health care practitioner licensed under chapter  
82 458, chapter 459, or chapter 464 in this state who administers  
83 vaccinations or causes vaccinations to be administered to  
84 children from birth to 18 years of age is required to report  
85 vaccination data to the immunization registry, unless a parent  
86 or guardian of a child has refused to have the child included in  
87 the immunization registry by meeting the requirements of

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88 subparagraph 2. A health care practitioner licensed under  
89 chapter 458, chapter 459, or chapter 464 in this state who  
90 administers vaccinations or causes vaccinations to be  
91 administered to college or university students from 19 years of  
92 age to 23 years of age at a Florida college or university  
93 student health center is required to report vaccination data to  
94 the immunization registry, unless the student has refused to be  
95 included in the immunization registry by meeting the  
96 requirements of subparagraph 3. Vaccination data for other age  
97 ranges may be submitted to the immunization registry on a  
98 voluntary basis. The upload of data from existing automated  
99 systems is an acceptable method for updating immunization  
100 information in the immunization registry. ~~complies with rules~~  
101 ~~adopted by the department to access the immunization registry~~  
102 ~~may, through the immunization registry, directly access~~  
103 ~~immunization records and update a child's immunization history~~  
104 ~~or exchange immunization information with another authorized~~  
105 ~~practitioner, entity, or agency involved in a child's care. The~~  
106 information ~~included~~ in the immunization registry must include  
107 the child's name, date of birth, address, and any other unique  
108 identifier necessary to correctly identify the child; the  
109 immunization record, including the date, type of administered  
110 vaccine, and vaccine lot number; and the presence or absence of  
111 any adverse reaction or contraindication related to the  
112 immunization. Information received by the department for the  
113 immunization registry retains its status as confidential medical  
114 information and the department must maintain the confidentiality  
115 of that information as otherwise required by law. A health care  
116 practitioner or other agency that obtains information from the

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117 immunization registry must maintain the confidentiality of any  
118 medical records in accordance with s. 456.057 or as otherwise  
119 required by law.

120 (2) The department may adopt rules pursuant to ss.  
121 120.536(1) and 120.54 to implement this section, ~~repeal, and~~  
122 ~~amend rules related to the prevention and control of~~  
123 ~~communicable diseases and the administration of the immunization~~  
124 ~~registry. Such rules may include procedures for investigating~~  
125 ~~disease, timeframes for reporting disease, definitions,~~  
126 ~~procedures for managing specific diseases, requirements for~~  
127 ~~followup reports of known or suspected exposure to disease, and~~  
128 ~~procedures for providing access to confidential information~~  
129 ~~necessary for disease investigations. For purposes of the~~  
130 ~~immunization registry, the rules may include procedures for a~~  
131 ~~health care practitioner to obtain authorization to use the~~  
132 ~~immunization registry, methods for a parent or guardian to elect~~  
133 ~~not to participate in the immunization registry, and procedures~~  
134 ~~for a health care practitioner licensed under chapter 458,~~  
135 ~~chapter 459, or chapter 464 to access and share electronic~~  
136 ~~immunization records with other entities allowed by law to have~~  
137 ~~access to the records.~~

138 Section 2. Subsection (4) of section 1003.22, Florida  
139 Statutes, is amended to read:

140 1003.22 School-entry health examinations; immunization  
141 against communicable diseases; exemptions; duties of Department  
142 of Health.—

143 (4) Each district school board and the governing authority  
144 of each private school shall establish and enforce a ~~as~~ policy  
145 that: r

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146        (a) Prior to admittance to or attendance in a public or  
147 private school, grades kindergarten through 12, or any other  
148 initial entrance into a Florida public or private school, each  
149 child ~~present or~~ have on file with the immunization registry  
150 ~~school~~ a certification of immunization for the prevention of  
151 those communicable diseases for which immunization is required  
152 by the Department of Health. Any child who is excluded from  
153 participation in the immunization registry pursuant to s.  
154 381.003(1)(e)2. must present or have on file with the school  
155 such certification of immunization and further shall provide for  
156 ~~appropriate screening of its students for scoliosis at the~~  
157 ~~proper age. Such~~ Certification of immunization shall be made on  
158 forms approved and provided by the Department of Health or be on  
159 file with the immunization registry and shall become a part of  
160 each student's permanent record, to be transferred when the  
161 student transfers, is promoted, or changes schools. The transfer  
162 of such immunization certification by Florida public schools  
163 shall be accomplished using the Florida Automated System for  
164 Transferring Education Records and shall be deemed to meet the  
165 requirements of this section.

166        (b) Provides for appropriate screening of its students for  
167 scoliosis at the proper age.

168        Section 3. This act shall take effect January 1, 2021.



# THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

**COMMITTEES:**  
Environment and Natural Resources, *Chair*  
Education, *Vice Chair*  
Agriculture  
Appropriations  
Appropriations Subcommittee on Education  
Rules

**JOINT COMMITTEE:**  
Joint Legislative Auditing Committee

## SENATOR BILL MONTFORD

*Minority Leader Pro Tempore*  
3rd District

February 5, 2019

Senator Gayle Harrell, Chair  
Senate Health Policy Committee  
310 Senate Office Building  
Tallahassee, Florida 32399-1100

Dear Chair Harrell,

I respectfully request that the following bills be placed on the next Health Policy Committee Agenda.

SB 354 – A bill relating to Immunization Registry.

Your consideration is greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Bill Montford".

William J. Montford III

WJM:lc

**REPLY TO:**

- 410 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5003
- 20 East Washington Street, Suite D, Quincy, Florida 32351 (850) 627-9100

Senate's Website: [www.flsenate.gov](http://www.flsenate.gov)

**BILL GALVANO**  
President of the Senate

**DAVID SIMMONS**  
President Pro Tempore



# 2019 AGENCY LEGISLATIVE BILL ANALYSIS

## AGENCY: Florida Department of Health

<b><u>BILL INFORMATION</u></b>	
<b>BILL NUMBER:</b>	SB 354
<b>BILL TITLE:</b>	Immunization Registry
<b>BILL SPONSOR:</b>	Montford
<b>EFFECTIVE DATE:</b>	1/1/2021

<b><u>COMMITTEES OF REFERENCE</u></b>
1) Health Policy
2) Education
3) Rules
4) Click or tap here to enter text.
5) Click or tap here to enter text.

<b><u>CURRENT COMMITTEE</u></b>
Click or tap here to enter text.

<b><u>SIMILAR BILLS</u></b>	
<b>BILL NUMBER:</b>	HB 213
<b>SPONSOR:</b>	Massullo

<b><u>PREVIOUS LEGISLATION</u></b>	
<b>BILL NUMBER:</b>	SB 1680
<b>SPONSOR:</b>	Montford
<b>YEAR:</b>	2018
<b>LAST ACTION:</b>	Died in Education

<b><u>IDENTICAL BILLS</u></b>	
<b>BILL NUMBER:</b>	N/A
<b>SPONSOR:</b>	Click or tap here to enter text.

<b>Is this bill part of an agency package?</b>
No

<b><u>BILL ANALYSIS INFORMATION</u></b>	
<b>DATE OF ANALYSIS:</b>	Jan 5, 2019
<b>LEAD AGENCY ANALYST:</b>	Robert Griffin
<b>ADDITIONAL ANALYST(S):</b>	Click or tap here to enter text.
<b>LEGAL ANALYST:</b>	Adrienne Rodgers
<b>FISCAL ANALYST:</b>	Darius Pelham

## **POLICY ANALYSIS**



**1. EXECUTIVE SUMMARY**

The bill requires vaccination data to be added to the immunization registry, unless a parent or guardian of a child or an adult college/university student refuses to be included in the immunization registry.

The bill requires children K-12 grade have on file with the state registry of immunizations a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health. Any child who is excluded from participation in the immunization registry must still present or have on file with the school such certification of immunization.

**2. SUBSTANTIVE BILL ANALYSIS**

**1. PRESENT SITUATION:**

s. 381.003, F.S. allows any health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who complies with rules adopted by the department to voluntarily access the immunization registry, directly access immunization records and update a child's immunization history or exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.

s. 381.003, FS. requires each district school board and the governing authority of each private school shall establish and enforce as policy that, prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other initial entrance into a Florida public or private school, each child present or have on file with the school state registry of immunizations a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health. Such certification shall be made on forms approved and provided by the Department of Health and shall become a part of each student's permanent record, to be transferred when the student transfers, is promoted, or changes schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

**2. EFFECT OF THE BILL:**

The bill establishes that "any health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes to administered to children age 0-18 or to students, age 19 to 23 years, attending a Florida college or university 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 or an adult college/university student refuses to be included in the immunization registry. Vaccination data for other students in other age ranges may be submitted to immunization registry only if the student consents to inclusion in the immunization registry." Thus, use of the immunization registry becomes required, rather than voluntary, for these practitioners in these situations/settings.

The bill establishes that each child's certificate of immunization be on file with the state registry of immunization rather than a parent or guardian presenting it to the school. This would eliminate the great majority of paper-based certificate of immunization forms (e.g., DH Form 680). The certification would be electronic and "become a part of each student's permanent record, to be transferred by public schools when the student transfers, is promoted, or changes schools through the Florida Automated System for Transferring Education Records." Schools will need to adapt their policies and procedures to comply with the sole use of an electronic immunization certification.

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

If yes, explain:	Authorizes the department to adopt rules revising school-entry health requirements to require students to have a certificate of immunization on file with the department's immunization registry.
Is the change consistent with the agency's core mission?	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>

Rule(s) impacted (provide references to F.A.C., etc.):	64D-3.046.
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**4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?**

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

**5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL?**

Y  N

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

**6. ARE THERE ANY NEW GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSIONS, ETC. REQUIRED BY THIS BILL?**

Y  N

Board:	N/A
Board Purpose:	N/A
Who Appoints:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

**FISCAL ANALYSIS**

**1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT?**

Y  N

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

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

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

**3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR?**Y  N 

Revenues:	None
Expenditures:	The use of the immunization registry has no cost. Practitioners may experience increased cost from their Electronic Health Record provider, depending on their current level of service. The majority of practitioners who administer vaccines to children are already users of the immunization registry, so it is a small minority of providers that may be impacted.
Other:	N/A

**4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES?**Y  N 

If yes, explain impact.	N/A
Bill Section Number:	N/A

**TECHNOLOGY IMPACT**

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

If yes, describe the anticipated impact to the agency including any fiscal impact.	N/A
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**FEDERAL IMPACT**

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

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

**LEGAL - GENERAL COUNSEL'S OFFICE REVIEW**

Issues/concerns/comments:	Potential changes to Rule 64D-3.046 may be required.
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THE FLORIDA SENATE

APPEARANCE RECORD

19 Feb 2019

Meeting Date

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

354

Bill Number (if applicable)

Topic SHOTS Bill (Infections Disease)

Amendment Barcode (if applicable)

Name D. Paul Robinson, M.D., F.A.A.P.

Job Title President Florida Chapter of the AAP

Address 4656 Inisheer Dr

Phone 850-431-3230

Street

Tallahassee FL 32309

Email Robinson23@gmail.com

City

State

Zip

Speaking: [X] For [ ] Against [ ] Information

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

Representing Florida Chapter of AAP

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

Lobbyist registered with Legislature: [ ] Yes [ ] No

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

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/19/19

Meeting Date

354

Bill Number (if applicable)

Topic Immunization Registry

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Dr

Phone 878-3056

Street

Tallahassee FL 32301

Email winnsr@earthlink.net

City

State

Zip

Speaking:  For  Against  Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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

**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 366

INTRODUCER: Health Policy Committee and Senators Braynon, Pizzo and Book

SUBJECT: Infectious Disease Elimination Programs

DATE: February 20, 2019

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	Fav/CS
2.			AHS	
3.			AP	

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

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 366 establishes the Infectious Disease Elimination Act (IDEA) and modifies s. 381.0038, F.S. The bill eliminates references to the current sterile needle and syringe exchange pilot program in Miami-Dade County except to authorize its continuation until the Miami-Dade County Board of County Commissioners authorizes the program under the IDEA or July 1, 2021, whichever occurs first.

Under the bill, through adoption of a county ordinance and satisfaction of the specified program requirements, county commissions may establish sterile needle and syringe exchange programs. An exchange program may not operate unless authorized and approved by the county commission. Programs must cooperate with the Department of Health (DOH) and the local county health department. Programs are prohibited from using state funds; however, programs may be funded with county funds or through private donations.

In authorizing an exchange program, a county commission must contract with one of the following entities to operate the program: a hospital licensed under chapter 395, F.S., a health care clinic licensed under part X of chapter 400, an accredited medical school associated with a university in the state, a licensed addictions receiving facility as defined in s. 397.311, F.S., or a 501(c)(3) HIV/AIDS service organization.

The bill includes a civil liability immunity clause for any law enforcement officer acting in good faith in arresting or charging a person who is later found to be immune from prosecution based on the conditions specified in IDEA.

A severability clause is included in CS/SB 366, providing that if any provision of the act or its application to any person or circumstance is found invalid, that invalidity does not affect the validity of the remaining provisions of the act.

The CS provides the DOH with rulemaking authority for data collection and reporting requirements.

The effective date of the bill is July 1, 2019.

## II. Present Situation:

### HIV/AIDS

The first cases of human immunodeficiency virus (HIV) were reported in 1981 and since then, approximately 77 million people have been infected with the virus.<sup>1</sup> HIV is a virus that is transmitted through certain body fluids and weakens the body's immune system. Over time, the body is unable to fight off infections and disease. No effective cure currently exists but with proper medical care, it can be controlled.<sup>2</sup>

HIV can eventually lead to the development of AIDS or acquired immunodeficiency syndrome.<sup>3</sup> The term *diagnosis of HIV infection* is defined by the Centers for Disease Control and Prevention (CDC) as a diagnosis of HIV infection regardless of the state of the disease (stage 0, 1, 2, 3 (AIDS), or unknown), and refers to all person with a diagnosis of HIV infection.<sup>4</sup>

The CDC's *HIV Surveillance Report* compares Florida to other states, the region, and nation. For example, in the South, a year-by-year and a cumulative death rate is given from 2012 through 2016. The surveillance reports provide one-year figures that show both the rate per 100,000 in population, raw totals, three-year rolling rates, raw totals for infection rates, and death totals. Cause of death or cause for infection are also broken out by state and by certain metropolitan statistical areas (MSA)<sup>5</sup>. The cumulative three-year death total for the South<sup>6</sup> is 134,957.<sup>7</sup> An

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<sup>1</sup> Kaiser Family Foundation, *The Global HIV/AIDS Epidemic*, (Jan 28, 2019) available at <https://www.kff.org/global-health-policy/fact-sheet/the-global-hiv-aids-epidemic/> (last visited Feb. 12, 2019).

<sup>2</sup> Centers for Disease Control and Prevention, *About HIV/AIDS*, (last updated: October 31, 2018) available at <https://www.cdc.gov/hiv/basics/whatishiv.html> (last visited Feb. 13, 2019).

<sup>3</sup> Kaiser Family Foundation, *supra* note 1.

<sup>4</sup> Centers for Disease Control and Prevention, *Diagnosis of HIV Infection in the United States and Dependent Areas, 2016*; vol. 28 (Nov. 2017), p. 5, available at <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf> (last visited Feb. 13, 2019).

<sup>5</sup> Formerly referred to as standard metropolitan statistical areas (SMSA).

<sup>6</sup> The CDC's South Region includes Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia.

<sup>7</sup> Centers for Disease Control and Prevention, *HIV Surveillance Report, Table 19b: Deaths of persons with diagnosed HIV infection ever classified as stage 3 (AIDS), by year of death and selected characteristics, 2012-2016 and cumulative – United*



HIV infection diagnosis rate attributed to injected drug use for the period of 2012 to 2017 in the South for men is 77 and 103 for women.<sup>8</sup>

For 2016, 4,708 adults and adolescents in Florida, plus 18 children (those under age 13) for a total of 4,726 in 2016 were newly diagnosed with HIV in Florida. This number increased in 2017 to 4,783 newly diagnosed adults or adolescents and 17 children for a total of 4,800.<sup>9</sup> The Florida Department of Health’s (DOH) annual report shows 116,944 persons of all ages living with an HIV diagnosis in Florida as of the end of the year, 2017.<sup>10</sup>

The Miami-Ft. Lauderdale-Palm Beach MSA had the highest prevalence of newly-diagnosed individuals with HIV infection in the nation. The prevalence rate translates to a total of 53,269 individuals who have been newly diagnosed with an HIV infection. For 2017, the Miami MSA is also ranked first in the nation for HIV infection diagnoses with a total of 2,177.<sup>11</sup> The table below shows the information in comparison to other Florida MSAs.

<b>Diagnoses of HIV Infection, 2017 and Persons Living with Diagnoses HIV Infection (Prevalence)<sup>12</sup></b>					
<b>MSA</b>	<b>Diagnosis – 2017</b>			<b>Prevalence of HIV Infection, 2016</b>	
	<b>Number</b>	<b>Rate</b>	<b>Rank</b>	<b>Number</b>	<b>Rate</b>
Cape Coral-Ft. Myers	81	11.0	49	2,103	2,91.1
Deltona-Daytona Beach-Ormond Beach	94	14.5	29	1,804	283.3
Jacksonville	353	23.5	7	6,759	457.8
Lakeland–Winter Haven	94	13.7	36	2,247	3,36.9
Miami-Ft. Lauderdale-Palm Beach	2,177	35.3	1	53,269	8,72.2
North Port-Sarasota-Bradenton	83	10.3	57	1,901	2,41.1
Orlando-Kissimmee-Sanford	718	28.6	2	11,316	4,61.3
Palm Bay-Melbourne-Titusville	55	9.3	62	14,979	2,59.0
Tampa-St. Petersburg-Clearwater	561	18.1	14	12,308	405.3

State and 6 dependent areas, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (last visited Feb. 12, 2019).

<sup>8</sup> Centers for Disease Control and Prevention, HIV Surveillance Report, *Tab 8b: Diagnosis of HIV Infection attributed to injection drug use, by selected characteristics, 2012-2017-United States and 6 dependent areas*, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (last visited Feb. 12, 2019).

<sup>9</sup> Centers for Disease Control and Prevention, *HIV Surveillance Report – Diagnoses of HIV Infection in the United States and Dependent Areas, 2017*, Table 26 – Diagnoses of HIV Infection, by area of residence, 2016 and 2017 – United States and 6 dependent areas <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (November 2018) (last visited Feb. 12, 2019).

<sup>10</sup> Florida Dep’t of Health, *Persons Living with an HIV Diagnosis in Florida, 2017*, [http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/fact-sheet/FloridaFactsheet\\_20180830.pdf](http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/fact-sheet/FloridaFactsheet_20180830.pdf) (last visited Feb. 12, 2019).

<sup>11</sup> Centers for Disease Control and Prevention, *HIV Surveillance Report – Diagnoses of HIV – Infection in the United States and Dependent Areas*, Table 30, Diagnosis of HIV Infection, 2017, and persons living with diagnosed infection prevalence, year-end 2016, by metropolitan statistical area of residence – United States and Puerto Rico <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (November 2018)(last visited Feb. 12, 2019).

<sup>12</sup> Florida Dep’t of Health, *supra* note 13.

Diagnoses of HIV Infection, 2017 and Persons Living with Diagnoses HIV Infection (Prevalence) <sup>12</sup>					
MSA	Diagnosis – 2017			Prevalence of HIV Infection, 2016	
	Number	Rate	Rank	Number	Rate
State <sup>13,14</sup>	4,949	24.1		116,944	568.9
<i>Explanation:</i>		<i>Per 100,000 population</i>	<i>Based on rate</i>		<i>Per 100,000 population</i>

The vast majority of Floridians who received an HIV diagnosis in 2017 report their mode of HIV exposure as male to male contact (61 percent), followed by heterosexual contact either female (19 percent) or male (13 percent) with male and female injection drug use at 2 percent each.<sup>15</sup> A combination of male-to-male contact and injection drug use was also at 2 percent. The age range with the most persons receiving an HIV diagnosis in 2017 was between 20-29 (30 percent) followed closely by ages 30 to 39 (27 percent).<sup>16</sup> In 2017, males were much more likely to receive an HIV diagnosis than a female, by more than three to one. Males represented 78 percent of the HIV diagnoses and females 22 percent.<sup>17</sup>

HIV Diagnosis in Florida, 2016 and 2017 <sup>18</sup> (Based on CDC Surveillance Reports)									
	2016				2017 (preliminary data)				Total Rate
	Adults (>13)	Adults (>13)*	Children	Child Rate*	Adults (>13)	Adults (>13)	Children	Child Rate*	
<b>Florida</b>	4,708	26.6	18	0.6	4,783	26.6	17	0.6	22.9
<b>National</b>	40,012	14.6	130	0.2	38,640	14.0	99	0.2	11.8

*\*Rates are per 100,000 population.*

On the continuum of HIV/AIDS care, an individual can move from receiving an initial diagnosis to a virally suppressed status. In Florida for 2017, 25 percent of those living with an HIV diagnosis were not in care.

<sup>13</sup> Florida Dep’t of Health, flhealthcharts.com, *HIV Cases*, <http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalHIVAIDSViewer.aspx?cid=0471>, (report generated on Feb. 12, 2019).

<sup>14</sup> Florida Dep’t of Health, flhealthcharts.com, *Persons Living with HIV (PLWH)*, <http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalHIVAIDSViewer.aspx?cid=0471> (report generated on Feb. 12, 2019).

<sup>15</sup> Florida Dep’t of Health, *supra* note 12.

<sup>16</sup> Florida Dep’t of Health, *supra* note 12.

<sup>17</sup> Florida Dep’t of Health, *supra* note 12.

<sup>18</sup> Centers for Disease Control and Prevention, *supra* note 4.

2017 – Florida’s Continuum of Care <sup>19</sup> From the beginning (a diagnosis to viral suppression)					
Status	Living with HIV Diagnosis	Ever in Care	In Care	Retained in Care	Virally Suppressed
Florida	116,944	108,461	87,184	79,831	71,955
% of Whole	100%	93%	75%	68%	62%
Documented care			Less than or equal to 1 medical visit for HIV in 2017	Less than or equal to 2 medical visits for HIV in 2017; greater than 3 mos. apart in 2017	Suppression of HIV viral load as measured by level of virus in blood.

The CDC recommends that anyone at increased risk of an HIV infection,<sup>20</sup> including injection drug users (IDUs), undergo HIV testing at least annually. Individuals between the ages of 13 and 64 who are not at risk should be tested for HIV at least once as part of their normal health care routine.<sup>21</sup>

**National HIV/AIDS Strategy**

Additionally, the CDC has four strategy goals aimed at achieving its overall mission:

*The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life extending care, free from stigma and discrimination.*<sup>22</sup>

The mission is supported by four strategy goals that focus on reducing the number of new infections, increasing access to care, reducing health disparities and inequities, and achieving a more coordinated response. The 13 national HIV indicators include three which were identified as under development. The 10 other national indicators are:

- Increase the percentage of people living with HIV who know their status to at least 90 percent.
- Reduce number of new diagnoses by 25 percent.
- Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by 10 percent.

<sup>19</sup> Florida Dep’t of Health, *supra* note 12.

<sup>20</sup> Those at increased risk for HIV include: men who have sex with men; individuals who have sex with an HIV-positive partner; individuals who have had more than one sexual partner since their last HIV test; individuals who have injected drugs and shared needles or the water or cotton with others; individuals who have been treated for hepatitis or tuberculosis; individuals who have traded sex for money; individuals who have been treated for another sexually transmitted disease; or individuals who have had sex with someone who can answer yes to any of the above questions or whose sexual history is unknown. See Centers for Disease Control and Prevention, *HIV Risk Reduction Tool*, <https://www.cdc.gov/hivrisk/how-know/testing.html> (last visited Feb. 13, 2019).

<sup>21</sup> Centers for Disease Control and Prevention, *Testing*, <https://www.cdc.gov/hiv/basics/testing.html> (last visited Feb. 13, 2019).

<sup>22</sup> United States Dep’t of Health and Human Services, Secretary’s Minority AIDS Initiative Fund, The Office of National AIDS Policy, *National HIV/AIDS Strategy*, <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview> (last visited Feb. 14, 2019).

- Increase the percentage of newly-diagnosed persons who are linked to HIV medical care within one month after HIV diagnosis to at least 85 percent.
- Increase the percentage of persons with diagnosed HIV infection who are retained in medical care (two or more visits at least 3 months apart) to at least 90 percent.
- Increase the percentage of persons who are virally suppressed to at least 80 percent.
- Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent.
- Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent.
- Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black and bisexual men, Black females, and persons living in the Southern United States.
- Increase the percentage of youth and persons who inject drugs with diagnosed HIV infections who are virally suppressed to at least 80 percent.<sup>23</sup>

Twenty-eight federal offices under the coordinating efforts of the Office of the National AIDS Policy in the White House and the Director of the Health and Human Services Office of HIV/AIDS and Infectious Disease Policy work to implement the National HIV/AIDS Strategy. The coordinating group meets on a regular basis to provide feedback and advice, review outcomes, and discuss research findings. The first set of policies was released in 2010 and the most recent list of 13 was updated in 2015 with its goals set for 2020.<sup>24</sup>

### Florida IDEA Pilot Program

In 2016, the IDEA, or the Miami-Dade Infectious Disease Elimination Act<sup>25</sup> was enacted by the Legislature and implemented by the University of Miami (UM) as a sterile needle and syringe exchange pilot program. The pilot program is prohibited by state law from accepting public funds. The pilot program currently receives funds from the Gilead COMPASS Initiative (Commitment to Partnership in Addressing HIV/AIDS in Southern States)<sup>26</sup> to support the program's screening component.<sup>27</sup> Funding is also obtained through grants from the MAC AIDS Fund, the Elton John AIDS Foundation, the Fishman Family Foundation, the Comer Family Foundation, and the Health Foundation of South Florida.<sup>28</sup>

Needle and syringe exchange programs provide sterile needles and syringes in exchange for used needles and syringes to reduce the transmission of human immunodeficiency virus (HIV) and other blood-borne infections associated with the reuse of contaminated needles and syringes by

<sup>23</sup> United States Dep't of Health and Human Services, Secretary's Minority AIDS Initiative Fund, The Office of National AIDS Policy, *National HIV/AIDS Strategy*, <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview> (last visited Feb. 14, 2019).

<sup>24</sup> United States Dep't of Health and Human Services, Secretary's Minority AIDS Initiative Fund, *Strategy Implementation*, <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview> (last visited Feb. 14, 2019)

<sup>25</sup> Chapter 2016-68, Laws of Fla., (amending s. 381.0038, F.S, effective July 1, 2016).

<sup>26</sup> COMPASS Initiative, *Who We Are* <https://www.gileadcompass.com/whoweare/> (last visited Feb. 12, 2019).

<sup>27</sup> Sammy Mack, *New HIV Cases and an Investigation on a Closed Street: Doctor Explains Situation under 836 Overpass* HEALTHNEWS FLORIDA (Nov. 8, 2018), available at <http://health.wusf.usf.edu/post/new-hiv-cases-and-investigation-closed-street-doctor-explains-situation-under-836-overpass#stream/0> (last visited Feb. 12, 2019).

<sup>28</sup> University of Miami Miller School of Medicine, *Senator Bill Nelson Tours Miller School's Needle Exchange, Sees Opioid Epidemic First Hand* (July 16, 2018), <http://med.miami.edu/news/senator-bill-nelson-tours-miller-schools-needle-exchange-sees-opioid-epidemic> (last visited Feb. 12, 2019).

IDUs. Florida's IDEA pilot program in Miami-Dade provides one-for-one needle exchange as well as prevention services at its main site and on its mobile unit. Services include providing basic wound care, bandages, antibiotics, sanitizers, and condoms. Rapid and anonymous testing for HIV and Hepatitis C is also offered at both the main site and on its mobile unit. For those that need referrals to rehabilitation and treatment, the pilot program will provide assistance linking individuals with community stakeholders who can provide those services.<sup>29</sup>

In addition to the services above, the pilot program offers two different kits. One is a *Safe Injection Pack* which is intended to reduce the need for sharing of needles and other related items, which the program hopes will lead to a decrease in the spread of HIV and Hepatitis C. The kit includes cottons, cookers, ties, sterile water, alcohol swabs, and portable sharps containers.<sup>30</sup> The other kit is the *Naloxone Pack* which includes Narcan, a prescription medication used to treat drug overdoses.

According to its August 1, 2018 annual report, the IDEA pilot program has:

- Enrolled over 800 participants.
- Exchanged 173,532 clean needles for 186,167 used needles.
- Distributed over 1,300 boxes of Narcan.
- Made 682 overdose referrals.
- Administered 600 HIV tests and 500 Hepatitis C tests.
- Added five mobile sites with 141 enrollees.
- Been selected as one of two international site for a multi-year grant which will allow 250 random patients to receive a direct-acting anti-viral medication on site.<sup>31</sup>

The IDEA pilot program annual report also notes that during the first half of the 2017, there were 133 fatal overdoses compared with 217 for the second half of 2016.<sup>32</sup> The overall death rate in Miami-Dade related to HIV/AIDS has also lowered while the pilot program has been in operation.

### **Intravenous Drug Use in Florida**

At the end of 2016, there were a total of 114,772 diagnosed persons living with HIV in Florida.<sup>33</sup> The modes of exposure for adults (age 13 and above) in 2016 are shown in the table below.

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<sup>29</sup> IDEA Exchange, *Services*, <http://ideaexchangeflorida.org/services/> (last visited Feb. 12, 2019).

<sup>30</sup> *Id.*

<sup>31</sup> Miami-Dade County Commission Agenda Item, *Resolution Urging the Florida Legislature to Authorize Additional Institutions to Collaborate with the University of Miami in the Operation of the Miami-Dade Infectious Disease Elimination Act Needle and Syringe Exchange Pilot Program*, Agenda Item 11(A)(19) (September 5, 2018), available at <http://www.miamidade.gov/govaction/legistarfiles/Matters/Y2018/181939.pdf> (last visited Feb. 12, 2019).

<sup>32</sup> *Id.*

<sup>33</sup> Florida Dep't of Health, *FL HealthCHARTS.com Statistical Brief, HV Trends in Florida 2007 Through 2016* (July 2018), available at <http://www.flhealthcharts.com/charts/StatisticalBriefs.aspx>.

<b>Adult (Age 13+) Diagnosed Persons Living with HIV, Year End 2016, Florida<sup>34</sup></b>		
<b>Mode of Exposure</b>	<b>Male Count (%)</b>	<b>Female Count (%)</b>
Men who have sex with Men (MSM)	56,829 (69%)	NA
Injection Drug Use	5,300 (6%)	3,977 (13%)
Heterosexual Contact	15,625 (19%)	26,894 (85%)
Other Risk	775 (1%)	874 (3%)
<b>State Total:</b>	<b>82,863</b>	<b>31,745</b>

During this same time period, the state’s total number of deaths from HIV was 864. This is a decrease over a nine-year period from 1,526 in 2007 to 864 in 2016.<sup>35</sup> However, within these rates there are differences between races and ethnicities. For example, the age-adjusted death rate due to HIV was nine times higher for non-Hispanic blacks compared to non-Hispanic whites. Among non-Hispanic blacks, the age-adjusted resident death rate due to HIV decreased by 56 percent from 2007, decreased by 49 percent for non-Hispanic whites, Hispanics by 58 percent, and other races by 55 percent.<sup>36</sup>

<b>Resident Deaths Due to HIV by Count and Rate per 100,000 Population, 2007-2016, Florida<sup>37</sup></b>										
<b>Year</b>	<b>White Non-Hispanic</b>		<b>Black Non-Hispanic</b>		<b>Hispanic</b>		<b>Other<sup>38</sup></b>		<b>State Total</b>	
	<b>Count</b>	<b>Rate</b>	<b>Count</b>	<b>Rate</b>	<b>Count</b>	<b>Rate</b>	<b>Count</b>	<b>Rate</b>	<b>Count</b>	<b>Rate</b>
2007	389	3.5	917	35.3	202	5.3	18	2	1,526	8.3
2016	244	1.8	482	15.7	112	2.2	26	0.9	864	3.9

A study conducted at the University of Miami and Jackson Health System from July 1, 2013, through June 30, 2014, reviewed the charts of patients hospitalized for injection drug use-related infections. Records from the emergency room and inpatient hospitalizations were researched for drug abuse and use, infection, and hospitalization during this time period.<sup>39</sup> The findings over the 12 month period included:

- 349 IDUs hospitalized with 423 total admissions for injection-related infections.
  - 59 percent abused cocaine.
  - The median hospital charge for an injection-related infection was \$39,896 with a range in claims from \$14,158 to \$104,912.
- Only 8 percent of the population had private insurance; 41 percent had Medicaid, 15 percent had Medicare, and 36 percent were uninsured.
- Of those hospitalized, 64 percent had skin and soft tissue infections (SSTIs) resulting from dirty or unsterile needles.

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

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> Other includes American Indian/Alaska Native, Asian/Pacific Islander, and multi-racial.

<sup>39</sup> Hansel Tookes, Chanelle Diaz, et al., *A Cost Analysis of Hospitalizations for Infections Related to Drug Use at a County Safety-Net Hospital in Miami, Florida*, (2015), PLOS ONE 10(6): e0129360, <https://doi.org/10.1371/journal.pone.0129360> (last visited February 12, 2019).

- Opiate abuse was diagnosed in 37 percent of patients.<sup>40</sup>
- Total costs over one year from hospitalizations relating to bacterial infections linked to dirty needles: \$11.4 million<sup>41</sup>

The study notated above occurred prior to the implementation of Miami-Dade's needle exchange pilot program.

### **Florida Comprehensive Drug Abuse Prevention and Control Act**

In Florida, the term “drug paraphernalia” is defined as all equipment, products, and materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body, a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.<sup>42</sup>

Section 893.147, F.S., regulates the use or possession of drug paraphernalia. Currently, it is unlawful for any person to use, or to possess with intent to use, drug paraphernalia:

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of ch. 893, F.S.; or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of ch. 893, F.S.

Any person who violates this provision commits a first degree misdemeanor.<sup>43</sup>

It is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used:

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of the Florida Comprehensive Drug Abuse Prevention and Control Act<sup>44</sup>, or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Any person who violates this provision commits a third degree felony.<sup>45</sup>

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<sup>40</sup> *Id.*

<sup>41</sup> Christine Dimattei, *Miami Doctor Behind Florida's New Needle-Exchange Programs Says It Will Save Lives*, (WLRN radio broadcast March 30, 2016)(transcript available at <http://www.wlrn.org/post/miami-doctor-behind-floridas-new-needle-exchange-program-says-it-will-save-lives>).

<sup>42</sup> Section 893.145, F.S.

<sup>43</sup> A first degree misdemeanor is punishable by up to 1-year imprisonment in a county jail, a fine of up to \$1,000, or both. *See* ss. 775.082 and 775.083, F.S.

<sup>44</sup> The act referred to is the Florida Comprehensive Drug Abuse Prevention and Control Act.

<sup>45</sup> A third degree felony is punishable by up to 5 years in state prison, a fine not to exceed \$5,000, or both. *See* ss. 775.082 and 775.083, F.S.

A court or jury is required to consider a number of factors in determining whether an object is drug paraphernalia, such as proximity of the object in time and space to a controlled substance, the existence of residue of controlled substances on the object, and expert testimony concerning its use.<sup>46</sup>

### **Safe Sharps Disposal**

Improperly discarded sharps pose a serious risk for injury and infection to sanitation workers and the community. “Sharps” is a medical term for devices with sharp points or edges that can puncture or cut the skin.<sup>47</sup> Examples of sharps include:

- Needles: hollow needles used to inject drugs or medications under the skin.
- Syringes: devices used to inject medication into or withdraw fluid from the body.
- Lancets, also called finger stick devices: instruments with a short, two-edged blade used to get drops of blood for testing.
- Auto injectors: includes epinephrine and insulin pens or syringes with pre-filled fluid medication designed to be self-injected into the body.
- Infusion sets: tubing systems with a needle used to deliver drugs to the body.
- Connection needles/set: needles that connect to a tube used to transfer fluids in and out of the body.<sup>48</sup>

Used needles and other sharps pose a dangerous risk to people and animals if not properly disposed of, as they can spread disease and cause injury. The most common infections from such actions are Hepatitis B (HBV), Hepatitis C (HCV), and HIV.<sup>49</sup>

A National HIV Behavioral Surveillance Report on HIV Infection, Risk, Prevention, and Testing Behaviors among Persons Who Inject Drugs, conducted in 20 cities in 2015, produced data from 10,485 participants, including participants from Miami and was released in 2016. Approximately one in three of the report participants reported using a syringe used by someone else with 25 percent indicating that the syringe had been used by an HIV-positive IDU. Fifty-two percent of the respondents indicated they had received syringes from a syringe services program or syringe exchange program during the past 12 months; however the range of participation varied greatly with the HIV-negative group by city, from 2 percent to 90 percent.

For the Miami site, 412 participants, or 88.6 percent of the survey respondents, indicated they had had at least one HIV test performed. Of those that had an HIV test performed, 300 participants, or 64.5 percent, had most recently had a test within the past 12 months, as recommended by the CDC. The national averages in the report were 91.4 percent had ever had a test done and 57.1 percent had done so within the past 12 months.

Safe disposal of syringes is also an important component to decrease the number of accidental transmission of infections and the re-use of spoiled syringes. Only 18 percent of IDUs reported

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<sup>46</sup> Section 893.146, F.S.

<sup>47</sup> United States Food and Drug Administration, *Safely Using Sharps* (page last updated August 30, 2018), available at <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm>, (last visited Feb. 13, 2019).

<sup>48</sup> U.S. Food and Drug Administration, *supra* note 24.

<sup>49</sup> *Id.*



the use of safe disposal methods for used syringes. The U.S. Food and Drug Administration’s guidelines for disposal are to never place loose needles or other sharps in household or public trashcans or recycling bins, and to never flush them down toilets.<sup>50</sup> Many Florida counties and municipalities have their own sharps disposal programs through their respective county health departments.<sup>51</sup>

### **Needle and Syringe Exchange Programs in Other States**

Sixteen other states have passed laws authorizing needle and syringe exchanges.<sup>52</sup> California has passed legislation permitting the sale of syringes and needles as non-prescription items for personal use if sold by a pharmacy, doctor, or by an authorized syringe exchange program.<sup>53</sup> As of January 1, 2015, California removed the prior limits on the number of the non-prescription sale of hypodermic needles and syringes by pharmacies and physicians that an adult may purchase and possess<sup>54</sup>

Louisville, Kentucky, has a syringe exchange program operated by Volunteer America in a mobile RV that also provides wound supplies, safe injection supplies, biohazard containers/sharps containers, HIV/HCV testing and referrals for care, naloxone testing and referrals for care, safe injection education, and referrals for drug treatment, medical care, and community resources.<sup>55</sup> Kentucky’s program also permits local health departments to operate outreach programs whereby individuals can exchange used hypodermic needs and syringes for clean needles and syringes.<sup>56</sup>

The Kentucky guidelines also discuss the different syringe and needle exchange transaction models:

- Needs Based Negotiation: The program does not set a limit on the number of syringes a participant can receive regardless of the number of returned syringes. The number of new,

<sup>50</sup> U.S. Food and Drug Administration, *Do’s and Don’ts – Safe Disposal of Needles and Other Sharps Used at Home, Work, or While Traveling*, <https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/UCM278775.pdf> (last visited February 13, 2019).

<sup>51</sup> Florida Dep’t of Health, *A Safe Way to Throw Away Needles*, <http://www.floridahealth.gov/environmental-health/biomedical-waste/documents/HomeDisposal.pdf> (last visited Feb. 13, 2019).

<sup>52</sup> Centers for Disease Control and Prevention, *Access to Clean Syringe – Improving Access to Prevent Spread of HIV and HCV*, <https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html> (last visited February 11, 2019).

<sup>53</sup> California Department of Public Health, Office of AIDS, *Fact Sheet – For Syringe Exchange Programs and Law Enforcement, Non-Prescription Sale and Provision of Syringes (January, 2017)* [https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/Fact%20Sheet%20-%20What%20the%20Law%20Says\\_ADA.pdf](https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/Fact%20Sheet%20-%20What%20the%20Law%20Says_ADA.pdf) (last visited Feb. 11, 2019).

<sup>54</sup> California Department of Public Health, Office of AIDS, *California Legal Code Related to Access to Sterile Needles and Syringes* (updated January 2017), available at [https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/CA%20Legal%20Code\\_Jan%202017\\_AD\\_A.pdf](https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/CA%20Legal%20Code_Jan%202017_AD_A.pdf).

<sup>55</sup> Louisville, Kentucky Office of Addiction Services, *Syringe Exchange*, [https://louisvilleky.gov/sites/default/files/health\\_and\\_wellness/educationalmaterials/2017julysepbrochure2.pdf](https://louisvilleky.gov/sites/default/files/health_and_wellness/educationalmaterials/2017julysepbrochure2.pdf) (last visited Feb. 11, 2019).

<sup>56</sup> Kentucky Public Health, *Kentucky Harm Reduction and Syringe Exchange Program (HRSEP) Guidelines for Local Health Departments Implementing Needle Exchange Programs* (May 11, 2015), available at [https://louisvilleky.gov/sites/default/files/health\\_and\\_wellness/clinics/2015\\_kydp\\_hrsep\\_guidelines\\_long\\_version.pdf](https://louisvilleky.gov/sites/default/files/health_and_wellness/clinics/2015_kydp_hrsep_guidelines_long_version.pdf) (last visited Feb. 11, 2019).

sterile syringes given out is based on the participant's need, frequency of injection, and the length of time until the participant can next visit the program. Some programs may place an upper limit on the number of sterile syringes distributed per individual.

- **Strict One-for-One Exchange:** Provides the participant with the exact same number of sterile syringes as the participant brings in for disposal. If the participant did not bring in any syringes or needles, the participant would not receive any new, sterile syringes or needles in return.
- **One-for-One-Plus Exchange:** Modifies the strict one-for-one exchange by providing a pre-determined number of needles that can be obtained beyond the one-for-one ratio. A voucher system could also be used for the additional syringes or needles.<sup>57</sup>

In Maine, the Church of Safe Injection distributes free supplies, including syringes and Narcan, a drug which can reduce an opioid overdose. The Church of Safe Injection operates in several states and is one of six programs certified in Maine.<sup>58</sup> It is also illegal in Maine to possess hypodermic needles unless you are a certified needle exchange.<sup>59</sup> For the time period of November 2014, through October 2015, Maine's six certified sites collected 545,475 contaminated needles from 4,264 individuals. By state law and administrative rule, certified needle exchange sites may only exchange needles on a strict one-for-one exchange policy, may only exchange needles with individuals age 18 and older who are enrolled in their program, and may only exchange ten clean hypodermic needles at a time.<sup>60</sup>

### **Federal Status of Needle Exchange Programs**

Syringe service programs are described as an effective component of a comprehensive, integrative approach to a community-based HIV prevention program in CDC and U.S. Department of Health and Human Services guidance documents.<sup>61</sup> On December 23, 2011, President Barack Obama signed the 2012 omnibus spending bill that reinstated a 1988 ban on the use of federal funds for sterile needle or syringe programs, which reversed the 111<sup>th</sup> Congress' 2009 decision to allow federal funds to be used for such programs.<sup>62</sup> However, on December 18, 2015, President Obama signed the Consolidated Appropriations Act of 2016 (Pub. L. 114-113), which modified the restriction on the use of federal funds for needle exchange programs for persons who inject drugs to allow the use of federal funds for certain services.<sup>63</sup>

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<sup>57</sup> *Id.*

<sup>58</sup> Deborah Becker, 'Church of Safe Injection' Offers Needles, Naloxone to Prevent Opioid Overdoses, NPR.org, [https://www.npr.org/sections/health-shots/2019/02/12/693653562/church-of-safe-injection-offers-needles-naloxone-to-prevent-opioid-overdoses?utm\\_medium=RSS&utm\\_campaign=shotshealthnews](https://www.npr.org/sections/health-shots/2019/02/12/693653562/church-of-safe-injection-offers-needles-naloxone-to-prevent-opioid-overdoses?utm_medium=RSS&utm_campaign=shotshealthnews) (February 12, 2019) (last visited Feb 12, 2019).

<sup>59</sup> *Id.*

<sup>60</sup> State of Maine, Dep't of Human Services, Maine Center for Disease Control and Prevention, Chapter 252: Rules Governing the Implementation of Hypodermic Apparatus Exchange Programs, *see* <https://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/provider/documents/nep-rules.pdf> (last visited Feb. 14, 2019).

<sup>61</sup> Centers for Disease Control and Prevention, *Syringe Services Programs*, <https://www.cdc.gov/hiv/risk/ssps.html> (last visited Feb. 13, 2019).

<sup>62</sup> Centers for Disease Control and Prevention, *U.S. Department of Health and Human Services Implementation Guide to Support Certain Component of Syringe Services Programs, 2016*, (Mar. 29, 2016), available at <https://www.cdc.gov/hiv/pdf/risk/hhs-ssp-guidance.pdf>, (last visited Feb. 13, 2019).

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

The Consolidated Act, 2016, allows:

*SEC. 520. Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug: Provided, That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law.<sup>64</sup>*

Additionally, under the Consolidated Appropriations Act of 2016, needle exchange programs must be part of a comprehensive service program that includes:

- Comprehensive sexual and injection risk reduction counselling.
- HIV, viral hepatitis, other sexually transmitted diseases and tuberculosis screening, other sexually transmitted diseases and tuberculosis prevention care and treatment services, referral and linkage to HIV, viral hepatitis A virus and human papillomavirus vaccinations.
- Referral to integrated and coordinated substance abuse disorder, mental health services, physical health care, social services, and recovery support services.
- Provision of naloxone to reverse opioid overdoses.
- Provision of sterile needles, syringes, and other drug preparation equipment purchased with non-federal funds and disposal services.<sup>65</sup>

While the federal government does continue to prohibit the use of federal funds to purchase sterile needles and syringes for exchange programs, it does allow the use of federal funds by the state or local health department for other needs of such programs.<sup>66</sup> In order to receive such funds from the Department of Health and Human Services, a state must first consult with the CDC and provide evidence that its jurisdiction is experiencing or is at risk for significant increases in hepatitis infections or an HIV outbreak due to injection drug use.<sup>67</sup> As of February 6, 2019, 37 states, the District of Columbia, one territory, six counties, and one city have demonstrated adequate need, according to federal law, and are thereby authorized to use federal funds to purchase needles or syringes.<sup>68</sup>

### **Federal Law Exemption**

Any person authorized by local, state, or federal law to manufacture, possess, or distribute drug paraphernalia is exempt from the federal drug paraphernalia statute.<sup>69</sup>

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<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> Other needs include personnel, virus testing, syringe disposal services, naloxone provisions, condom dissemination, outreach activities, and educational materials.

<sup>67</sup> U.S. Department of Health and Human Services, *supra* note 59.

<sup>68</sup> Centers for Disease Control and Prevention, *Syringe Service Program Determination of Need*, (Feb. 8, 2019) available at <https://www.cdc.gov/hiv/risk/ssps-jurisdictions.html> (last visited Feb. 13, 2019).

<sup>69</sup> 21 U.S.C. § 863(f)(1).

### III. Effect of Proposed Changes:

**Section 1** provides that the act may be cited as the “Infectious Disease Elimination Act (IDEA).”

**Section 2** amends subsection (4) of section 381.0038, F.S., to authorize sterile needle and syringe exchange programs in counties other than Miami-Dade rather than limiting such programs to a single pilot program at the University of Miami.

CS/SB 366 allows a county commission to authorize a sterile needle and syringe program within its county boundaries. The program may operate at one or more fixed or mobile locations. The bill prohibits a needle and syringe exchange program from being established unless authorized by the county commission through a county ordinance.

The stated goal for the sterile needle and syringe exchange program is the prevention of disease transmission. The bill defines an “exchange program” as a sterile needle and syringe program established by a county commission.

Before a program can be established, a county commission must complete a number of steps:

1. Authorize the program through a county ordinance.
2. Enter into a letter of agreement with the Department of Health (DOH) in which the county commission agrees that any needle and syringe exchange program will operate in accordance with the provisions of the IDEA.
3. Enlist the local county health department to provide ongoing advice, consultation, and recommendations for the operation of the program.
4. Contract with one of the following entities to operate the program:
  - a. A hospital licensed under chapter 395.
  - b. A health care clinic licensed under part X of chapter 400.
  - c. An accredited medical school associated with a university in the state.
  - d. A licensed addictions receiving facility as defined in s. 397.311, F.S.<sup>70</sup>
  - e. A 501(c) (3) HIV/AIDS service organization.

An exchange program is required to:

- Develop an oversight and accountability system with measurable objectives to track the program’s progress towards its goals and report routinely to the county commission and the DOH.
- Incorporate into its accountability system mechanisms to address issues of compliance or noncompliance with contractual obligations.
- Provide for maximum security of sites where needles and syringes are exchanged as with the current pilot program, including an accounting of the number of needles and syringes in use, the number in storage, safe disposal of returned needles, and other measures.
- Operate a one-to-one exchange; however, a waiver of this requirement may be granted under exigent circumstances.

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<sup>70</sup> A licensed addictions receiving facility is defined as a secure, acute care facility that provides, at a minimum, detoxification and stabilization services; is operated 24 hours per day, 7 days per week; and is designated by the department to serve individuals found to be substance abuse impaired as described in s. 397.675, F.S., who meet the placement criteria for this component.

- Require the program operator to offer educational materials whenever needles or syringes are exchanged.
- Provide onsite counseling or referrals for drug abuse prevention, education, and treatment, and provide onsite HIV and viral hepatitis screening, and, if such services are not provided onsite, referrals for same services must be available within 72 hours of a referral. The county commission may adjust the 72-hour time period in rural areas if the availability of providers warrants such an adjustment.
- Provide kits containing an emergency opioid antagonist,<sup>71</sup> as defined in s. 381.887, F.S., or if unable to provide kits directly, then provide a referral to a program that can provide a kit.
- Collect data for annual reporting purposes, including the number of people served, services provided, types of services provided, and number of needles and syringes exchanged and received.

The DOH is required to compile annual reports of exchange programs and submit the compilation to the Governor, President of the Senate, and the Speaker of the House of Representatives annually by October 1<sup>st</sup>. The bill provides the DOH with rulemaking authority for the parameters for data collection and reporting.

Immunity is provided, notwithstanding chapter 893 or any other law, to any program staff member, volunteer, or participant, from criminal prosecution for possession of a needle or syringe that is obtained or surrendered as part of this program. The extension of this immunity protects volunteers, staff members, or participants who are handling needles and syringes that are being turned in or exchanged pursuant to the terms of the program.

The bill prohibits state funds being used to operate an exchange, but funding by the county or through grants and donations from private resources or funds is allowed.

The bill provides that a law enforcement officer who acts in good faith by arresting or charging an individual with a needle or syringe who is thereafter found to be immune from prosecution is granted immunity from any civil liability that may be incurred because of his or her actions.

**Section 3** authorizes the continued operation of the Miami-Dade pilot program, as authorized under chapter 2016-68, Laws of Florida, until the Miami-Dade County Board of County Commissioners establishes an exchange program under this act or until July 1, 2021, whichever occurs first.

**Section 4** contains a severability clause so that if any provision of the act is found to be invalid, that invalidity does not affect the ability of the other provisions of the act to go into effect. If that provision is severed, the other provisions of this act can be given effect.

**Section 5** provides an effective date of July 1, 2019.

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<sup>71</sup> An “emergency opioid antagonist” means naloxone hydrochloride or any similarly acting drug that block the effects of opioids administered from outside the body and that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose.

**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:

Areas that elect to participate in this program may see a reduction in the number of infectious diseases consistent with the results seen in the pilot program in Miami-Dade County.

## C. Government Sector Impact:

Local governments may elect to provide funding for a sterile needle and syringe program; however, the bill specifically prohibits the use of state funding. The program is voluntary and requires the county commission to opt-in through adoption of an ordinance and satisfaction of statutory requirements. There is no requirement for any minimum funding level.

Local law enforcement are also impacted as the bill provides limited immunity to program staff, volunteers, and participants who are in possession of a syringe or needle that was obtained through the program or was surrendered to the program. If the syringe

or needle was obtained in this manner, then the individual may be immune from prosecution under chapter 893, Drug Abuse Prevention and Control statutes.<sup>72,73</sup> Additionally, for those local governments that elect to participate, they may see a reduction in other health care expenditures related to the treatment of blood-borne diseases associated with intravenous drug use. For example, local governments pay a portion of costs for some patients with AIDS who are enrolled in Medicaid, the AIDS Drug Assistance Program, and the AIDS Insurance Continuation Program. The lifetime cost per individual for HIV treatment is estimated to be \$379,668 in 2010 dollars.<sup>74</sup>

Studies of the New York City needle syringe exchange program showed an estimated savings of \$1,300 to \$3,000 per individual and a drop in the HIV prevalence rate from 50 percent to 17 percent in the time period of 1990 to 2002.<sup>75</sup>

In 2015, for those who do not have insurance and for whom the hospital or other local charity programs or local government must pay, a study which involved the Miami-Dade area found that the median hospital charge for an injection-related infection was \$39,896 with a range in claims from \$14,158 to \$104,912.<sup>76</sup>

The DOH and the county commission are required to enter into a letter of agreement before an exchange program is established. In the letter of agreement, the county agrees that the program will abide by all of the provisions of the IDEA. Included in that oversight role is the collection of annual data from the program sites for the compilation of the annual report for submission to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

In addition, the county commission must also enlist its county health department to provide ongoing advice, consultation, and recommendations for the program. The local county health department could play an ongoing advisory and oversight role in the program.

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<sup>72</sup> Under s. 893.147(3)(b), F.S., it is unlawful for any person to sell or otherwise deliver hypodermic syringes, needles, or other objects which may be used, are intended for use, or are designed for use in parenterally injecting substances into the human body to any person under 18 years of age, except that hypodermic syringes, needles, or other such objects may be lawfully dispensed to a person under 18 years of age by a licensed practitioner, parent, or legal guardian or by a pharmacist pursuant to a valid prescription for same. Any person who violates the provisions of this paragraph is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For a misdemeanor of the first degree, it may be punishable by a term of imprisonment of not more than one year or a fine of not more than \$1,000.

<sup>73</sup> Drug paraphernalia is defined in statute under s. 893.145, F.S., and means all equipment, products, and materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this chapter or s. 877.111. Drug paraphernalia is deemed to be contraband which shall be subject to civil forfeiture. The term includes, but is not limited to... (11) Hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body.

<sup>74</sup> Centers for Disease Control, *Improving access to prevent the spread of HIV and HCV*, (page last updated Aug. 5, 2016) available at <https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html> (last visited Feb. 8, 2019).

<sup>75</sup> *Id.*

<sup>76</sup> Hansel Tookes, Chanelle Diaz, et al., *Supra* note 46.

The bill prohibits the use of any state funds to operate an exchange program. The DOH has questioned in the past how it could effectively administer the program or complete any comprehensive reports without any state funds to conduct its administrative duties or promulgate rules.<sup>77</sup> The DOH is authorized, but not required, to promulgate rules related to the collection of data and the compilation of the annual report.

**VI. Technical Deficiencies:**

None

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 381.0038 of the Florida Statutes.

**IX. Additional Information:**

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

**CS by Health Policy on February 19, 2019:**

The CS modifies the sterile needle and syringe exchange program and provides a process by which a county commission may authorize an exchange program. A program’s goal of disease prevention is specifically stated. The CS also defines the term “exchange program” as a sterile needle and syringe exchange program established by a county commission and provides that an exchange program may not operate unless it has been approved by the county commission in accordance with the IDEA.

The CS provides specific requirements for the county commission before an exchange program may be established. Those requirements for the county commission include specific adoption of a county ordinance approving the program, approval of the program’s needle and syringe exchange program operator, coordination with the DOH and county health department, and development of an accountability and tracking system.

Exchange programs have several operational requirements under the CS including:

- Operate a one-to-one exchange; however, the CS permits the county commission to grant a waiver of this requirement for exigent circumstances.
- Offer educational materials to program participants whenever needles or syringes are exchanged.
- Provide onsite counseling or referrals for drug abuse prevention, education, treatment, and provide onsite HIV and viral hepatitis screening or referrals. If not available on

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<sup>77</sup> Florida Dep’t of Health, *Senate Bill 800 Analysis* (November 13, 2017) (on file with Senate Committee on Health Policy).



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site, must be available within 72 hours. The CS also provides for a rural exception if providers are not readily available.

- Provide kits or refer to a program that can provide the kits containing an opioid antagonist.
- Collect and submit data to the county commission and the DOH.

The CS also recognizes the existence of the pilot program in Miami-Dade County and authorizes its continuation until the Miami-Dade County Board of County Commissioners establishes an exchange program as defined under the IDEA or until July 1, 2021, whichever occurs first.

**B. Amendments:**

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/19/2019	.	
	.	
	.	
	.	

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

**Senate Amendment (with title amendment)**

Delete everything after the enacting clause  
and insert:

Section 1. This act may be cited as the "Infectious Disease Elimination Act (IDEA)."

Section 2. Subsection (4) of section 381.0038, Florida Statutes, is amended to read:

381.0038 Education; sterile needle and syringe exchange programs ~~pilot program~~.—The Department of Health shall establish



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11 a program to educate the public about the threat of acquired  
12 immune deficiency syndrome.

13 (4) A county commission ~~The University of Miami and its~~  
14 ~~affiliates~~ may authorize ~~establish~~ a ~~single~~ sterile needle and  
15 syringe exchange ~~pilot~~ program to operate within its county  
16 boundaries in Miami-Dade County. The ~~pilot~~ program may operate  
17 at one or more fixed locations ~~a fixed location~~ or through a  
18 mobile health units ~~unit~~. The ~~pilot~~ program shall offer the free  
19 exchange of clean, unused needles and hypodermic syringes for  
20 used needles and hypodermic syringes as a means to prevent the  
21 transmission of HIV, AIDS, viral hepatitis, or other blood-borne  
22 diseases among intravenous drug users and their sexual partners  
23 and offspring. Prevention of disease transmission must be the  
24 goal of the program. For the purposes of this subsection, the  
25 term "exchange program" means a sterile needle and syringe  
26 exchange program established by a county commission under this  
27 subsection. A sterile needle and syringe exchange program may  
28 not operate unless it is authorized and approved by a county  
29 commission in accordance with this subsection.

30 (a) Before an exchange program may be established, a county  
31 commission must:

32 1. Authorize the program under the provisions of a county  
33 ordinance;

34 2. Enter into a letter of agreement with the department in  
35 which the county commission agrees that any exchange program  
36 authorized by the county commission will operate in accordance  
37 with this subsection;

38 3. Enlist the local county health department to provide  
39 ongoing advice, consultation, and recommendations for the



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40 operation of the program;  
41 4. Contract with one of the following entities to operate  
42 the program:  
43 a. A hospital licensed under chapter 395.  
44 b. A health care clinic licensed under part X of chapter  
45 400.  
46 c. An accredited medical school associated with a  
47 university in this state.  
48 d. A licensed addictions receiving facility as defined in  
49 s. 397.311.  
50 e. A 501(c)(3) HIV/AIDS service organization.  
51 (b)(a) An exchange ~~The pilot~~ program must:  
52 1. Develop an oversight and accountability system to ensure  
53 the program's compliance with statutory and contractual  
54 requirements. The system must include measurable objectives for  
55 meeting the goal of the program and must track the progress in  
56 achieving those objectives. The system must require the program  
57 operator to routinely report its progress in achieving the  
58 objectives and the goal of the program. The system must also  
59 incorporate mechanisms to track the program operator's  
60 compliance or noncompliance with contractual obligations and to  
61 apply consequences for noncompliance. The program must receive  
62 the county commission's approval of the oversight and  
63 accountability system before commencing operations.  
64 2.1. Provide for maximum security of ~~exchange~~ sites where  
65 needles and syringes are exchanged and of any equipment used  
66 under the program, including, at a minimum, an accounting of the  
67 number of needles and syringes in use, the number of needles and  
68 syringes in storage, safe disposal of returned needles, and any



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69 other measure that may be required to control the use and  
70 dispersal of sterile needles and syringes.

71 32. Operate a one-to-one exchange, whereby a the  
72 participant shall receive one sterile needle and syringe unit in  
73 exchange for each used one. The county commission is authorized  
74 to grant a waiver of this requirement under its contract with  
75 the program operator if the terms of such a waiver require the  
76 operator to maintain the one-to-one ratio except for exigent  
77 circumstances delineated in the waiver.

78 43. Make available educational materials and referrals to  
79 education regarding the transmission of HIV, viral hepatitis,  
80 and other blood-borne diseases. The program operator must offer  
81 such materials to program participants whenever needles or  
82 syringes are exchanged; provide referrals for drug abuse  
83 prevention and treatment; and provide or refer for HIV and viral  
84 hepatitis screening.

85 5. Provide onsite counseling or referrals for drug abuse  
86 prevention, education, and treatment, and provide onsite HIV and  
87 viral hepatitis screening or referrals for such screening. If  
88 such services are offered solely by referral, they must be made  
89 available to participants within 72 hours. The county commission  
90 in a rural county may, under its contract with the program  
91 operator, adjust the 72-hour requirement if the commission finds  
92 that the availability of providers warrants an extended  
93 timeframe.

94 6. Provide kits containing an emergency opioid antagonist,  
95 as defined in s. 381.887, or provide referrals to a program that  
96 can provide such kits.

97 7. Collect data for annual reporting purposes. The data



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98 must include the number of participants served; the number of  
99 used needles and syringes received and the number of clean,  
100 unused needles and syringes distributed through exchange with  
101 participants; the demographic profiles of the participants  
102 served; the number of participants entering drug counseling or  
103 treatment; the number of participants receiving testing for HIV,  
104 AIDS, viral hepatitis, or other blood-borne diseases; and other  
105 data that may be required under department rule. However, a  
106 participant's personal identifying information may not be  
107 collected for any purpose. Each exchange program must submit a  
108 report to its county commission and to the department by August  
109 1 annually. The department must submit a compilation report  
110 encompassing data from all exchange programs annually by October  
111 1 to the Governor, the President of the Senate, and the Speaker  
112 of the House of Representatives. The department may adopt rules  
113 to implement this subparagraph.

114 (c)-(b) The possession, distribution, or exchange of needles  
115 or syringes as part of an exchange ~~the pilot~~ program established  
116 under this subsection is not a violation of any part of chapter  
117 893 or any other law.

118 (d)-(e) An exchange ~~A pilot~~ program staff member, volunteer,  
119 or participant is not immune from criminal prosecution for:

120 1. The possession of needles or syringes that are not a  
121 part of the exchange ~~pilot~~ program; or

122 2. The redistribution of needles or syringes in any form,  
123 if acting outside the exchange ~~pilot~~ program.

124 ~~(d) The pilot program must collect data for quarterly,~~  
125 ~~annual, and final reporting purposes. The annual report must~~  
126 ~~include information on the number of participants served, the~~



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127 ~~number of needles and syringes exchanged and distributed, the~~  
128 ~~demographic profiles of the participants served, the number of~~  
129 ~~participants entering drug counseling and treatment; the number~~  
130 ~~of participants receiving testing for HIV, AIDS, viral~~  
131 ~~hepatitis, or other blood-borne diseases; and other data~~  
132 ~~necessary for the pilot program. However, personal identifying~~  
133 ~~information may not be collected from a participant for any~~  
134 ~~purpose. Quarterly reports must be submitted to the Department~~  
135 ~~of Health in Miami-Dade County by October 15, January 15, April~~  
136 ~~15, and July 15 of each year. An annual report must be submitted~~  
137 ~~to the Department of Health by August 1 every year until the~~  
138 ~~program expires. A final report is due on August 1, 2021, to the~~  
139 ~~Department of Health and must describe the performance and~~  
140 ~~outcomes of the pilot program and include a summary of the~~  
141 ~~information in the annual reports for all pilot program years.~~

142 (e) A law enforcement officer acting in good faith who  
143 arrests or charges a person who is thereafter determined to be  
144 immune from prosecution under this section shall be immune from  
145 civil liability that might otherwise be incurred or imposed by  
146 reason of the officer's actions.

147 (f) State, county, or municipal funds may not be used to  
148 operate an exchange the pilot program. Exchange programs may  
149 the pilot program shall be funded fully or partially through county  
150 commission expenditures or through grants and donations from  
151 private resources and funds.

152 ~~(f) The pilot program shall expire July 1, 2021.~~

153 Section 3. Notwithstanding s. 381.0038(4), Florida  
154 Statutes, as amended by this act, the pilot program established  
155 in Miami-Dade County under chapter 2016-68, Laws of Florida, may



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156 continue to operate under that chapter until the Miami-Dade  
157 County Board of County Commissioners establishes an exchange  
158 program as defined under this act or until July 1, 2021,  
159 whichever occurs first.

160       Section 4. If any provision of this act or its application  
161 to any person or circumstance is held invalid, the invalidity  
162 does not affect other provisions or applications of the act  
163 which can be given effect without the invalid provision or  
164 application, and to this end the provisions of this act are  
165 severable.

166       Section 5. This act shall take effect July 1, 2019.

167

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

169 And the title is amended as follows:

170       Delete everything before the enacting clause  
171 and insert:

172                               A bill to be entitled  
173       An act relating to infectious disease elimination  
174       programs; providing a short title; amending s.  
175       381.0038, F.S.; providing that a county commission may  
176       authorize a sterile needle and syringe exchange  
177       program; defining the term "exchange program";  
178       prohibiting the establishment of an exchange program  
179       under certain conditions; providing requirements for  
180       establishing an exchange program; specifying entities  
181       that may operate an exchange program; requiring the  
182       development of an oversight and accountability system  
183       for certain purposes; specifying requirements for  
184       exchange programs; requiring the collection of data





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185 and submission of reports; authorizing the Department  
186 of Health to adopt certain rules; providing for  
187 immunity from civil liability under certain  
188 circumstances; authorizing sources of funding for  
189 exchange programs; authorizing the continuation of a  
190 specified pilot project under certain circumstances;  
191 providing severability; providing an effective date.

By Senator Braynon

35-00882-19

2019366\_\_

1                   A bill to be entitled  
 2       An act relating to infectious disease elimination  
 3       programs; providing a short title; amending s.  
 4       381.0038, F.S.; authorizing certain eligible entities  
 5       to establish sterile needle and syringe exchange  
 6       programs, rather than a single program established in  
 7       Miami-Dade County; requiring an eligible entity to  
 8       notify the Department of Health of specified  
 9       information; revising program requirements; exempting  
 10      certain persons affiliated with a program from  
 11      prosecution for possession of a needle or syringe  
 12      under certain circumstances; authorizing a county to  
 13      prohibit a program within its boundaries; providing  
 14      immunity from civil liability for certain law  
 15      enforcement officers; providing severability;  
 16      providing an effective date.

17  
 18 Be It Enacted by the Legislature of the State of Florida:

19  
 20       Section 1. This act may be cited as the "Infectious Disease  
 21 Elimination Act (IDEA)."

22       Section 2. Subsection (4) of section 381.0038, Florida  
 23 Statutes, is amended to read:

24       381.0038 Education; sterile needle and syringe exchange  
 25 ~~pilot~~ program.—The Department of Health shall establish a  
 26 program to educate the public about the threat of acquired  
 27 immune deficiency syndrome.

28       (4) An eligible entity ~~The University of Miami and its~~  
 29 ~~affiliates~~ may establish and operate a ~~single~~ sterile needle and

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30 syringe exchange ~~pilot~~ program in ~~Miami Dade County~~. An eligible  
31 entity shall notify the department when it establishes such a  
32 program and provide the eligible entity's name; the program's  
33 name and address; and the name, address, and telephone number of  
34 a contact person. The ~~pilot~~ program may operate at a fixed  
35 location or through a mobile health unit. The ~~pilot~~ program  
36 shall offer the free exchange of clean, unused needles and  
37 hypodermic syringes for used needles and hypodermic syringes as  
38 a means to prevent the transmission of HIV, AIDS, viral  
39 hepatitis, or other blood-borne diseases among intravenous drug  
40 users and their sexual partners and offspring. For purposes of  
41 this subsection, an eligible entity includes a hospital licensed  
42 under chapter 395, a health care clinic licensed under part X of  
43 chapter 400, an accredited medical school, a substance abuse  
44 treatment program, or an HIV or AIDS service organization.

45 (a) The ~~pilot~~ program must:

46 1. Provide for maximum security of exchange sites and  
47 equipment, including an accounting of the number of needles and  
48 syringes in use, the number of needles and syringes in storage,  
49 safe disposal of returned needles, and any other measure that  
50 may be required to control the use and dispersal of sterile  
51 needles and syringes.

52 2. Provide needle and syringe exchange services for all  
53 program participants ~~Operate a one-to-one exchange, whereby the~~  
54 ~~participant shall receive one sterile needle and syringe unit in~~  
55 ~~exchange for each used one.~~

56 3. Make available educational materials and referrals to  
57 education regarding the transmission of HIV, viral hepatitis,  
58 and other blood-borne diseases; provide referrals for drug abuse

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59 prevention and treatment; and provide or refer for HIV and viral  
60 hepatitis screening.

61 4. Make available kits containing an emergency opioid  
62 antagonist, as defined in s. 381.887, or provide a referral to a  
63 program that can make available such kits.

64 (b)1. The possession, distribution, or exchange of needles  
65 or syringes as part of a ~~the pilot~~ program established under  
66 this subsection is not a violation of any part of chapter 893 or  
67 any other law.

68 2. Notwithstanding chapter 893 or any other law, a program  
69 staff member, volunteer, or participant is immune from criminal  
70 prosecution for possession of a needle or syringe obtained from  
71 or surrendered to the program.

72 (c) A ~~pilot~~ program staff member, volunteer, or participant  
73 is not immune from criminal prosecution for:

74 1. The possession of needles or syringes that are not a  
75 part of the ~~pilot~~ program; or

76 2. The redistribution of needles or syringes in any form,  
77 if acting outside the ~~pilot~~ program.

78 (d) Each ~~The pilot~~ program must collect data for ~~quarterly,~~  
79 ~~annual,~~ and final reporting purposes. An ~~The~~ annual report must  
80 include information on the number of participants served, the  
81 number of needles and syringes exchanged and distributed, the  
82 demographic profiles of the participants served, the number of  
83 participants entering drug counseling and treatment; the number  
84 of participants receiving testing for HIV, AIDS, viral  
85 hepatitis, or other blood-borne diseases; and other data  
86 necessary for the ~~pilot~~ program. However, personal identifying  
87 information may not be collected from a participant for any

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88 purpose. Each program must submit ~~Quarterly reports must be~~  
89 ~~submitted to the department of Health in Miami Dade County by~~  
90 ~~October 15, January 15, April 15, and July 15 of each year.~~ an  
91 annual report ~~must be submitted~~ to the department of Health by  
92 August 1 every year which describes ~~until the program expires.~~ A  
93 ~~final report is due on August 1, 2021, to the department of~~  
94 ~~Health and must describe~~ the performance and outcomes of the  
95 ~~pilot program and include a summary of the information in the~~  
96 ~~annual reports for all pilot program years.~~

97 (e) ~~State, county, or municipal~~ funds may not be used to  
98 operate a the pilot program. ~~A The pilot program may shall~~ be  
99 funded through grants and donations from private resources and  
100 funds or through county or municipal funding.

101 (f) A county may, by ordinance, prohibit a sterile needle  
102 and syringe exchange program from being located within the  
103 boundaries of that county.

104 (g) A law enforcement officer acting in good faith who  
105 arrests or charges a person who is thereafter determined to be  
106 immune from prosecution under this section shall be immune from  
107 civil liability that might otherwise be incurred or imposed by  
108 reason of the officer's actions.

109 ~~(f) The pilot program shall expire July 1, 2021.~~

110 Section 3. If any provision of this act or its application  
111 to any person or circumstance is held invalid, the invalidity  
112 does not affect other provisions or applications of the act  
113 which can be given effect without the invalid provision or  
114 application, and to this end the provisions of this act are  
115 severable.

116 Section 4. This act shall take effect July 1, 2019.



The Florida Senate

## Committee Agenda Request

**To:** Senator Gayle Harrell, Chair  
Committee on Health Policy

**Subject:** Committee Agenda Request

**Date:** February 4, 2019

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I respectfully request that **Senate Bill # 366**, relating to *Infectious Disease Elimination Programs; Citing this act as the "Infectious Disease Elimination Act (IDEA)"; authorizing certain eligible entities to establish sterile needle and syringe exchange programs, rather than a single program established in Miami-Dade County; exempting certain persons affiliated with a program from prosecution for possession of a needle or syringe under certain circumstances, etc.*, be placed on the:

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

\_\_\_\_\_  
Senator Oscar Braynon II  
Florida Senate, District 35

cc. Celia Georigiades



# 2018 AGENCY LEGISLATIVE BILL ANALYSIS

## AGENCY: Florida Department of Health

<b><u>BILL INFORMATION</u></b>	
<b>BILL NUMBER:</b>	SB 800
<b>BILL TITLE:</b>	Infectious Disease Elimination Pilot Programs
<b>BILL SPONSOR:</b>	Sen. Braynon
<b>EFFECTIVE DATE:</b>	7/1/2018

<b><u>COMMITTEES OF REFERENCE</u></b>
1) Health Policy
2) Appropriations Subcommittee on Health and Human Services
3) Appropriations
4) Click or tap here to enter text.
5) Click or tap here to enter text.

<b><u>PREVIOUS LEGISLATION</u></b>	
<b>BILL NUMBER:</b>	Click or tap here to enter text.
<b>SPONSOR:</b>	Click or tap here to enter text.
<b>YEAR:</b>	Click or tap here to enter text.
<b>LAST ACTION:</b>	Click or tap here to enter text.

<b><u>CURRENT COMMITTEE</u></b>
Click or tap here to enter text.

<b><u>SIMILAR BILLS</u></b>	
<b>BILL NUMBER:</b>	Click or tap here to enter text.
<b>SPONSOR:</b>	Click or tap here to enter text.

<b><u>IDENTICAL BILLS</u></b>	
<b>BILL NUMBER:</b>	HB 579
<b>SPONSOR:</b>	Rep. Jones

<b>Is this bill part of an agency package?</b>
No

<b><u>BILL ANALYSIS INFORMATION</u></b>	
<b>DATE OF ANALYSIS:</b>	11/13/2017
<b>LEAD AGENCY ANALYST:</b>	Jamaicia Cob, MPH
<b>ADDITIONAL ANALYST(S):</b>	Laura Reeves
<b>LEGAL ANALYST:</b>	Nichole Geary
<b>FISCAL ANALYST:</b>	Wesley Hagler

## **POLICY ANALYSIS**

## 1. EXECUTIVE SUMMARY

The bill amends s. 381.0038, *Florida Statutes (F.S.)*, to authorize the Department of Health to establish sterile needle and syringe exchange pilot programs upon request from eligible entities, rather than a single program established in Miami-Dade County through the University of Miami and its affiliates. The bill specifies who may be designated to operate a program and provides the expiration of all pilot programs by July 1, 2023. The bill provides a severability clause and an effective date of July 1, 2018.

## 2. SUBSTANTIVE BILL ANALYSIS

### 1. PRESENT SITUATION:

Section 893.147(1) (b), *F.S.*, makes it unlawful for any person to use, or to possess with intent to use, drug paraphernalia “(t)o inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this chapter.” Section 893.145(11) includes in the definition of drug paraphernalia “hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body.”

Of the 50,303 HIV cases reported in Florida in the past ten years (2007-2016), 5,245 (10 percent) were identified as intravenous drug users (IDU). Two percent of the total cases (1,148) were identified as men who had sex with men and used injection drugs (IDU/MSM).<sup>1</sup> From 1979–2016, there were 1,238 babies born with perinatally acquired HIV infection. The mother was an IDU in 21 percent of the cases (N=256) and 14 percent (N=174) of the mothers had a sex partner who was an IDU. The number of perinatally-acquired HIV cases attributable to IDU was 430 (35 percent).<sup>2</sup>

There were 114,608 adult (age 13+) persons living with HIV (PLWH) in 2016. A total of 17,866 (16 percent of the adult PLWH) identified with an IDU-associated risk. Among those with an IDU-associated risk, 52 percent were IDUs; 22 percent were heterosexual partners of an IDU. Geographically, sixty percent of the adult PLWH with an IDU-related risk lived in the top seven counties of Florida. Approximately 9% of the adult PLWH were reported to be co-infected with HIV and Hepatitis C virus (HCV); of which 27% of males and 48% of females had a documented IDU-related risk.<sup>3</sup>

### Adults (Age 13+) Living with HIV (PLWH) with an Injection Drug Use–Associated Risk, for Selected Counties, Diagnosed through 2016, Florida

County	Total PLWH Cases	IDU <sup>1</sup>	IDU	Sex w/IDU <sup>2</sup>	Sex w/IDU
Miami-Dade	26,946	2,873	11%	1,216	5%
Broward	20,020	2,188	11%	1,041	5%
Orange	8,663	1,389	16%	583	7%
Palm Beach	8,198	1,323	16%	723	9%
Hillsborough	6,941	1,229	18%	586	8%
Duval	6,199	981	16%	446	7%
Pinellas	4,589	830	18%	452	10%
Lee	2,238	333	15%	153	7%
Volusia	1,698	410	24%	151	9%
St. Lucie	1,610	284	18%	132	8%
Brevard	1,566	307	20%	124	8%
<b>STATE TOTAL<sup>3</sup></b>	<b>114,608</b>	<b>17,886</b>	<b>16%</b>	<b>8,216</b>	<b>7%</b>

In 2016, the University of Miami’s IDEA Exchange was founded as Florida’s first harm reduction program. As of Friday October 13, 2017, the University of Miami’s IDEA Exchange has had 469 enrollments at the fixed site and on the mobile unit. An additional 36 participants enrolled through the program’s backpacking initiative, bringing



the total number of participants to 505. The IDEA Exchange has provided 63,049 new sterile syringes in exchange for 70,877 used syringes. In addition, the IDEA Exchange has recovered 7,828 syringes through daily exchanges and the program's neighborhood clean-up initiatives. To date, The IDEA Exchange has linked 13 participants living with HIV to treatment and care. The program has referred 47 participants to HCV treatment services. A total of 232 participants have either self-reported or tested HCV positive.<sup>4</sup>

The Centers for Disease Control and Prevention (CDC) report that injection drug use is the most common risk factor for HCV infection.<sup>5</sup> IDUs have over 25 times greater odds of being infected with HCV than non-IDUs due to needle sharing practices.<sup>6</sup> A 1995 study in Washington State concluded that the use of a needle exchange program would have led to a 61 percent reduction in hepatitis B (HBV) and a 65 percent reduction in HCV infection in IDUs.<sup>7</sup> In 2015, there were 5,346 cases of hepatitis B and 23,191 cases of hepatitis C diagnosed in Florida. The CDC also found that approximately one-third of PLWHs are co-infected with HBV or HCV. Viral hepatitis progresses faster among PLWH and persons who are infected with both have greater health problems than those who are HIV negative. Although advances in antiretroviral treatment has substantially prolonged the lives of PLWHs, liver disease, much of which is related to HCV and HBV, has become the leading cause of non-AIDS-related deaths among this population.<sup>8</sup>

Syringe exchange programs (SEPs) have been found to benefit communities as well as public safety. Studies have found that SEPs reduce the number of needle-stick injuries to law enforcement officers and firefighters, thus reducing the chance of transmission of HIV, HBV or HCV.<sup>9</sup> Multiple studies have found that SEPs lead to reductions in injecting risk behaviors among IDUs when the IDUs concurrently participated in substance abuse treatment<sup>10</sup>. In the U.S., HIV incidence among IDUs declined by approximately 48 percent from 2008-2014. Injection-related transmission is the only category to show this level of reduction. Most SEPs also provide supplies, such as alcohol pads and condoms, offer preventive health services and referrals to drug treatment. The studies also find that SEPs do not increase crime or drug use.<sup>11</sup> These studies were cited in the White House's 2010 *National HIV/AIDS Strategy for the United States*, noting that access to sterile needles and syringes is among the "scientifically proven biomedical and behavioral approaches that reduce the probability of HIV transmission."<sup>12</sup>

The North American Syringe Exchange Network lists 43 states and the District of Columbia as having at least one SEP.<sup>13</sup> Some of these programs operate outside of the law. According to the CDC, 29.1 million syringes were exchanged by 123 of the 184 SEPs operating in 2008; 120 SEPs reported budgets totaling \$21.3 million, of which 79 percent came from state and local governments.<sup>14</sup> The federal government has gone back and forth between funding and banning SEPs. The ban on using federal funds for SEPs was lifted in 2016 through the Consolidated Appropriations Act, 2016.<sup>15</sup> To support implementation of this change in law, HHS has released new guidance for state, local, tribal, and territorial health departments that will allow them to request permission to use federal funds to support SEPs. Federal funds can now be used to support a comprehensive set of services, but they cannot be used to purchase sterile needles or syringes for illegal drug injection.<sup>16</sup> According to the CDC, the average lifetime treatment cost of one HIV-infected person is estimated at \$379,668 (in 2010 dollars).<sup>17</sup>

## 2. EFFECT OF THE BILL:

Section 1. Cites the name of the act.

Section 2. The bill amends subsection (4) of section 381.0038, *Florida Statutes (F.S.)* to authorize the Department of Health to establish sterile needle and syringe exchange pilot programs upon request from eligible entities, rather than a single program established in Miami-Dade County. This section adds language that outlines who is designated to operate a program which includes:

- A hospital licensed under chapter 395
- A health care clinic licensed under part X of chapter 400
- A substance abuse treatment program
- An HIV or AIDS service organization, or another nonprofit entity designated by the Department

The exchange programs must:

- Provide maximum security of the exchange site and equipment
- Account for needles and syringes in use and in storage
- Offer Hepatitis testing
- Adopt any measure to control the use and dispersal of sterile needles and syringes
- Strive for a 1 sterile-to-1 used exchange ratio

- Make available educational materials, HIV counseling and testing and referrals

The bill provides that the possession, distribution, or exchange of needles or syringes as part of an exchange program established by this pilot program does not violate the Florida Comprehensive Drug Abuse Prevention and Control Act regulated under Chapter 893, F.S., or any other provision in law. However, the exchange program staff or participant is not immune from prosecution for the possession or redistribution of needles or syringes in any form or needles or syringes that are not part of the exchange program.

The bill replaces Department of Health in Miami Dade as the entity in which quarterly progress reports must be submitted to and establishes the Department as the entity for all programs.

The bill amends the due date of final reports to August 1, 2023 to be submitted to the Department.

The bill requires that no state funds be used to operate the program. Program must be funded through grants and private donations.

The bill provides that all programs will expire on July 1, 2023.

Section 3. The bill includes a severability clause.

Section 4. Sets the effective date of the bill as July 1, 2018.

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

If yes, explain:	Click or tap here to enter text.
Is the change consistent with the agency's core mission?	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
Rule(s) impacted (provide references to F.A.C., etc.):	Click or tap here to enter text.

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

Proponents and summary of position:	<p>The following organizations are among those that endorse syringe exchange programs:</p> <ul style="list-style-type: none"> <li>• Florida Medical Association</li> <li>• Florida Osteopathic Medical Association</li> <li>• American Medical Association (AMA)</li> <li>• Association of State and Territorial Health Officials (ASTHO)</li> <li>• Centers for Disease Control and Prevention (CDC)</li> <li>• National Institute on Drug Abuse (NIDA)</li> <li>• National Institute of Health (NIH)</li> <li>• World AIDS Organization (WHO)</li> </ul> <p>Benefits to the healthcare system include reduction in disease transmission, wounds, blood infections, phlebitis, blood clots, and fewer acute episodes that demand significant, more costly health system resources. Benefits to the community include: reduction in needle-stick injuries and improper disposal of syringes in public places; protects health and safety of families, law enforcement and public workers. Benefits to the patient include improvement in health outcomes, empowers the individual with ability to administer preventative self-care and reduces stigma.</p>
Opponents and summary of position:	<p>Opponents support zero-tolerance drug policies and are concerned that mixed messages are being sent when needles and other paraphernalia are supplied, an implicit endorsement of drug use. Some communities worry that the drug users may pick up the syringes in their neighborhoods and stay there.</p>

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

If yes, provide a description:	The bill requires all pilot programs to submit a final report that describes the performance and outcomes of the pilot program and include a summary of the information in the annual reports for all pilot program years.
Date Due:	August 1, 2023
Bill Section Number(s):	2

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

Board:	Click or tap here to enter text.
Board Purpose:	Click or tap here to enter text.
Who Appoints:	Click or tap here to enter text.
Changes:	Click or tap here to enter text.
Bill Section Number(s):	Click or tap here to enter text.

**FISCAL ANALYSIS**

**1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT?** Y  N

Revenues:	Click or tap here to enter text.
Expenditures:	Click or tap here to enter text.
Does the legislation increase local taxes or fees? If yes, explain.	Click or tap here to enter text.
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?	Click or tap here to enter text.

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

Revenues:	Click or tap here to enter text.
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Expenditures:	Click or tap here to enter text.
Does the legislation contain a State Government appropriation?	Click or tap here to enter text.
If yes, was this appropriated last year?	Click or tap here to enter text.

**3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR? Y  N**

Revenues:	Click or tap here to enter text.
Expenditures:	Click or tap here to enter text.
Other:	Click or tap here to enter text.

**4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y  N**

If yes, explain impact.	Click or tap here to enter text.
Bill Section Number:	Click or tap here to enter text.

**TECHNOLOGY IMPACT**

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

If yes, describe the anticipated impact to the agency including any fiscal impact.	Click or tap here to enter text.
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**FEDERAL IMPACT**

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

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

Concerning the Department's role in operating or administering pilot programs throughout the state, it is unclear how the Department could effectively administer or operate programs if no state funds can be used to carry out these responsibilities. It would be difficult for the Department to administer pilot programs and not use state funds to conduct programs appropriately. Some areas of concern include the Department ability to receive reports, summarize and provide state level program updates or compose comprehensive reports of programs.

Currently, no data exists to estimate the potential fiscal impact of the pilot program. However, the CDC indicates that HIV prevention interventions, such as SEPs, are intended to prevent infection in people who are HIV- and HCV-negative. Such programs can be evaluated to determine the number of infections prevented that would have otherwise occurred had the intervention not been provided.

The lifetime treatment cost of an HIV infection can be used as a conservative threshold value for the cost of averting one infection. Currently, the lifetime treatment cost of an HIV infection is estimated at \$379,668 (in 2010 dollars). Therefore, a prevention intervention is deemed cost-saving if its cost-effectiveness ratio (cost of the intervention/number of infections averted) is less than \$379,668 per infection averted.

The bill also does not allow the Department to develop, adopt or eliminate rules, it would be highly beneficial to grant the Department rulemaking authority. Suggested language: "The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section."

The Department of Children and Families may see an increase in referrals to drug treatment programs from the syringe exchange programs.

Notes:

1 HIV/AIDS and Hepatitis Program, Florida Department of Health, revised 6/30/13, HIV Infection among Those with an Injection Drug Use-Associated Risk, Florida, 2012. Retrieved 11/13/17 from <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/co-infection.html>

2 HIV/AIDS and Hepatitis Program, Florida Department of Health, revised 6/30/13, HIV Infection among Those with an Injection Drug Use-Associated Risk, Florida, 2012. Retrieved 11/13/17 from <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/co-infection.html>

3 HIV/AIDS and Hepatitis Program, Florida Department of Health, revised 6/30/13, HIV Infection among Those with an Injection Drug Use-Associated Risk, Florida, 2012. Retrieved 11/13/17 from <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/co-infection.html>

4 University of Miami Miller School of Medicine IDEA Exchange, 11/14/17.

5 Centers for Disease Control and Prevention. "Syringe Exchange Programs --- United States, 2008." Morbidity and Mortality Weekly Report (MMWR) 11/19/10, 59(45);1488-1491, Retrieved 11/13/17 from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5945a4.htm>.

6 O'Neill, DL, Topolski, JM, Klinkenberg, DW, "Needle Exchange Programs, A Review of the Issues." Missouri Institute of Mental Health, 2004.

7 Hagan, H, Des Jarlais, DC, Friedman, SR, Purchase, D, Alter, M. "Reduction Risk of Hepatitis B and Hepatitis C among Injection Drug Users in the Tacoma Syringe Exchange Program." American Journal of Public Health, November 1995, Vol. 85, No. 11, pp 1531-1537.

8 Centers for Disease Control and Prevention. "HIV and VIRAL Hepatitis." Retrieved 11/13/17 from <https://www.cdc.gov/hiv/library/factsheets/index.html>

9 The Foundation for AIDS Research (amfAR). Fact Sheet: Federal Funding for Syringe Services Programs: Saving Money, Promoting Public Safety, and Improving Public Health. January 2013. Retrieved 11/13/17 from [http://www.amfar.org/uploadedFiles/On\\_The\\_Hill/Resources/fact%20sheet%204pg%20Syringe%20ExchangeD.pdf?n=1733](http://www.amfar.org/uploadedFiles/On_The_Hill/Resources/fact%20sheet%204pg%20Syringe%20ExchangeD.pdf?n=1733)

10 Kidorf, M, King, VL, Pierce, J, Kolodner, K, Brooner, RK. "Benefits of Concurrent Syringe Exchange and Substance Abuse Treatment Participation." *Journal of Substance Abuse Treatment*, April 2011; 40(3): 265-271. Retrieved 1/29/15 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3056913/>.

11 MMWR 10/19/10; amfAR 5/11.

12 The White House. National HIV/AIDS Strategy for the United States. July 2010. Retrieved 11/13/17 from <http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf>.

13 North American Syringe Exchange Network. US Syringe Exchange Program Database. Retrieved 11/13/17 from <http://www.nasen.org/programs/>.

14 MMWR 11/19/10.

15 114<sup>th</sup> Congress of the United States. "Consolidated Appropriations Act, 2016." Retrieved 11/13/17 from <https://www.congress.gov/114/bills/hr2029/BILLS-114hr2029enr.pdf>

16 Centers for Disease Control and Prevention. "Syringe Services Programs." Retrieved 11/13/2017 from <https://www.cdc.gov/hiv/risk/ssps.html>

17 Centers for Disease Control and Prevention. "HIV Cost Effectiveness." Retrieved 11/13/2017 from <http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/>

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**LEGAL - GENERAL COUNSEL'S OFFICE REVIEW**

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Issues/concerns/comments:	While it is clear that the department cannot use state funds to operate a pilot program, it seems unclear to what extent, if any, the department may use state funds to facilitate the establishment of a pilot program and to designate the operation of the program to an eligible entity, i.e., through the use of department staff and salary.
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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

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

2/19/19

Meeting Date

3660

Bill Number (if applicable)

783258

Amendment Barcode (if applicable)

Topic Infectious Disease Elimination Programs

Name Daphnee Sainvil

Job Title Legislative Policy Advisor

Address 100 S. Andrews Ave, Main Library, 8<sup>th</sup> Fl

Street

Ft. Lauderdale FL 33301

City

State

Zip

Phone 954-253-7320

Email dsainvi@broward.org

Speaking:  For  Against  Information

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

Representing Broward County Bd. of County Commissioners

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)

# APPEARANCE RECORD

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

2/19

Meeting Date

366

Bill Number (if applicable)

783258

Amendment Barcode (if applicable)

Topic \_\_\_\_\_

Name Claudia Davant

Job Title President - Adams St. Advocates

Address 205 S Adams St  
Street

Phone \_\_\_\_\_

Tallahassee FL 32301  
City State Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

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

Representing Broward County

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

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

2/19/19

Meeting Date

364

Bill Number (if applicable)

Topic Infectious Disease Elimination Programs

Amendment Barcode (if applicable)

Name Daphnee Sainvil

Job Title Legislative Policy Advisor

Address 100 S. Andrews Ave, Main Library, 8<sup>th</sup> Fl

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Street

Ft. Lauderdale

FL

33301

Email dsainvil@broward.org

City

State

Zip

Speaking:  For  Against  Information

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

Representing Broward County Bd. of County Commissioners

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)

APPEARANCE RECORD

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

2/19/2019

Meeting Date

3606

Bill Number (if applicable)

Topic Infectious Disease / Needle Exchange Program

Amendment Barcode (if applicable)

Name Jorge Chamizo

Job Title Attorney

Address 108 South Monroe Street

Phone (850) 681-0024

Tallahassee, FL 32301

Email jorge@flapartners.com

City State Zip

Speaking: [X] For [ ] Against [ ] Information

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

Representing North Broward Hospital District

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

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

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

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

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

2/19/19

Meeting Date

366

Bill Number (if applicable)

Topic Infectious Disease

Amendment Barcode (if applicable)

Name Doug Bell

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

Address 119 S. Monroe

Street

Phone 205 9000

TLH

City

State

Zip

Email doug.belle@midfirm.com

Speaking:  For  Against  Information

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

Representing AIDS Institute

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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

S-001 (10/14/14)

412 K - 10a

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/19/19

Meeting Date

366

Bill Number (if applicable)

Topic IDEA

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Dr  
Street

Phone 878-3056

Tallahassee FL 32301  
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 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.

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

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

2/19/19

Meeting Date

366

Bill Number (if applicable)

Topic Needle Exchange

Amendment Barcode (if applicable)

Name Mary Thomas

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

Address 8 H36 Piedmont Dr E

Phone PSO 2246496

Street

TLH FL 32308

Email \_\_\_\_\_

City

State

Zip

Speaking:  For  Against  Information

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

Representing Florida Medical Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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S-001 (10/14/14)

# APPEARANCE RECORD

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

2/19  
Meeting Date

SB 366  
Bill Number (if applicable)

Topic Needle exchange

Amendment Barcode (if applicable)

Name Monica Rodriguez

Job Title Partner / Ballard Partner

Address 201 E Park Avenue

Phone 850 766-6287

Tallahassee FL 32302

Email monica@ballardfl.com

City State Zip

Speaking:  For  Against  Information

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

Representing Broward County

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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# APPEARANCE RECORD

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

2/19  
Meeting Date

0346  
Bill Number (if applicable)

Topic Needle Exchange

Amendment Barcode (if applicable)

Name Kara Saintfleur

Job Title Contract Lobbyist

Address 401 SW 86th Ave  
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Phone 4/4518922

Pembroke FL 33074  
City State Zip

Email Kara@KSFandP.com

Speaking:  For  Against  Information

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

Representing League of Women Voters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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

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

2/19/19  
Meeting Date

SB366  
Bill Number (if applicable)

Topic Needle Exchange

Amendment Barcode (if applicable)

Name Lauren Rosenfeld

Job Title University of Miami Medical student

Address 690 SW 1<sup>st</sup> Ct 1205  
Street

Phone 503-260-6279

Miami, FL 33130  
City State Zip

Email lkr38@med.miami.edu

Speaking:  For  Against  Information

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

Representing University of Miami Miller School of Medicine

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)

2/19/2019  
Meeting Date

SB 366  
Bill Number (if applicable)

Topic Needle Exchange

Amendment Barcode (if applicable)

Name Jan Motz

Job Title FSU College of Medicine Student

Address 1817 W Call St Apt 64  
Street

Phone 407 540 6234

Tallahassee FL 32304  
City State Zip

Email jan12@med.fsu.edu

Speaking:  For  Against  Information

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

Representing Florida State University College of Medicine

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:** CS/SB 434

**INTRODUCER:** Health Policy Committee and Senator Harrell

**SUBJECT:** Ambulatory Surgical Centers

**DATE:** February 20, 2019      **REVISED:** \_\_\_\_\_

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

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

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**I. Summary:**

CS/SB 434 amends s. 395.002, F.S., to allow a patient to stay in an ambulatory surgical center (ASC) for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day.

The bill also amends s. 395.1005, F.S., to require the Agency for Health Care Administration (AHCA) in consultation with the Board of Medicine (BOM) and the Board of Osteopathic (BOOM) Medicine, to adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill provides an effective date of July 1, 2019.

**II. Present Situation:**

**Ambulatory Surgical Centers**

An ASC is a facility that is not a part of a hospital and which has the primary purpose of providing elective surgical care in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.<sup>1</sup>

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<sup>1</sup> Section 395.002(3), F.S.

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. As of January 2019, there are 458 ASCs and 308 licensed hospitals in Florida. Of the 308 licensed hospitals, 212 report providing hospital-based outpatient surgical services.<sup>2</sup>

Between April 2017 and March 2018, there were 3,049,558 visits to ASCs in Florida.<sup>3</sup> Hospital outpatient facilities accounted for 1,419,020 visits (46.5 percent) and freestanding ASCs accounted for 1,622,013 visits (53.5 percent). Freestanding ASC average charges range from \$3,516 to \$9,347 and hospital-based ASC average charges range from \$10,522 to \$34,291 for the same time period.<sup>4</sup> According to 2017 utilization data submitted to the AHCA, less than 5 percent of all outpatient surgical visits at hospitals and ASCs were for pediatric patients (age 0 to 17 years).<sup>5</sup>

Age Group	Visits	% of Visits
Age 0 (Less than 1 year old)	10,348	0.34%
1 – 4 years	48,802	1.60%
5 – 9 years	37,398	1.22%
10 – 14 years	25,958	0.85%
15 – 17 years	24,992	0.82%
Total Pediatrics	147,498	4.83%
Total All Ages	3,056,789	100%

### *ASC Licensure*

ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.<sup>6</sup> Applicants for ASC licensure must submit certain information to the AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Registration of articles of incorporation; and
- The applicant's zoning certificate or proof of compliance with zoning requirements.<sup>7</sup>

Upon receipt of an initial ASC application, the AHCA is required to conduct a survey to determine compliance with all laws and rules. Applicants are required to provide certain information during the initial inspection, including:

- Governing body bylaws, rules, and regulations;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and

<sup>2</sup> Agency for Health Care Administration, *Senate Bill 434 Analysis* (Jan. 24, 2019) (on file with the Senate Committee on Health Policy).

<sup>3</sup> Agency for Health Care Administration, *Florida Health Finder*, <http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx> (last viewed Feb. 14, 2017).

<sup>4</sup> Id.

<sup>5</sup> Id. note 4

<sup>6</sup> Sections 395.001-395.1065, F.S., and part II, ch. 408, F.S.

<sup>7</sup> Rule 59A-5.003(4), F.A.C.

- A comprehensive emergency management plan.<sup>8</sup>

### ***Rules for ASCs***

Pursuant to s. 395.1055, F.S., the AHCA is authorized to adopt rules for hospitals and ASCs. Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals, but the rules for all hospitals and ASCs must include minimum standards for ensuring that:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.

Rule 59A-5 of the Florida Administrative Code implements the minimum standards for ASCs. Those rules require policies and procedures to ensure the protection of patient rights.

### ***Staff and Personnel Rules***

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, laboratory services, and radiologic services. In providing these services, ACSs are required to have certain professional staff available, including:

- A qualified person responsible for the daily functioning and maintenance of the surgical suite;
- An anesthesiologist or other physician, or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician, or an anesthesiologist assistant under the direct supervision of an anesthesiologist, who must be in the center during the anesthesia and post-anesthesia recovery period until all patients are cleared for discharge;
- A registered professional nurse who is responsible for coordinating and supervising all nursing services;
- A registered professional circulating nurse for a patient during that patient's surgical procedure; and
- A registered professional nurse who must be in the recovery area at all times when a patient is present.<sup>9</sup>

### ***Infection Control Rules***

ASCs are required to establish an infection control program involving members of the medical, nursing, and administrative staff. The program must include written policies and procedures reflecting the scope of the infection control program. The written policies and procedures must

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<sup>8</sup> Rule 59A-5.003(5), F.A.C.

<sup>9</sup> Rule 59A-5.0085, F.A.C.

be reviewed at least every two years by the infection control program members. The infection control program must include:

- Surveillance, prevention, and control of infection among patients and personnel;
- A system for identifying, reporting, evaluating, and maintaining records of infections;
- Ongoing review and evaluation of aseptic, isolation, and sanitation techniques employed by the ASC; and
- Development and coordination of training programs in infection control for all personnel.<sup>10</sup>

### ***Emergency Management Plan Rules***

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency. The ASC must review the plan and update it annually.<sup>11</sup>

### ***Accreditation***

ASCs may seek voluntary accreditation by an accrediting organization whose standards are determined by the AHCA to be comparable to state licensure requirements. The AHCA is required to conduct a licensure inspection survey for non-accredited ASCs. The AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. The AHCA is required to conduct annual validation inspections on a minimum of five percent of the ASCs which were inspected by an accreditation organization.<sup>12</sup>

The AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.<sup>13</sup>

### ***Medicare Requirements***

ASCs are required to have an agreement with the federal Centers for Medicare & Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. The CMS defines “ASC” as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and for whom the expected duration of services would not exceed 24 hours following an admission.<sup>14</sup>

The CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body or licensed by a state agency and if the CMS determines that such accreditation or licensure provides reasonable assurance that the conditions

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<sup>10</sup> Rule 59A-5.011, F.A.C.

<sup>11</sup> Rule 59A-5.018, F.A.C.

<sup>12</sup> Rule 59A-5.004, F.A.C.

<sup>13</sup> Id.

<sup>14</sup> 42 C.F.R. s. 416.2

for coverage are met.<sup>15</sup> All of the CMS conditions for coverage requirements are specifically required in Rule 59A-5 of the Florida Administrative Code, and apply to all ASCs in Florida. The conditions for coverage require ASCs to have a:

- Governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- Quality assessment and performance improvement program;
- Transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- Disaster preparedness plan;
- Organized medical staff;
- Fire control plan;
- Sanitary environment;
- Infection control program; and
- Procedure for patient admission, assessment and discharge.

### **American College of Surgeons: Optimal Resources for Children's Surgical Care v. 1**

The American College of Surgeons (ACS) was founded in 1913 on the basic principles of improving the care of surgical patients and strengthening the education of surgeons. With these principles in mind, the ACS Children's Surgery Verification Committee was created in 2015 to continue, on a permanent basis within the ACS, the work of the ad hoc Task Force for Children's Surgical Care. This group was first convened in 2012. The recommendations of this task force are contained in the document *Optimal Resources for Children's Surgical Care v. 1*.<sup>16</sup>

Specific to ASCs, the report found that:

Children's ambulatory surgical centers must have treatment protocols for resuscitation, transfer protocols, and data reporting and must participate in systems for performance improvement. Children's ambulatory centers must have good working relationships and be fully integrated with a Level I, II, or III inpatient children's surgical center<sup>17</sup> to be verified in this program... It is essential for the children's ambulatory surgical center to have the involvement of one or more committed and appropriately trained pediatric health care providers to provide leadership and sustain the integration with other relevant components of an integrated children's health care system.<sup>18</sup>

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<sup>15</sup> 42 C.F.R. s. 416.26(a)(1)

<sup>16</sup> American College of Surgeons, *Optimal Resources for Children's Surgical Care v.1*, (released in 2015) available at [https://www.facs.org/~media/files/quality%20programs/csv/acs%20csv\\_standardsmanual.ashx](https://www.facs.org/~media/files/quality%20programs/csv/acs%20csv_standardsmanual.ashx) (last visited on Feb. 14, 2019).

<sup>17</sup> The report details such relationship on page 19. "*Ideally, one hospital, typically a Level I center, would be looked upon as the resource leader within a given region. This hospital would serve as a resource to all other hospitals within the system. Outside major population centers, a Level II center may serve as the lead hospital for extended geographic areas. In some rural areas, where population densities are low and distances great, a Level III center may be the only resource for miles. Ambulatory surgical centers are considered separately but in any system will have clearly identified relationships and demonstrable integration with one or more verified Level I, II, or III children's inpatient facilities.*" Id.

<sup>18</sup> Id.

**III. Effect of Proposed Changes:**

CS/SB 434 amends s. 395.002, F.S., to allow a patient to stay in an ASC for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day. This change complies with federal CMS requirements for an ASC.<sup>19</sup>

The bill also amends s. 395.1005, F.S., to require the AHCA to, in consultation with the BOM and the BOOM, adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The rules must be consistent with the American College of Surgeons' 2015 standards document entitled "Optimal Resources for Children's Surgical Care."

The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill provides an effective date of July 1, 2019.

**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.

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<sup>19</sup> 42 C.F.R. s. 416.2.

**B. Private Sector Impact:**

CS/SB 434 may have an indeterminate positive fiscal impact on patients seeking surgical services if such patients are able to obtain the surgical services at an ASC for lower costs than the costs of receiving comparable services at a hospital.

The bill may have an indeterminate negative fiscal impact on hospitals if more patients choose to have their surgical procedures performed in an ASC.

**C. Government Sector Impact:**

The bill has an indeterminate fiscal impact on the Florida Medicaid program.

ASCs are reimbursed by Medicaid through an outpatient prospective payment reimbursement methodology called Enhanced Ambulatory Patient Groups (EAPGs). EAPGs categorize outpatient services and procedures into groups for payment based on clinical information present on an outpatient claim. ASCs are not currently reimbursed for an overnight stay. If ASCs are allowed to bill for an overnight stay through the EAPG system, there could potentially be an increase in the volume of ASC claims and there is the potential for an increase in ASC expenditures. However, these potential increased claim volumes and expenditures may be offset due to a decrease in claims and expenditures for services provided in the outpatient or inpatient hospital setting.<sup>20</sup>

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 395.002 and 395.1055.

**IX. Additional Information:****A. Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)**CS by Health Policy on February 19, 2019:**

The CS revises the bill's requirement for the AHCA to adopt rules related to pediatric care in ASCs and eliminates the requirement that the AHCA adopt rules regulating practitioners providing such care. Additionally the CS eliminates specified items that the rules must address.

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<sup>20</sup> *Supra* note 2



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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719818

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/19/2019	.	
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The Committee on Health Policy (Harrell) recommended the following:

**Senate Amendment (with title amendment)**

Delete lines 41 - 52

and insert:

(3) (a) The agency, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, shall adopt rules that establish requirements to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The rules must be consistent with the American College of Surgeons' 2015 standards document entitled "Optimal



719818

11 Resources for Children's Surgical Care" and must establish  
12 minimum standards for pediatric patient care in ambulatory  
13 surgical centers.

14

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

16 And the title is amended as follows:

17       Delete lines 8 - 13

18 and insert:

19       adopt rules that establish requirements related to the  
20       delivery of surgical care to children in ambulatory  
21       surgical centers, in accordance with specified  
22       standards;

By Senator Harrell

25-00536-19

2019434\_\_

1                                   A bill to be entitled  
2       An act relating to ambulatory surgical centers;  
3       amending s. 395.002, F.S.; revising the definition of  
4       the term "ambulatory surgical center"; amending s.  
5       395.1055, F.S.; requiring the Agency for Health Care  
6       Administration, in consultation with the Board of  
7       Medicine and the Board of Osteopathic Medicine, to  
8       adopt rules that establish requirements for  
9       practitioners and facilities related to the delivery  
10      of surgical care to children in ambulatory surgical  
11      centers, in accordance with specified standards;  
12      requiring that the rules establish minimum standards  
13      for certain pediatric patient care practices;  
14      specifying that ambulatory surgical centers may  
15      provide certain procedures only if authorized by  
16      agency rule; providing an effective date.

17  
18 Be It Enacted by the Legislature of the State of Florida:

19  
20       Section 1. Subsection (3) of section 395.002, Florida  
21       Statutes, is amended to read:

22       395.002 Definitions.—As used in this chapter:

23       (3) "Ambulatory surgical center" means a facility the  
24       primary purpose of which is to provide elective surgical care,  
25       in which the patient is admitted to and discharged from such  
26       facility within 24 hours ~~the same working day and is not~~  
27       ~~permitted to stay overnight~~, and which is not part of a  
28       hospital. However, a facility existing for the primary purpose  
29       of performing terminations of pregnancy, an office maintained by

25-00536-19

2019434\_\_

30 a physician for the practice of medicine, or an office  
31 maintained for the practice of dentistry may not be construed to  
32 be an ambulatory surgical center, provided that any facility or  
33 office which is certified or seeks certification as a Medicare  
34 ambulatory surgical center shall be licensed as an ambulatory  
35 surgical center pursuant to s. 395.003.

36 Section 2. Present subsections (3) through (12) of section  
37 395.1055, Florida Statutes, are redesignated as subsections (4)  
38 through (13), respectively, and a new subsection (3) is added to  
39 that section, to read:

40 395.1055 Rules and enforcement.—

41 (3) (a) The agency, in consultation with the Board of  
42 Medicine and the Board of Osteopathic Medicine, shall adopt  
43 rules that establish requirements for practitioners and  
44 facilities to ensure the safe and effective delivery of surgical  
45 care to children in ambulatory surgical centers. The rules must  
46 be consistent with the American College of Surgeons' 2015  
47 standards document entitled "Optimal Resources for Children's  
48 Surgical Care" and must establish minimum standards for  
49 pediatric patient care treatment practices, including at least  
50 all of the following: surgical risk assessment; anesthetic care;  
51 resuscitation; transfer agreements; and training and  
52 certification requirements for pediatric health care providers.

53 (b) Ambulatory surgical centers may provide operative  
54 procedures that require a length of stay past midnight on the  
55 day of surgery for children younger than 18 years of age only if  
56 the agency authorizes the performance of such procedures by  
57 rule.

58 Section 3. This act shall take effect July 1, 2019.



# 2019 AGENCY LEGISLATIVE BILL ANALYSIS

**AGENCY:** Agency for Health Care Administration

<u>BILL INFORMATION</u>	
<b>BILL NUMBER:</b>	SB 434
<b>BILL TITLE:</b>	Ambulatory Surgical Centers
<b>BILL SPONSOR:</b>	Sen. Harrell
<b>EFFECTIVE DATE:</b>	July 1, 2019

<u>COMMITTEES OF REFERENCE</u>
1)
2)
3)
4)
5)

<u>CURRENT COMMITTEE</u>	
<u>SIMILAR BILLS</u>	
<b>BILL NUMBER:</b>	
<b>SPONSOR:</b>	

<u>PREVIOUS LEGISLATION</u>	
<b>BILL NUMBER:</b>	SB 250
<b>SPONSOR:</b>	Sen. Steube
<b>YEAR:</b>	2018
<b>LAST ACTION:</b>	Died in Second Committee of Reference

<u>IDENTICAL BILLS</u>	
<b>BILL NUMBER:</b>	
<b>SPONSOR:</b>	
<b>Is this bill part of an agency package?</b>	
Y ___ N _x_	

<u>BILL ANALYSIS INFORMATION</u>	
<b>DATE OF ANALYSIS:</b>	01/24/2019
<b>LEAD AGENCY ANALYST:</b>	Jessica Munn
<b>ADDITIONAL ANALYST(S):</b>	Jack Plagge
<b>LEGAL ANALYST:</b>	
<b>FISCAL ANALYST:</b>	

# POLICY ANALYSIS

## 1. EXECUTIVE SUMMARY

The bill changes the allowable length of stay in an ambulatory surgical center (ASC) by requiring patients be discharged within 24 hours rather than within the same working day, thus allowing patients to stay overnight. The bill also grants rulemaking authority to the Agency to establish standards for pediatric surgery performed in ASCs. The amended discharge time will apply to pediatric patients unless the Agency's rules say otherwise. The bill will have an indeterminate fiscal impact on the Florida Medicaid program. The bill provides an effective date of July 1, 2019.

## 2. SUBSTANTIVE BILL ANALYSIS

### 1. PRESENT SITUATION:

An ASC is a facility, that is not part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.

Chapter 395, Part I, F.S., is the licensing statute for ASCs. Chapter 408, Part II, F.S., is the core licensing statute for all licensed programs regulated by the Agency. Together, they contain the minimum requirements for the initial licensure and continued operation of health care providers. Standards for surgery in ASCs are in rule Chapter 59A-5, F.A.C. The standards require the governing board of each licensed facility to establish by-laws, policies, and procedures regarding the activities of the medical staff, including granting privileges, delineating the surgical procedures to be performed, and the type of patient (age, risk factors) to be accepted. The governing board is responsible for assuring the surgeons at the ASC are licensed and credentialed appropriately for the procedures and types of patients.

In Florida, outpatient surgeries are conducted in three facility types: hospitals, ASCs, and physician offices/clinics with a valid office surgery registration (office-based surgery). As of January 2019, there are 458 ASCs and 308 licensed hospitals in Florida. Of the 308 licensed hospitals, 212 report providing hospital based outpatient surgical services. Office-based surgery must register with the Department of Health (DOH), Board of Medicine and meet certain qualifications set by the Board. According to the DOH's license search web page, <http://ww2.doh.state.fl.us/IRM00PRAES/PRASLIST.ASP>, there are currently 618 active office-based surgery registrations.

According to 2017 utilization data submitted to the Agency, less than 5% of all outpatient surgical visits at hospitals and ASCs were for pediatric patients (age 0 to 17 years).

Source: <http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=0>

Age Group	Visits	% of Visits
Age 0 (Less than 1 year old)	10,348	0.34%
1 – 4 years	48,802	1.60%
5 – 9 years	37,398	1.22%
10 – 14 years	25,958	0.85%
15 – 17 years	24,992	0.82%
Total Pediatrics	147,498	4.83%
Total All Ages	3,056,789	100%

### 2. EFFECT OF THE BILL:

The definition of ambulatory surgical center (ASC) is amended in s. 395.002, F.S., by changing the requirement from discharging a patient on the same working day to discharging a patient within 24 hours of admission. This change matches the current definition of an ASC in the Medicare requirements. This change allows facilities to remain open in case their final patients of the day are not ready for discharge by midnight. The extended recovery time may allow for more complex surgeries and will allow physicians to begin surgeries later in the day.

ASCs are reimbursed by Medicaid through an outpatient prospective payment reimbursement methodology called Enhanced Ambulatory Patient Groups (EAPGs). EAPGs categorize outpatient services and procedures into groups for payment based on clinical information present on an outpatient claim. ASCs are not currently reimbursed, specifically, for an overnight stay. If ASCs are allowed to bill for an overnight stay through the EAPG system, there could potentially be an increase in the volume of ASC claims and there is the potential for an increase in expenditures. However, these potential increased claim volumes and expenditures may be offset due to a decrease in claims and expenditures for

services provided in the outpatient or inpatient hospital setting. As a result, the bill has an indeterminate fiscal impact on the Florida Medicaid program.

The bill amends s. 395.1055, F.S., to include rulemaking authority to establish standards for pediatric surgery performed in ASCs, requiring the Agency with the Department of Health Board of Medicine and the Board of Osteopathic Medicine to develop rules consistent with the American College of Surgeons' 2015 standards. The bill lists the following specific topics for rule writing: surgical risk assessment; anesthetic care; resuscitation; transfer agreements; and training and certification requirements for pediatric health care providers. The Agency must include an allowance in rule in order for ASCs to keep a pediatric patient past midnight.

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

If yes, explain:	Lines 41 through 52 requires the Agency, in consultation with DOH, to write rules related to surgical procedures for pediatric patients in an ASC.
Is the change consistent with the agency's core mission?	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
Rule(s) impacted (provide references to F.A.C., etc.):	59A-5, F.A.C.

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

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

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

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

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

Board:	N/A
Board Purpose:	N/A
Who Appointments:	N/A
Appointee Term:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

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## FISCAL ANALYSIS

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**1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y  N**

Revenues:	N/A
Expenditures:	N/A



Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

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

Revenues:	N/A
Expenditures:	ASCs are reimbursed by Medicaid through an outpatient prospective payment reimbursement methodology called Enhanced Ambulatory Patient Groups (EAPGs). EAPGs categorize outpatient services and procedures into groups for payment based on clinical information present on an outpatient claim. ASCs are not currently reimbursed, specifically, for an overnight stay. If ASCs are allowed to bill for an overnight stay through the EAPG system, there could potentially be an increase in the volume of ASC claims and there is the potential for an increase in expenditures. However, these potential increased claim volumes and expenditures may be offset due to a decrease in claims and expenditures for services provided in the outpatient or inpatient hospital setting. As a result, the bill has an indeterminate fiscal impact on the Florida Medicaid program.
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 \_\_\_ N X

If yes, describe the anticipated impact to the agency including any fiscal impact.	N/A
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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.	N/A
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**ADDITIONAL COMMENTS**

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**None**

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

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Issues/concerns/comments:	
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# APPEARANCE RECORD

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

2/19/19

Meeting Date

SB 434

Bill Number (if applicable)

Topic   Ambulatory Surgical Centers  

Amendment Barcode (if applicable)

Name   Demetrius Minor  

Job Title   Dir. of Coalitions  

Address \_\_\_\_\_

Street

Phone   727-270-1407  

City

State

Zip

Email   dminor@afphq.org  

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

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

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

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

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

2/19/2019

SB 434

Meeting DateBill Number (if applicable)Topic Ambulatory Surgical CentersAmendment Barcode (if applicable)Name Zayne SmithJob Title Associate State DirectorAddress 200 W. College AvePhone 850-228-4243StreetTallahasseeFL32301Email zsmith@aarp.orgCityStateZipSpeaking:  For  Against  InformationWaive Speaking:  In Support  Against  
*(The Chair will read this information into the record.)*Representing AARP FloridaAppearing at request of Chair:  Yes  NoLobbyist registered with Legislature:  Yes  No

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

***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)

2-19-2019

Meeting Date

SB 434

Bill Number (if applicable)

Topic ASC's

Amendment Barcode (if applicable)

Name Michael Madewell

Job Title Administrator - Panama City Surgery

Address 1800 Jenks Ave

Phone 850-769-3191

Street

Panama City FL 32405

City

State

Zip

Email mike@pcsurgery.org

Speaking:  For  Against  Information

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

Representing Panama City Surgery 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)

# APPEARANCE RECORD

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

2/19/19

Meeting Date

439

Bill Number (if applicable)

Topic ASC

Amendment Barcode (if applicable)

Name Chris Nuland

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

Address 1000 Riverside Ave #240

Phone 904-233-3051

Street

Jax, FL

Email nulandlaw@aol.com

City

State

Zip

Speaking:  For  Against  Information

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

Representing Florida Chapter, American College of 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.

APPEARANCE RECORD

Feb 19, 19

Meeting Date

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

434

Bill Number (if applicable)

Topic ASC

Amendment Barcode (if applicable)

Name Toni Large

Job Title

Address PO Box 1737

Phone (850) 556-1461

Tallahassee FL 32308

Email toni@sulaw.net

Street City State Zip

Speaking: [X] For [ ] Against [ ] Information

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

Representing Florida Orthopedic Society

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

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

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

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# Health Care Certificate of Need

**Molly McKinstry**  
**Deputy Secretary**  
**Agency for Health Care Administration**

Senate Health Care Committee  
February 19, 2019





# Certificate of Need

- Certificate of Need (CON) is a population based health planning program that tries to direct new development to areas of greatest need.
- CON began as a required federal program in 1974.
- Florida CON became state-only in 1982.
- 35 states have a CON program.



# Certificate of Need

- CONs are required for new hospitals, nursing homes, hospices and intermediate care facilities for the developmentally disabled.
- CON includes
  - Competitive batched reviews
  - Expedited reviews
  - Exemptions
  - Annual monitoring of CON conditions
  - Biannual publications of utilization of services

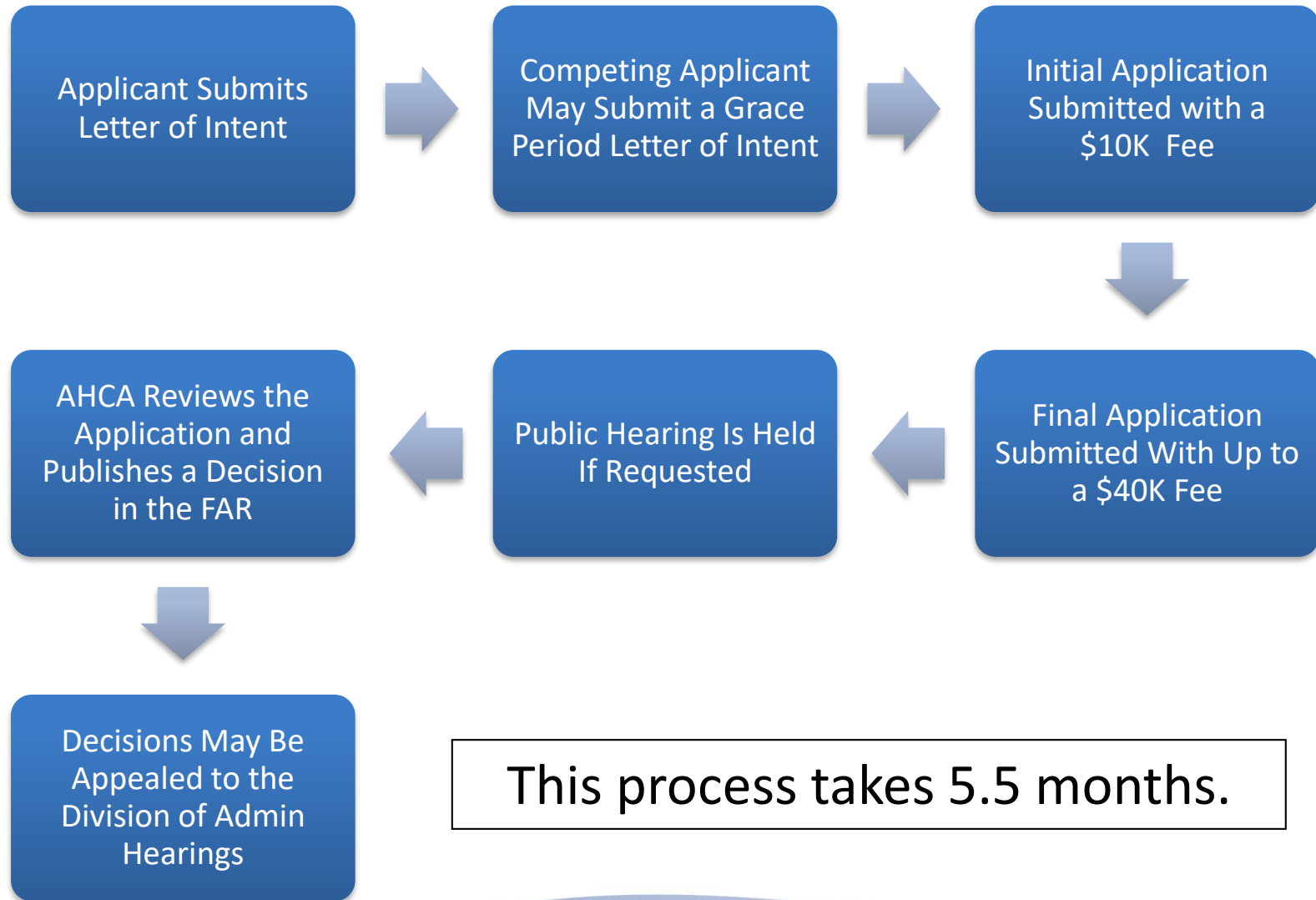


# CON Program – Fixed Need Pool

- Have Fixed Need Pools - Hospice, Nursing Homes, Neonatal Intensive Care Units (NICU) II and NICU III, Comprehensive Medical Rehabilitation (CMR), Pediatric Catheterization and Pediatric Open Heart Surgery, Psychiatric, and Substance Abuse
- Need Calculation
  - Population for the identified service area (depending on the service this can be regional, district, county or ZIP code based)
  - Considers the utilization of existing services (occupancy or penetration rates) to determine whether additional services are needed for the identified service areas
  - For NICU services, the calculation includes birth data supplied by the Department of Health (DOH)
  - For hospices, the calculation includes death data supplied by DOH
- No Fixed Need Pool
  - Intermediate Care Facilities for the Developmentally Disabled, inpatient hospice, acute care hospitals, long-term care hospital, and transplant programs



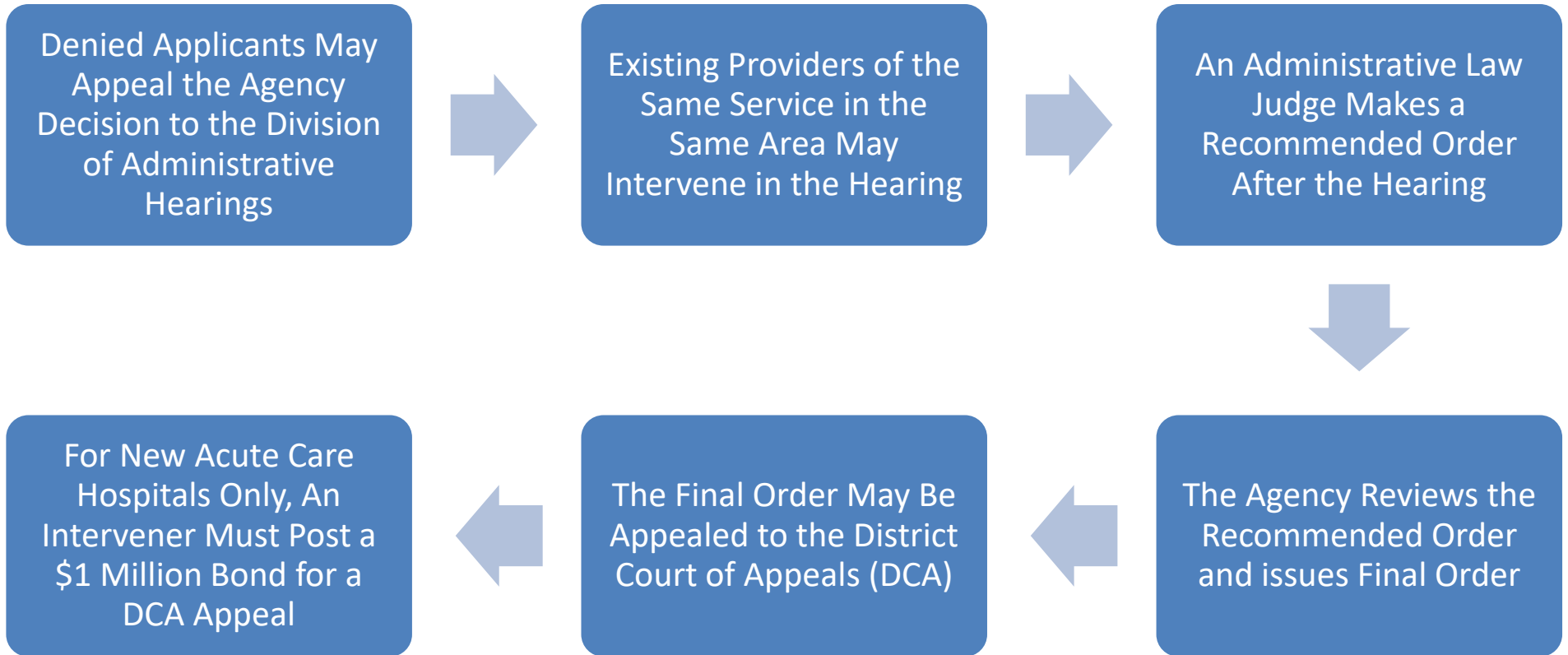
# CON Batched Competitive Reviews



This process takes 5.5 months.



# CON Appeals



This process takes 1 to 2 years.



# Hospital CON

- Competitive Review
  - New general acute care or long-term care hospitals
  - Hospital replacement more than one mile
  - New units for Comprehensive Medical Rehabilitation (CMR), Neonatal Intensive Care Unit (NICU), organ transplant, or pediatric cardiovascular services
- Exemption
  - NICUs in hospitals with large numbers of births
  - Adult and child/adolescent psychiatric beds
  - Substance abuse beds
  - Adding CMR beds
- Notification
  - Adding acute care beds
  - Hospital-based skilled nursing units
  - Hospital replacement within one mile



# Nursing Home CON

- Competitive Review (Moratorium 2001-2014)
  - New community nursing homes
  - Adding community nursing beds
- Expedited Review
  - Nursing home replacement within 30 miles with conditions
  - Moving a portion of a nursing home's beds within 30 miles to add to an existing nursing home or create a new nursing home



# Nursing Home CON

- Exemption
  - Nursing homes may add 10 beds or 10%, if 92% occupancy\* and no serious deficiencies
  - Gold Seal nursing homes may add 20 beds or 10%, if 92% occupancy\*
    - \*May add again if 92% occupancy 12 months after new beds are licensed
  - Add 30 beds or 25% when building a replacement nursing home
  - New State Veteran's Affairs nursing home
  - Nursing home replacement within five miles in the same sub-district
  - Move nursing home beds between facilities with shared controlling interest same sub-district
  - Prior to implementation of a CON:
    - Combine multiple CONs in the same sub-district into one facility
    - Division of one or more CONs into separate facilities in the same sub-district





# Hospice CON

- Competitive Review
  - New hospice
  - New hospice inpatient facility
  - Adding a new service area to a hospice
- Notification
  - Adding inpatient hospice beds to an existing inpatient hospice



# Intermediate Care Facility for Developmentally Disabled (ICF-DD)

- Competitive Review
  - New ICF-DD
  - Adding ICF-DD beds
- Notification
  - Replacement of an ICF-DD within one mile



# CON Regulatory Authority

- CON regulates program entry and sets standards for program establishment, including many tertiary services such as NICU, CMR, transplants and pediatric cardiac services.
- A CON does not impose standards once implemented and cannot be revoked unless a program has ended or fails to renew license.
- During the application process, a program can self-impose a condition for approval which will be monitored on an annual basis once a CON has been implemented.



# CON Condition Monitoring

- CON holders commit to providing certain services or certain levels of a service
- The most common CON condition is an agreement by a hospital to serve a certain level of Medicaid residents
  - Penalties for failure to meet nursing home Medicaid conditions were eliminated
- CON holders report annually

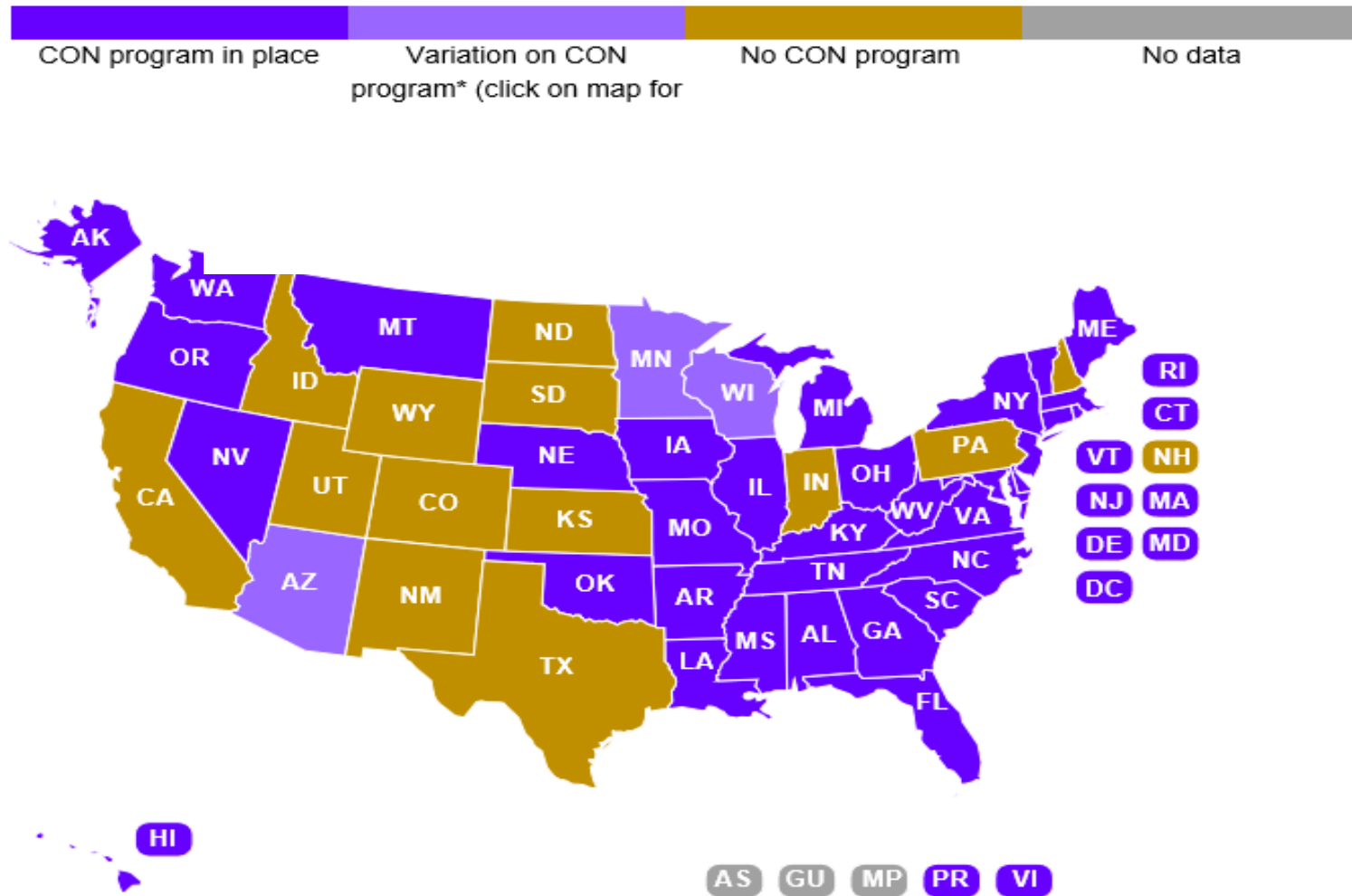


# How Florida Compares

- Nationally 31 services subject to CON in various states.
- Florida requires CON for 10 of 31 services.
- Regulated services that require CON are new hospitals, specialty hospital beds and services, ICF-DDs, nursing homes and hospices.
- Equipment costs, medical buildings, regular procedures (i.e. lithotripsy, adult cardiac catheterization), outpatient services, assisted living facilities, and home health agencies are not regulated by the CON program as they are in other states.



# CERTIFICATE OF NEED STATE LAWS



Source: NCSL, August 2016

\*Indiana Passed Legislation in 2018 to Establish CON



# CON Programs in Other States

## CON “Light” States

- Arizona
  - No CON program, but they have a planning approval process in place for ambulances and ambulance services
- Louisiana
  - Approval process before becoming a licensed assisted living facility

## CON “Heavy” States

- Vermont and District of Columbia
  - Majority of all facilities and services including major medical equipment, hospital beds, home health, obstetrics and ultrasound
- Alabama
  - Major medical equipment, obstetrics, nursing homes, open heart surgery, outpatient services, dialysis



# CON Timeline in Florida

1973	Certificate of Need created
1982	Elimination of local Health System Agencies--eliminated local CON review
1987	<u>CON eliminated:</u> Obstetric services Capital expenditure of inpatient projects under \$1 million Major medical equipment reclassified as equipment which costs more than \$1 million and which has been approved by the FDA for less than three years Outpatient services <u>CON expanded:</u> Specified tertiary services Statutory authority to levy fines for non-compliance of conditions
1988	Rules promulgated specify a list of tertiary services
1997	<u>CON eliminated:</u> Acquisition of medical equipment, regardless of cost





# CON Timeline in Florida

2000	Exemption authorized for increase of up to 10 beds or 10 percent of a hospital's or nursing home's licensed capacity <u>CON eliminated:</u> Cost overruns of approved projects Home health agencies
2001	CON moratorium established for new community nursing home beds
2003	<u>CON eliminated:</u> Rural hospitals when specific criteria is met
2007	<u>CON eliminated:</u> Hospital burn units - moved regulation to licensure Adult cardiac catheterization and adult open heart surgery services - moved regulation to licensure

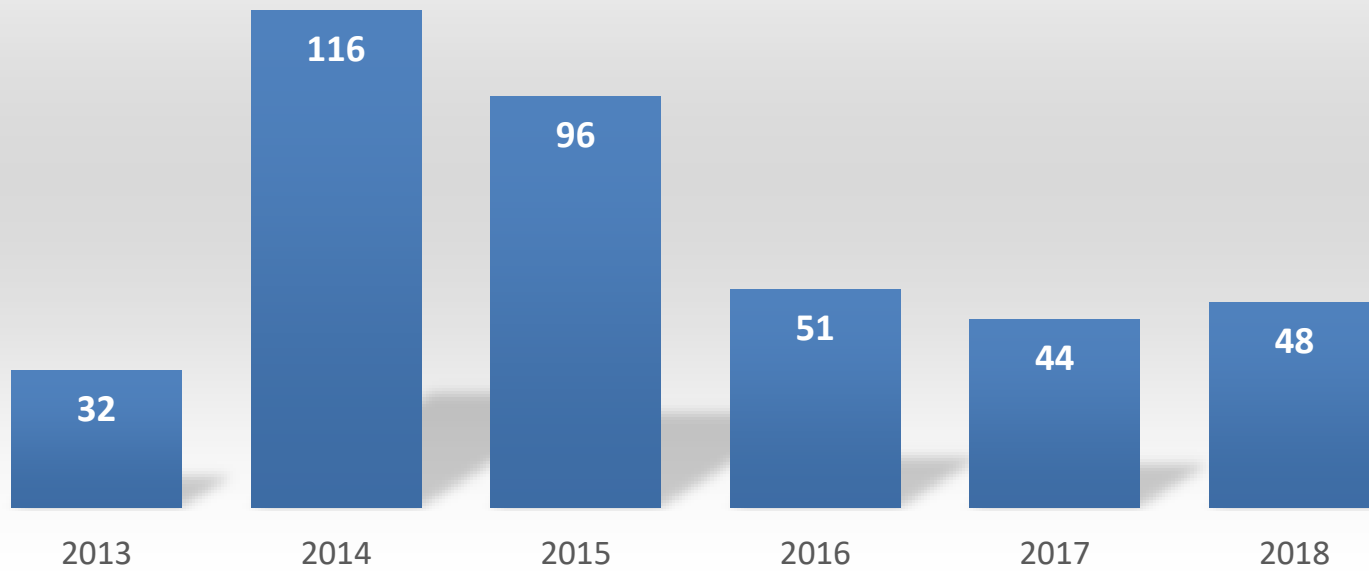


# CON Timeline in Florida

<b>2008</b>	Streamlined the approval process for new acute care hospitals
<b>2011</b>	Eliminated authority to fine community nursing home beds for failure to meet Medicaid conditions
<b>2013</b>	Modified requirements to allow deed restricted communities to apply for nursing homes through expedited review
<b>2014</b>	CON moratorium for new community nursing home beds lifted with limit on new community nursing home beds as of cycle approving statewide total of 3,750 beds Published need for new community nursing home beds for the first time since 1999 Modified requirements to allow maternity beds in children's hospitals under certain conditions
<b>2016</b>	Reached limit of new community nursing home beds – effective moratorium on community nursing home beds
<b>2017</b>	2016 Restriction on new community nursing home beds repealed



## CON Applications Received



# CON Processing

	2013	2014	2015	2016	2017	2018
<b>CON Applications Received</b>	32	116	96	51	44	48
<b>CON Applications Reviewed</b>	24	25	149	47	42	45
<b>CON Condition Compliance Reports</b>	617	696	673	669	663	659
<b>CON Exemptions</b>	17	31	49	26	32	37



# THANK YOU

**For more information:**

<http://ahca.myflorida.com/>

[http://ahca.myflorida.com/MCHQ/CON\\_FA/](http://ahca.myflorida.com/MCHQ/CON_FA/)





# CourtSmart Tag Report

Room: KN 412

Case:

Type:

Caption: Senate Health Policy Committee

Judge:

Started: 2/19/2019 10:02:51 AM

Ends: 2/19/2019 11:27:56 AM

Length: 01:25:06

10:02:50 AM Meeting called to order  
10:02:56 AM Roll Call. Quorum is present  
10:03:21 AM Comments from Chair  
10:03:51 AM Tab 1 - SB 302 by Senator Brandes - Non Emergency Medical Transportation Services  
10:05:00 AM Questions?  
10:05:14 AM Senator Rouson  
10:05:22 AM Chair  
10:05:27 AM Senator Rouson  
10:05:41 AM Senator Brandes  
10:05:51 AM Senator Cruz  
10:07:08 AM Senator Brandes  
10:07:13 AM Senator Cruz  
10:07:49 AM Senator Brandes  
10:08:34 AM Chair  
10:08:43 AM Amendment 388104 by Senator Brandes  
10:09:16 AM Chair  
10:09:56 AM Questions of amendment?  
10:10:02 AM Senator Hooper  
10:10:35 AM Senator Brandes  
10:11:06 AM Senator Hooper  
10:11:41 AM Senator Brandes  
10:11:51 AM Chair  
10:12:23 AM Senator Mayfield  
10:12:32 AM Senator Brandes  
10:13:27 AM Senator Mayfield  
10:14:27 AM Senator Brandes  
10:14:33 AM Senator Mayfield  
10:14:40 AM Senator Brandes  
10:15:42 AM Chair  
10:15:45 AM Questions on amendment? None  
10:15:48 AM Public Testimony  
10:15:58 AM Cari Roth, FL Ambulance Association, Lee, Manatee, Charlotte Counties speaking against amendment  
10:17:22 AM Chair  
10:17:57 AM Questions? None  
10:18:01 AM Jorge Chamizon, Attorney, Uber Technologies, waives in support  
10:18:09 AM Audrey Brown, CEO, Fla. Association of Healthplans, speaking for the amendment  
10:19:24 AM Chair  
10:20:19 AM Debate on amendment?  
10:20:27 AM Senator Hooper  
10:21:36 AM Senator Brandes to close on amendment 388104  
10:22:56 AM Chair. All those in favor of the amendment ? The yeas have it.  
10:23:06 AM Chair, back on bill as amended  
10:23:11 AM Back on bill as amended  
10:23:13 AM Ron Watson, Lobbyist, Florida Renal Coalition, waives in support  
10:23:19 AM Audrey Brown, CEO, FL Association of Healthplans, waives in support  
10:23:23 AM Christin R. Camera, Legislative Fellow, Institute for Justice, waives in support  
10:23:29 AM Cari Roth, FI Ambulance Association, Lee, Manatee, Charlotte Counties, waive in opposition  
10:23:37 AM Debate on bill as amended?  
10:23:44 AM Chair  
10:24:07 AM Senator Brandes waives close  
10:24:14 AM Roll call - favorable as CS/SB 302  
10:24:48 AM Tab 2 - SB 592 by Senator Albritton - Prescription Drug Monitoring Program

10:26:07 AM Questions? None  
10:26:16 AM Zane Smith, Associate State Director, AARP, waives in support  
10:26:21 AM Stephen Winn - Florida Osteopathic Association, waives in support  
10:26:27 AM Mary Thomas, Fl. Medical Association, waives in support  
10:26:34 AM Paul Ledford, Florida Hospice Association, waives in support  
10:26:43 AM Debate? None  
10:26:46 AM Chair  
10:27:03 AM Senator Albritton waives to close  
10:27:23 AM Chair  
10:27:25 AM Roll Call - SB 592 - favorable  
10:27:44 AM Tab 3 - SB 354 by Senator Muntford - Immunization Registry  
10:29:32 AM Chair  
10:29:36 AM Questions  
10:29:40 AM Senator Diaz  
10:29:44 AM Senator Montford  
10:29:52 AM Chair  
10:29:56 AM Senator Diaz  
10:30:08 AM Chair  
10:30:11 AM Questions? None  
10:30:17 AM Dr. Paul Robinson, M.D, F.A. A.P., President, Florida Chapter of the AAP, waives in support  
10:30:40 AM Steve Winn, Exec. Director, Fla. Osteopathic Medical Association, waives in support  
10:30:44 AM Chair  
10:30:48 AM Debate? None  
10:30:52 AM Senator Montford waives to close  
10:31:00 AM Roll call SB 354 - Favorable  
10:31:28 AM Tab 4 - SB 366 by Senator Braynon - Infectious Disease Elimination  
10:31:49 AM Strike all amendment 783258 by Senator Braynon  
10:34:38 AM Chair  
10:35:39 AM Questions on amendment?  
10:35:45 AM Senator Bean  
10:36:16 AM Senator Braynon  
10:36:39 AM Senator Diaz  
10:36:48 AM Senator Braynon  
10:37:16 AM Chair  
10:37:54 AM Questions? None  
10:37:58 AM Public Testimony on amendment 783258  
10:38:05 AM Daphnee Sainvill, Legislative Policy Advisor, Broward County Board of County Commissioners, waives in support  
10:38:14 AM Claudia Davant, President Adams Street Advocates. waives in support  
10:38:19 AM Debate on amendment?  
10:38:27 AM Senator Baxley  
10:39:11 AM Chair  
10:40:16 AM Senator Bryson waives to close  
10:41:00 AM All in favor of strike all amendment 783258 - favorable  
10:41:08 AM Back on the bill as amended  
10:41:16 AM Dephnee Sainvil, Legislative Policy Advisor, - to speak in support of bill  
10:42:24 AM Jorge Chamizo, Attorney, North Broward Hospital District, waives in support  
10:42:32 AM Doug Bell, Aids Institute, waives in support  
10:42:37 AM Steve Winn, Exec. Director, FI Osteopathic Medical Association, waives in support  
10:42:41 AM May Thomas, FMA - waives in support  
10:42:50 AM Monica Rodriguez, Broward County, waives in support  
10:43:09 AM Katia Saimtfier, Contact Lobbyist, League of Women's Voters, speaking in support  
10:43:59 AM Lauren Rosenfeld, Student, Univ. Of Miami School of Medicine, waive in support  
10:44:18 AM Jan Mote, Student, FSU College of Medicine, waives in support  
10:44:35 AM Chair  
10:44:37 AM Debate?  
10:44:42 AM Senator Rouson  
10:45:36 AM Chair  
10:46:36 AM Debate? None  
10:46:41 AM Senator Braynon to close on SB 366  
10:47:15 AM Chair  
10:47:30 AM Roll Call SB 366 - Favorable as CS



10:47:50 AM Tab 5 - SB 434 by Senator Harrell - Ambulatory Surgical Centers  
10:48:16 AM Chair passed to Vice Chair Berman  
10:50:43 AM Chair  
10:50:45 AM Questions?  
10:50:49 AM Senator Cruz  
10:51:00 AM Senator Harrell  
10:51:35 AM Chair  
10:52:02 AM Amendment 719818 by Senator Harrell  
10:52:30 AM Chair  
10:52:35 AM Questions on amendment?  
10:52:41 AM Senator Rouson  
10:53:06 AM Senator Harrell  
10:53:29 AM Senator Rouson  
10:53:34 AM Senator Harrell  
10:54:40 AM Chair  
10:54:45 AM Appearance cards on amendment  
10:54:52 AM Debate?  
10:54:56 AM Senator Harrell  
10:55:04 AM Amendment 719818 adopted  
10:55:10 AM Appearance cards on SB 434  
10:55:18 AM Demetrius Minor, Director of Coalitions, Americans for Prosperity, speaking for the bill  
10:56:47 AM Senator Cruz  
10:57:53 AM Demetius  
10:58:19 AM Senator Rouson  
10:58:33 AM Demetrius  
10:58:53 AM Senator Rouson  
10:59:03 AM Demetrius  
10:59:11 AM Chair  
10:59:16 AM Michael Medewell, Administrator, Panama City Surgery Center, speaking for the bill  
11:06:25 AM Senator Cruz  
11:07:26 AM Michael  
11:07:56 AM Chair  
11:08:05 AM Zayne Smith, Associate State Director, AARP Florida, waives in support  
11:08:11 AM Chris Nuland, Florida Chapter American College of Surgeons, waives in support  
11:08:18 AM Toni Large, Florida Orthopedic Society, waives in support  
11:08:25 AM Debate?  
11:08:28 AM Senator Mayfield  
11:09:26 AM Chair  
11:09:29 AM Debate? None  
11:09:58 AM Senator Harrell to close on SB 434  
11:10:49 AM Chair  
11:11:50 AM Roll Call CS/SB 434 -Favorable  
11:12:06 AM Chair Harrell back in Chair  
11:12:13 AM Chair - Conversation Certificate of Need  
11:12:41 AM Deputy Secretary Molly McKinstry, Agency for Health Care Administration  
11:25:02 AM Questions?  
11:26:02 AM Senator Cruz  
11:26:44 AM Deputy Secretary McKinstry  
11:27:03 AM Chair  
11:27:25 AM Senator Book, show as voting in the affirmative for Tab 1 - Tab 5  
11:27:41 AM Senator Berman moves to adjourn. No objection we are adjourned.