The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Harrell, Chair
Senator Berman, Vice Chair

MEETING DATE: Monday, March 11, 2019
TIME: 1:30—3:30 p.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	**SB 1088** Albritton (Similar H 897)	Nursing Home Facility Staffing; Revising direct care staffing requirements for nursing home facilities; requiring the Agency for Health Care Administration to include such requirements in rule, etc. HP 03/11/2019 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
2	**SB 732** Flores (Identical H 933)	Office Surgery; Revising the definition of the term "ambulatory surgical center" to remove the exclusion of physician offices; relocating the requirements that a person who seeks to operate an office surgery center must register with the Department of Health and pay registration costs; prohibiting a physician from practicing medicine in a center that is not registered with the department; establishing requirements for a surgeon to perform a level III procedure in a center; authorizing the department to revoke a center's certificate of registration and prohibit associated physicians from practicing at the center for failure to comply with certain provisions, etc. HP 03/11/2019 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
3	**SB 1124** Harrell (Identical H 1115)	Dispensing Medicinal Drugs; Authorizing individuals licensed to prescribe medicinal drugs to dispense a 48-hour supply, rather than a 24-hour supply, of such drugs to any patient, including a discharged patient, under certain circumstances, etc. HP 03/11/2019 Favorable IT RC	Favorable Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 1126** Harrell (Identical H 1207)	Pediatric Cardiac Technical Advisory Panel; Authorizing the reimbursement of per diem and travel expenses to members of the pediatric cardiac technical advisory panel, established within the Agency for Health Care Administration; providing immunity from civil and criminal liabilities to members of the panel; requiring the Secretary of Health Care Administration to consult the panel for advisory recommendations on certain certificate of need applications, etc. HP 03/11/2019 Favorable AHS AP	Favorable Yeas 10 Nays 0
5	Alternatives to Opioids Tool Kit: Manatee Memorial Hospital		Presented
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1088
INTRODUCER:	Health Policy Committee and Senator Albritton
SUBJECT:	Nursing Home Facility Staffing
DATE:	March 13, 2019
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1088 amends nursing home staffing requirements established in s. 400.23, F.S., to define the term "direct care staff" and to replace requirements for staffing a nursing home with certified nursing assistants (CNA) with requirements for staffing with direct care staff. The bill requires a minimum weekly average of 3.9 hours of direct care staffing (increased from 3.6 hours of staffing by CNAs or licensed nurses) per resident per day and a minimum of 2.5 hours of non-nursing direct care staffing per resident per day.

The bill's provisions take effect on July 1, 2019.

II. Present Situation:

Direct Care Staff

Federal law defines "direct care staff" as those individuals who, through interpersonal contact with nursing home residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long-term care facility (for example, housekeeping).[1]

[1] 42 CFR s. 483.70(q)(1)

Direct care staff are the primary providers of paid, hands-on care for more than 13 million elderly and disabled Americans. They assist individuals with a broad range of support, including preparing meals, helping with medications, bathing, dressing, getting about (mobility), and getting to planned activities on a daily basis.[2]

Direct care staff fall into three main categories tracked by the U.S. Bureau of Labor Statistics: Nursing Assistants (usually known as Certified Nursing Assistants or CNAs), Home Health Aides, and Personal Care Aides:

- Nursing Assistants or Nursing Aides generally work in nursing homes, although some work in assisted living facilities, other community-based settings, or hospitals. They assist residents with activities of daily living (ADLs) such as eating, dressing, bathing, and toileting. They also perform clinical tasks such as range-of motion exercises and blood pressure readings.
- Home Health Aides provide essentially the same care and services as nursing assistants, but they assist people in their homes or in community settings under the supervision of a nurse or therapist. They may also perform light housekeeping tasks such as preparing food or changing linens.
- Personal Care Aides work in either private or group homes. They have many titles, including personal care attendant, home care worker, homemaker, and direct support professional. (The latter work with people with intellectual and developmental disabilities). In addition to providing assistance with ADLs, these aides often help with housekeeping chores, meal preparation, and medication management. They also help individuals go to work and remain engaged in their communities. A growing number of these workers are employed and supervised directly by consumers.[3]

The federal government requires training only for nursing assistants and home health aides who work in Medicare-certified and Medicaid-certified nursing homes and home health agencies. Such training includes training on residents' rights; abuse, neglect, and exploitation; quality assurance; infection control; and compliance and ethics; and specifies that direct care staff must be trained in effective communications.[4]

Nursing Home Staffing Standards

Section 400.23(3), F.S., requires the Agency for Health Care Administration to adopt rules providing minimum staffing requirements for nursing home facilities. The requirements must include:

- A minimum weekly average of 3.6 hours of direct care per resident per day provided by a combination of certified nursing assistants and licensed nursing staff. A week is defined as Sunday through Saturday.

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[2] Understanding Direct Care Workers: a Snapshot of Two of America's Most Important Jobs, *Certified Nursing Assistants and Home Health Aides*, Khatutsky, et al., (March 2011), *available at* https://aspe.hhs.gov/basic-report/understanding-direct-care-workers-snapshot-two-americas-most-important-jobs-certified-nursing-assistants-and-home-health-aides#intro (last visited on Mar. 7, 2019).

[3] See *Who are Direct Care Workers?* available at https://phinational.org/wp-content/uploads/legacy/clearinghouse/NCDCW%20Fact%20Sheet-1.pdf (last visited on Mar. 7, 2019)

[4] 42 CFR s. 483.95

- A minimum of 2.5 hours of direct care per resident per day provided by certified nursing assistant staff. A facility may not staff at a ratio of less than one certified nursing assistant per 20 residents.
- A minimum of 1.0 hour of direct care per resident per day provided by licensed nursing staff. A facility may not staff at a ratio of less than one licensed nurse per 40 residents.
- Nursing assistants employed under s. 400.211(2), F.S., may be included in computing the staffing ratio for certified nursing assistants if their job responsibilities include only nursing-assistant-related duties.
- Each nursing home facility must document compliance with staffing standards and post daily the names of staff on duty for the benefit of facility residents and the public.
- Licensed nurses may be used to meet staffing requirements for CNAs if the licensed nurses are performing the duties of a CNA and the facility otherwise meets minimum staffing requirements for licensed nurses.
- Non-nursing staff providing eating assistance to residents do not count toward compliance with minimum staffing standards.

III. Effect of Proposed Changes:

CS/SB 1088 amends s. 400.23, F.S., to:

- Define the term "direct care staff" to mean individuals who, through interpersonal contact with residents or resident care management, provide care and services that allow residents to attain or maintain their highest practicable physical, mental, and psychosocial states of well-being.
  - The term does not include individuals whose primary duty is maintaining the physical environment of the facility.
  - Direct care staffing hours do not include time spent on: nursing administration, staff development, staffing coordination, and the administrative portion of the minimum data set and care plan coordination.
- Replace requirements for staffing with CNAs with requirements for staffing with direct care staff, except that a facility may not staff below one CNA per 20 residents at any time.
- Establish staffing requirements as follows:
  - A minimum weekly average of 3.9 hours of direct care staffing per resident per day (increased from 3.6 hours of staffing by CNAs or licensed nurses) as determined by facility assessment staffing needs in accordance with 42 C.F.R. part 483, subpart B; and
  - A minimum of 2.5 hours of non-nursing direct care staffing per resident per day. The bill allows non-nursing staff who provide eating assistance to count toward compliance with minimum staffing standards.
- Specify that a facility may not staff below one licensed nurse per 40 residents at any time.
- Make conforming changes.

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.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 400.23 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 11, 2019:
The CS specifies that a nursing home must meet facility assessment staffing needs as

established in 42 C.F.R. part 483, subpart B, and clarifies that the definition of "direct care staff" applies to the paragraph rather than the sub-subparagraph.

B. Amendments:

None.

614608

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/13/2019	.	
	.	
	.	
	.	

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

Senate Amendment

Delete lines 19 - 22
and insert:
~~and licensed nursing staffing combined of~~ 3.9 ~~3.6~~ hours of direct care staffing per resident per day as determined by facility assessment staffing needs in accordance with 42 C.F.R. part 483, subpart B. As used in this paragraph ~~sub-subparagraph~~,

By Senator Albritton

26-01180-19 20191088__

A bill to be entitled

An act relating to nursing home facility staffing; amending s. 400.23, F.S.; revising direct care staffing requirements for nursing home facilities; requiring the Agency for Health Care Administration to include such requirements in rule; defining the term "direct care staff"; providing an effective date.

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

Section 1. Subsection (3) of section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(3)(a)1. The agency shall adopt rules providing minimum staffing requirements for nursing home facilities. These requirements must include, for each facility:

a. A minimum weekly average of ~~certified nursing assistant and licensed nursing staffing combined~~ of 3.9 ~~3.6~~ hours of direct care staffing per resident per day as determined by facility assessment staffing needs in accordance with Federal Requirements of Participation. As used in this sub-subparagraph, a week is defined as Sunday through Saturday, and the term "direct care staff" includes those individuals who, through interpersonal contact with residents or resident care management, provide care and services that allow residents to attain or maintain their highest practicable physical, mental, and psychosocial states of well-being. The term does not include individuals whose primary duty is maintaining the physical

environment of the facility. Direct care staffing hours do not include time spent on the following functions: nursing administration, staff development, staffing coordination, and the administrative portion of the minimum data set and care plan coordination.

b. A minimum nonnursing direct care ~~certified nursing assistant~~ staffing of 2.5 hours of direct care per resident per day. A facility may not staff below one certified nursing assistant per 20 residents at any time.

c. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day. A facility may not staff below one licensed nurse per 40 residents at any time.

~~2. Nursing assistants employed under s. 400.211(2) may be included in computing the staffing ratio for certified nursing assistants if their job responsibilities include only nursing-assistant-related duties.~~

2.~~3.~~ Each nursing home facility must document compliance with staffing standards as required under this paragraph and post daily the names of staff on duty for the benefit of facility residents and the public.

3.~~4.~~ The agency shall recognize the use of licensed nurses for compliance with minimum staffing requirements for direct care staff ~~certified nursing assistants~~ if the nursing home facility otherwise meets the minimum staffing requirements for licensed nurses and the licensed nurses are performing the duties of direct care staff ~~a certified nursing assistant~~. Unless otherwise approved by the agency, licensed nurses counted toward the minimum staffing requirements for direct care staff ~~certified nursing assistants~~ must exclusively perform the duties

of direct care staff ~~a certified nursing assistant for the entire shift~~ and not also be counted toward the minimum staffing requirements for licensed nurses. If the agency approved a facility's request to use a licensed nurse to perform both licensed nursing and direct care staff ~~certified nursing assistant~~ duties, the facility must allocate the amount of staff time specifically spent on direct care staff ~~certified nursing assistant~~ duties for the purpose of documenting compliance with minimum staffing requirements for certified and licensed nursing staff. The hours of a licensed nurse with dual job responsibilities may not be counted twice.

~~(b) Nonnursing staff providing eating assistance to residents shall not count toward compliance with minimum staffing standards.~~

(b) ~~(c)~~ Licensed practical nurses licensed under chapter 464 who are providing nursing services in nursing home facilities under this part may supervise the activities of other licensed practical nurses, certified nursing assistants, and other unlicensed personnel providing services in such facilities in accordance with rules adopted by the Board of Nursing.

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 22, 2019

I respectfully request that **Senate Bill #1088**, relating to Nursing Home Facility Staffing, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ben Albritton
Florida Senate, District 26

File signed original with committee office

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

SB 1088
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name Michael Milliken

Job Title State Ombudsman

Address 4040 Esplanade Way
Street

Phone 850-414-2331

Tallahassee FL 32399
City *State* *Zip*

Email Milliken.m@elderaffairs.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing State Long Term Care Ombudsman Program

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

1088
Bill Number (if applicable)

Topic Modernize Nursing home staffing

Amendment Barcode (if applicable)

Name Tracy Greene

Job Title Vice President of Operations

Address 101 Sunny town Rd Ste 201
Street

Phone 813-393-0214

Casselberry, FL 32707
City *State* *Zip*

Email TGreene@southernltc.com

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

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

Representing Southern Health Care Management

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

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

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3/11/19
Meeting Date

1088
Bill Number (if applicable)

Topic Modernize Nursing home staffing
Amendment Barcode (if applicable)

Name Peggy R. Norris

Job Title SCC. Signature Care Consultant - Signature Healthcare

Address 30 Moreno Point Rd Unit 203C
Street
Destin FL 32541
City *State* *Zip*

Phone 850/598.6151

Email pnorris@shccs.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Signature Healthcare

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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3-11-2019
Meeting Date

1088
Bill Number (if applicable)

Topic Modernization of Nursing Home Staffing

Amendment Barcode (if applicable)

Name Mauri Mizrahi

Job Title Associate Administrator River Garden

Address 11401 Old St Augustine Road
Street

Phone 904-260-1818

Jacksonville FL 32258
City *State* *Zip*

Email mmizrahi@rivergarden.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing River Garden

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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3/11/19
Meeting Date

SB 1088
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name Martin Goetz

Job Title CEO

Address 11401 Old St. Augustine Rd. Phone 904 886-8409
Street

Jacksonville FL 32258 Email MGoetz@RiverGardens.com
City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

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

Representing River Garden Hebron Home

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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3-11-19
Meeting Date

SB 1088
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name Steve Watrel

Job Title Attorney

Address 6129 Atlantic Blvd
Street
Jacksonville FL 32211
City *State* *Zip*

Phone 904 723-0030

Email swatrel@stevewatrel.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Victims of Nursing Home Abuse and Neglect

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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3-11-19
Meeting Date

1088
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Nursing Home Staffing

Name LISA LYONS

Job Title Executive Direror

Address 1095 Pinellas Point Dr S
Street
St. Petersburg FL 33705
City *State* *Zip*

Phone 727-867-4241

Email llyons@wsmres.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Westminster Communities of FL LEADINGAGE FL

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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3/11/2019
Meeting Date

SB1088
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name Tanya C. Jackson

Job Title Partner, PinPoint Results

Address 150 S. Monroe, Suite 303
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850 445 0107

Email Tanya@PinPointresults.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing SEIU-1199

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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3/11/19
Meeting Date

1088
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name Connie E. Cheek

Job Title Regulatory Compliance Specialist

Address 2001 BRFC 1812 Riggins Rd. Phone 678 778-0561
Street

Tall., 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 LeadingAge Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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3/11/19
Meeting Date

1088
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name Bruce Jones

Job Title CEO

Address 1000 Vicar's Landing Way
Street

Phone 904-273-1701

Ponte Vedra Beach FL 32082
City *State* *Zip*

Email bjones@vicarslanding.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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3/11/19
Meeting Date

SB 1088
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Nursing Home Staffing

Name Kip Corriveau

Job Title Director of Mission

Address 10300 4th Street North
Street

St Petersburg
City *State* *Zip*

Phone 727 568 1042

Email Kip_Corriveau@bshs.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Bon Secours St. Petersburg Health System

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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3/11/19
Meeting Date

1088
Bill Number (if applicable)

Topic Modernize Nursing home Staffing

Amendment Barcode (if applicable)

Name Deborah Franklin

Job Title Sr Director of Quality Affairs

Address 2806 Fritzke Rd
Street
Dover FL 33527
City *State* *Zip*

Phone 813-679-7533

Email dfranklin@fhca.org

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

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

Representing Florida Health Care Assoc

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

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

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S-001 (10/14/14)

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3/11/19
Meeting Date

SB 1088
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name Steve Bahmer

Job Title CEO/President

Address 1812 Riggins Rd
Street

Tallahassee FL 32333
City *State* *Zip*

Phone 850/671-3700

Email Sbahmer@leadingagefla.org

Speaking: ☐ For ☑ Against ☐ Information

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

Representing LeadingAge Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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3/11/19
Meeting Date

1058
Bill Number (if applicable)

Topic Nursing Home Staffing

Amendment Barcode (if applicable)

Name JACK MURRAY

Job Title

Address 200 W. COLLEGE ST., #304 Phone 850-577-5107
Street

TLH FL 32301 Email j.murray@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

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 732
INTRODUCER:	Health Policy Committee and Senator Flores
SUBJECT:	Office Surgery
DATE:	March 13, 2019
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 732 revises regulations pertaining to health care clinics and creates new regulations for the provision of health care services in health care settings where office surgeries are performed.

The bill amends the Health Care Clinic Act to:

- Specify that the definition of "clinic" means an entity that provides health care services to individuals and that "receives compensation" for those services, as opposed to such an entity that "tenders charges for reimbursement" for such services;
- Require that an applicant for a clinic license must provide proof that it maintains the financial responsibility to pay claims and related costs that could result from the provision of medical care and services, or the failure to provide such care and services, for physicians and osteopathic physicians who perform liposuction procedures under certain conditions in an office setting;
- Require a clinic director or medical director to ensure that the clinic complies with the standards of practice adopted by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) for office surgery; and
- Require the Agency for Health Care Administration to impose an administrative fine on a clinic not registered with the Department of Health (DOH) that performs certain office surgeries.

The bill requires the DOH to deny or revoke the registration of or impose certain penalties against any facility where certain office surgeries are performed under certain circumstances. If a

facility's registration is revoked, the DOH is authorized to deny any person named in the facility's registration documents from registering a facility to perform surgical procedures for five years after the revocation date. The DOH is also authorized to issue an emergency order suspending or restricting the registration of a facility under certain conditions upon a finding of probable cause that the facility or its surgeons are not in compliance with the standards of practice for office surgery.

The bill provides definitions for numerous terms relating to office surgery. The bill requires medical doctors and doctors of osteopathic medicine who perform certain types of office surgery, and the office in which the surgery is performed, to maintain specified levels of financial responsibility. The bill authorizes the DOH to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery and requires the BOD and the BOOM to impose a specified fine on medical doctors and doctors of osteopathic medicine who perform certain office surgeries in an unregistered office. The bill provides that a medical doctor or doctor of osteopathic medicine performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action.

The bill provides that a certified registered nurse anesthetist may provide services in an office registered to perform office surgery within the framework of an established protocol with a licensed anesthesiologist.

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

II. Present Situation:

Health Care Clinic Act

The Agency for Health Care Administration (AHCA) is created in s. 20.42, F.S. The AHCA is the chief health policy and planning entity for the state and is responsible for, among other things, health care clinic licensure, inspection, and regulatory enforcement.[1] Part X of ch. 400, F.S., is known as the Health Care Clinic Act (the Act). The purpose of the Act is to provide for the licensure, establishment, and enforcement of basic standards for health care clinics and to provide administrative oversight to the AHCA.[2]

"Clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and portable equipment provider.[3] Health care clinics in the state must be licensed by the AHCA;[4] however, there are numerous exclusions from the definition of "clinic" in s. 400.9905, F.S.,[5] and from the requirement to obtain a license as a clinic. The definition of "clinic" includes only entities that "tender charges for reimbursement." The AHCA interprets this phrase to include only entities that bill third parties, such as Medicare, Medicaid, and insurance companies. Entities that

[1] *See* Agency for Health Care Administration, *Division of Health Quality Assurance*, available at http://ahca.myflorida.com/MCHQ/index.shtml (last visited Mar. 12, 2019).
[2] Section 400.990, F.S.
[3] Section 400.9905(4)
[4] Section 400.991, F.S.
[5] Section 400.9905(4)(a)-(n), F.S.

provide health care services and accept "cash only" for services are excluded from the definition of "clinic" and are not subject to licensure by the AHCA.[6]

Clinic License Application

In order to obtain a clinic license, an applicant must file an application with the AHCA and pay a fee not to exceed $2,000.[7] The Act defines "applicant" to mean an individual owner, corporation, partnership, firm, business, association, or other entity that owns or controls, directly or indirectly, 5 percent or more of an interest in the clinic and that applies for a clinic license.[8]

The application requires a variety of information, including, but not limited to, the name, residence and business address, phone number, social security number, and license number of the medical or clinic director. The applicant must also provide proof of compliance with the Act, including a listing of services to be provided, the number and discipline of each professional staff member to be employed and proof of financial ability to operate.[9] The AHCA requires a Level 2 background screening for applicants and personnel as required in s. 408.809(1)(e), F.S., pursuant to ch. 435 and s. 408.809, F.S.[10]

Clinic Director Responsibilities

The Act requires that each clinic must appoint a medical director or clinic director who must agree in writing to accept legal responsibility for the following activities on behalf of the clinic:[11]

- Have signs identifying the medical director or clinic director posted in a conspicuous location within the clinic readily visible to all patients;
- Ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license;
- Review any patient referral contracts or agreements executed by the clinic;
- Ensure that all health care practitioners at the clinic have active, appropriate certification or licensure for the level of care being provided;
- Serve as the clinic records owner;
- Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements;
- Conduct systematic reviews of clinic billings to ensure the billings are neither fraudulent nor unlawful;
- Refrain from referring a patient to the clinic if the referral would constitute a conflict of interest; and
- Ensure that the clinic publishes a schedule of charges for the medical services offered to patients.

[6] *See* Agency for Health Care Administration, *Senate Bill 486 Analysis* (2015) (on file with the Senate Committee on Health Policy).
[7] *Supra* note 3 and s. 400.9925(3), F.S.
[8] Section 400.9905(2), F.S.
[9] *Supra* note 3.
[10] Section 400.991(5)(b), F.S.
[11] Section 400.9935, F.S.

Unlicensed Clinics and Administrative Penalties

The Act provides that operating a clinic without a license is a third degree felony punishable as provided in ss. 775.082, 775.083, or 775.084, F.S., with each day of continued operation being a separate offense.[12] Any person found guilty of unlicensed activity a second or subsequent time commits a felony of the second degree, with each day of continued operation being a separate offense.[13] Additionally, any health care provider who is aware of the operation of an unlicensed clinic must report that facility to the AHCA. Failure to report a clinic that the provider knows or has reasonable cause to suspect is unlicensed must be reported to the provider's licensing board.[14]

The AHCA also has the authority to deny the application for a license renewal, revoke and suspend the license, and impose administrative fines of up to $5,000 per violation for violations of the requirements of the Act or rules of the AHCA.

Each day of continuing violation after the date fixed for termination of the violation constitutes an additional, separate, and distinct violation. Any action taken to correct a violation shall be documented in writing by the owner, medical director, or clinic director of the clinic and verified through follow up visits by AHCA personnel.[15]

Any licensed clinic whose owner, medical director, or clinic director concurrently operates an unlicensed clinic shall be subject to an administrative fine of $5,000 per day. Any clinic whose owner fails to apply for a change-of-ownership license and operates the clinic under the new ownership is subject to a fine of $5,000. During an inspection, the AHCA must make a reasonable attempt to discuss each violation with the owner, medical director, or clinic director, prior to written notification.[16]

Regulation of Office Surgery

The practice of medicine in Florida is regulated under ch. 458, F.S., and the practice of osteopathic medicine is regulated under ch. 459, F.S. Both professions have broad authority to adopt rules to implement the provisions of their respective practice acts.[17] The Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) were created within the Department of Health (DOH) to ensure that every physician practicing in the state meets minimum requirements for safe practice.[18]

In Florida, surgeries performed in a doctor's office, outside a facility licensed under ch. 390 or ch. 395, F.S., are regulated by ss. 458.309(3) and 459.005(2), F.S. Both sections are identical except for the references to the BOM or the BOOM. Both require that a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level 2 procedures lasting more than five minutes, and all Level 3 surgical procedures

[12] Section 400.993(1), F.S.
[13] Section 400.993(2), F.S.
[14] Section 400.993(3), F.S.
[15] *Id*.
[16] *Id*.
[17] Sections 458.309(1) and 459.005(1), F.S.
[18] Sections 458.307(1), 458.301, 459.004 and 459.001, F.S.

in an office setting, to register the doctor's office with the DOH, unless that office is licensed as a facility under ch. 395, F.S. Level 2 procedures and Level 3 procedures are not defined in statutes, but the respective boards have defined three levels of office surgery by administrative rule,[19] which are subject to change by the boards through the administrative rule propagation process.

The DOH is required to inspect a registered doctor's office annually unless the office is accredited by a nationally-recognized accrediting agency or an accrediting organization approved by the BOM or the BOOM. The actual costs of registration, inspection and/or accreditation are to be paid by the person seeking to register and operate the office in which office surgeries are performed.

All other aspects of office surgeries are regulated by administrative rules promulgated by the BOM and the BOOM.

Specifically, the BOM and the BOOM may establish by rule standards of practice and standards of care for particular practice settings, including but not limited to:

- Education and training;
- Equipment and supplies;
- Medications, including anesthetics;
- Assistance of and delegation to other personnel;
- Transfer agreements;
- Sterilization;
- Records;
- Performance of complex or multiple procedures;
- Informed consent; and
- Policy and procedure manuals.[20]

The BOM rule relating to the standard of care for office surgery was initially adopted in February 1994; the BOOM in November 2001, and both have been amended numerous times.[21]

The current BOM and BOOM rules are very similar, with only three substantive differences. The BOOM's rule requires the following, and the BOM's rule does not require, that:

- If a surgeon is unavailable to provide post-operative care, the surgeon must notify the patient, prior to the procedure, of his or her unavailability after the procedure;[22]
- When Level II, IIA, or III procedures are performed, the surgeon is responsible for providing the patient, in writing, prior to the procedure, the name and location of the hospital where the surgeon has privileges to perform the same procedure as that being performed in the outpatient setting, or the name and location of the hospital where the surgeon or facility has a transfer agreement;23 and

[19] Rules 64B8-9.009 and 64B15-14.007, F.A.C.
[20] Sections 458.331(1)(v) and 459.015(1)(z), F.S.
[21] *See* the Florida Administrative Code, History Note for Rule 64B8-9.009, *available at:* https://www.flrules.org/gateway/ruleNo.asp?id=64B8-9.009 (last visited Feb. 14, 2019).
[22] Rule 64B15-14.007(2)(h), F.A.C.
[23] Rule 64B15-14.007(2)(o), F.A.C.

- The surgeon performing Level I procedures in an office setting must hold a current certification in an Advanced Cardiac Life Support (ACLS) course with didactic and skills components, approved by Pacific Medical Training (PMT), the American Heart Association (AHA), or the American Safety and Health Institute (ASHI).[24]

The BOM and BOOM rules regarding levels of office surgeries (I, II. IIA and III) differentiate each level primarily by the level of sedation and anesthesia required for the procedure and patient risk.

As the BOM and the BOOM general requirements for all office surgery,[25] as well as specific standards for the levels of office surgery, are virtually identical, other than the three substantive differences noted above, further reference to the rules in this analysis will pertain to BOM Rule 64B8-9.009, F.A.C.

General Office Surgery Practice Standards

Rule 64B-9.009(2), F.A.C., requires the surgeon[26] to examine the patient immediately before the surgery to evaluate the patient's risk of anesthesia and the surgical procedure to be performed. The surgeon may delegate the preoperative heart and lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol. The surgeon must maintain complete records[27] of each surgical procedure, including:

- Anesthesia records;
- A written informed consent from the patient reflecting the patient's knowledge of:
  - Identified risks;
  - Consent to the procedure;[28]
  - Type of anesthesia;
  - Anesthesia provider; and
  - The availability of a choice of anesthesia provider, including an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.[29]

The rule further requires the surgeon to maintain a log of all Level II and Level III surgical procedures performed, which must include:

- A confidential patient identifier;
- The time the patient arrives in the operating suite;
- The name of the physician who provided medical clearance;
- The surgeon's name;

[24] Rule 64B15-14.003(3)(b)1., F.A.C. The BOM recommends the surgeon have Basic Life Support Certification, but it is not required. *See* 64B8-9.009(3)(b)1., F.A.C.
[25] "Office surgery" is defined by the BOM and the BOOM, as surgery which is performed outside of any facility licensed under ch. 390, F.S., (an abortion clinic) or ch. 395, F.S., (a hospital or ambulatory surgical center). *See* Rules 64B8-9.009(1)(d) and 64B15-14.007(d), F.A.C.
[26] Rules 64B8-9.009(d) and 64B15-14.007(d), F.A.C., define a "surgeon" as a licensed physician performing any procedure included within the definition of surgery.
[27] *See* Rules 64B8-9.003 and 64B-15.007, F.A.C.
[28] A written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa. See Rule 64B8-9.009(2)(b), F.A.C.
[29] Rule 64B8-9.009(2), F.A.C.

- The diagnosis;
- The CPT Codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;
- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;
- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

The log and all surgical records must be provided to the DOH investigators upon request.

The BOM has set out the general requirements for all office surgery in Rule 64B8-9.009(2), F.A.C.,[30] which are as follows:

- The surgeon must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed.[31]
- The surgeon must maintain complete records of each surgical procedure, as set forth in Rule 64B8-9.003, F.A.C., including anesthesia records, when applicable and the records shall contain written informed consent from the patient reflecting the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists, i.e., anesthesiologist, anesthesiologist assistant, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant.
- The requirement set forth above for written informed consent is not necessary for minor Level I procedures that are limited to the skin and mucosa.
- The surgeon must maintain a log of all liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and Level III surgical procedures performed The log and all surgical records shall be provided to investigators of the DOH upon request and must be maintained for six years from the last patient contact.
- For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined must not exceed eight hours.
- Except for elective cosmetic and plastic surgery, the surgeon must not keep patients past midnight in a physician's office.
- For elective cosmetic and plastic surgical procedures, the patient must be discharged within 24 hours of presenting to the office for surgery. An overnight stay is permitted in the office provided the total time the patient is at the office does not exceed 23 hours and 59 minutes, including the surgery time. An overnight stay in a physician's office for elective cosmetic and plastic surgery shall be strictly limited to the physician's office. If the patient has not

[30] See Rule 64B-15.007(2), F.A.C.

[31] The surgeon may delegate the preoperative heart lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol. Rule 64B8-9.009(2) and 64B15-14.007(7), F.A.C.

recovered sufficiently to be safely discharged within the timeframes set forth, the patient must be transferred to a hospital for continued post-operative care.

Rule 64B8-9.009, F.A.C.,[32] defines the three levels of office surgery as follows:

Level I Office Surgery[33] includes:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient;
- Liposuction involving the removal of less than 4000cc supernatant fat;
- Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints);
- The patient's level of sedation is that of minimal sedation and anxiolysis[34] and the chances of complications requiring hospitalization are remote. Minimal sedation and anxiolysis is a defined as a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilation and cardiovascular functions are unaffected. Controlled substances, as defined in ss. 893.02 and 893.03, F.S., are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain; and
- Chances of complication requiring hospitalization are remote.

Level II Office Surgery[35] includes, but is not limited to:

- Hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4,000cc supernatant fat;
- Any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. Moderate sedation and analgesia or conscious sedation is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response;
- The physician, or the facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within reasonable proximity if the physician performing the procedure does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity; and "Reasonable proximity" is defined as not to exceed 30 minutes transport time to the hospital.

Level III Office Surgery, includes:

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[32] *See also* Rule 64B-14.007, F.A.C., for the BOOM rule.
[33] Rule 64B8-9.009(3), F.A.C.
[34] "Anxiolysis" is defined as a state of mild sedation obtained with minor tranquilizers or antianxiety medication. See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1993866/
[35] Rule 64B8-9.009(4) and (5), F.A.C.

- Surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. Deep sedation and analgesia is defined as a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. The use of spinal or epidural anesthesia shall be considered Level III;
- Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery, and require:
  - All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center; and
  - For all ASA II patients above the age of 50, the surgeon must obtain a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative EKG and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.
- In addition to the standards for Level II Office Surgery, the surgeon must:
  - Have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. Such Board certification or comparable background, training and experience must also be directly related to and include the procedure(s) being performed by the physician in the office surgery facility. In addition, the surgeon must have knowledge of the principles of general anesthesia;
  - Have one assistant who is currently certified by an American Heart Association, American Safety and Health Institute, American Red Cross, Pacific Medical Training approved Basic Life Support course with didactic and skills components, or ACLS Certification Institute Basic Life Support course with didactic and skills components, and the surgeon must be currently certified by an American Heart Association, American Safety and Health Institute, Pacific Medical Training approved Advanced Cardiac Life Support course with didactic and skills components, or ACLS Certification Institute Advanced Cardiac Life Support course with didactic and skills components;
- Have emergency policies and procedures related to serious anesthesia complications must be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location. Topics to be covered shall include the following:

- Airway Blockage (foreign body obstruction),
- Allergic Reactions,
- Bradycardia,
- Bronchospasm,
- Cardiac Arrest,
- Chest Pain,
- Hypoglycemia,
- Hypotension,
- Hypoventilation,
- Laryngospasm,
- Local Anesthetic Toxicity Reaction; and,
- Malignant Hyperthermia.

Liposuction Procedures in an Office Setting

Liposuction is the surgical removal of subcutaneous fat by means of an aspiration cannula introduced through small skin incisions, assisted by suction. Synonyms used in literature include liposuction surgery, suction-assisted lipectomy, suction lipoplasty, fat suction, blunt suction lipectomy, and liposculpture.[36]

History of Liposuction

Liposuction was initially developed in the late seventies in Italy and France. At that time, liposuction was performed under general anesthesia without any introduction of fluid, hence, called "dry liposuction." Later, a small amount of fluid was introduced into the fat (the "wet technique"). These methods were associated with much blood loss, and patients frequently required blood transfusions.

In 1985, Dr. Jeffrey A. Klein, a dermatologist in California, revolutionized liposuction surgery when he developed the tumescent technique, which permits liposuction totally by local anesthesia and with minimal surgical blood loss. Further modifications such as power liposuction and ultrasonic liposuction have been introduced with variable results. Despite these advances, the tumescent technique remains the worldwide standard of care for liposuction.[37]

Liposuction is one of the most commonly performed cosmetic procedures and is performed by general surgeons, plastic surgeon, and dermatologists. Dermatologists now perform about one third of these procedures in the United States and have pioneered many of the advances in liposuction, especially in the fields of ambulatory surgery and local anesthesia.[38]

The BOM, in rule 64B8-9.009(2)(b) through (e), F.A.C.,[39] sets the general requirements for all liposuction procedures in an office setting as follows:

- The surgeon must maintain a log of all liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and Level III surgical procedures

[36] Venkataram, Jayashree, Journal of Cutaneous and Aesthetic Surgery, *Tumescent Liposuction: A Review* July – December, 2008, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2840906/ (last visited Feb. 27, 2019).
[37] Id.
[38] *Supra* note 17.
[39] *See* also Rule 64B15-14.007(2), F.A.C.

performed, which must include a confidential patient identifier, time of arrival in the operating suite, documentation of completion of the medical clearance as performed by the anesthesiologist or the operating physician, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, and any adverse incidents, as identified in s. 458.351, F.S.

- In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.
- Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operation, only in the following circumstances:
  - When combined with abdominoplasty, liposuction may not exceed 1000cc of supernatant fat;
  - When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000 cc of supernatant fat; and
  - Major liposuction in excess of 1000cc supernatant fat may not be performed in a remote location from any other procedure.

III. Effect of Proposed Changes:

CS/SB 732 defines a "clinic" in ch. 400 F.S., to include an entity that provides health care services and "that receives compensation," expanding the definition to include more entities than those that bill third parties, such as Medicare, Medicaid, and insurance companies. The bill creates additional responsibilities for clinics to ensure that clinics comply with the standards of practice defined by the BOM and the BOOM for office surgery.

The bill directs the AHCA to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the Department of Health (DOH) as an office surgery facility. The bill directs that a clinic must maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic.

The CS/SB 732 also regulates office surgery procedures performed by physicians in an office setting. The bill amends ss. 458.305 and 459. 003, F.S., to define the following terms:

- "Surgeon" means a licensed physician performing any procedure included within the definition of surgery;
- "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture;

extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic;

- "Office surgery" means surgery which is performed outside of any facility licensed under chapter 390 or 395, F.S., and includes:
  - "Level I Office Surgery" means surgery limited to minor procedures where anesthesia is limited to minimal sedation;
  - "Level II Office Surgery means any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation; and
  - Level III Office Surgery means surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The use of spinal or epidural anesthesia shall be considered Level III.

The bill amends ss. 458.003 and 459.003, F.S., to define six levels of anesthesia that are used to describe the three levels of office surgery as the following:

- "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected;
- "Moderate sedation and analgesia", or "conscious sedation", means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response;
- "Deep sedation and analgesia" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain respiratory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.
- "General anesthesia" means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain respiratory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
- "Epidural anesthesia" means the injection of an anesthetic agent into the epidural space of the spinal cord to produce regional anesthesia resulting in loss of sensation in the lower abdominal, genital and/or pelvic areas.
- "Spinal Anesthesia" means the injection of an anesthetic agent beneath the arachnoid membrane that surrounds the spinal cord to produce a loss of sensation to the lower half of the body.

The bill amends ss. 458.309 and 459.005, F.S., to authorize the DOH to develop rules to administer the registration, inspection, and safety of an office performing office surgery; and directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians

practicing in an office registered to perform office surgery. The BOM and BOOM must impose a fine of $5,000 per day on a physician who performs certain office surgical procedures in an office that has not registered with the DOH. As a condition of registration, a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and level III office surgeries in an office setting, and the office itself is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S.

The bill amends ss. 458.331 and 459. 015(1), F.S., to establish specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH.

The bill amends s. 464.012, F.S., to direct that any certified registered nurse anesthetist who provide services in an office registered under ss. 458.309(3) or 459.005(2), F.S., must do so within the framework of an established protocol with an anesthesiologist.

The bill amends s 456.004, F.S., to direct the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules; and authorized the DOH to deny future office surgery registrations for five years to any person named in office surgery registration documents, including owners and operators, of an office surgery facility that has had a registration revoked by the DOH.

The bill amends s. 456.074, F.S., to authorize the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a finding of:

- Probable cause that the office, facility. or surgeons are not in compliance with the standards of practice for office surgery adopted by the BOM and the BOOM; and
- That such noncompliance constitutes an immediate danger to the public;

The bill amends s. 400.9905, (4), F.S., to include in the definition of "clinic" a "mobile clinic and a portable equipment provider and excludes specific other entities from the definition;" and amends s. 400.9935, F.S., to direct that if the clinic is registered with the DOH to perform office surgery, the clinic must ensure that it complies with the standards of practice for office surgery promulgated by the BOM and the BOOM.

The bill amends s. 400.995, F.S., to direct AHCA to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the DOH.

The bill amends s. 400.991, F.S., to direct that a clinic maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than

1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic,

The effective date of the bill is 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.

B. Private Sector Impact:

As a condition of registration under ss. 458.308 and 459.003, F.S., a physician who performs office surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must now maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S. This may produce an additional cost to the physician and office if it is a separate legal entity.

C. Government Sector Impact:

The DOH, BOM and BOOM are required to promulgate rules, which may create a fiscal impact that should be absorbed within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill substantially amends the following sections of the Florida Statutes: 400.9905, 400.991, 400.9935, 400.995, 456.004, 456.074, 458.305, 458.309, 458.331, 459.003, 459.005, 459.015, 464.012, and 766.101.

IX. Additional Information:

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

CS by Health Policy on March 11, 2019:
The committee substitute:

- Defines a "clinic" in ch. 400 F.S., to include an entity that provides health care services "that receives compensation," expanding the definition to include more than just those that bill third parties, such as Medicare, Medicaid, and insurance companies;
- Creates additional responsibilities for clinics to ensure that clinics complies with the standards of practice defined by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) for office surgery;
- Directs the Agency for Health Care Administration (AHCA) to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the Department of Health (DOH) as an office surgery facility;
- Directs that the clinic maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic;
- Regulates office surgery procedures performed by physicians; and defines surgeon, surgery, and office surgery, and six levels of anesthesia used to describe the three levels of office surgery as: Minimal sedation; Moderate sedation with analgesia or conscious sedation; Deep sedation with analgesia; General anesthesia; Epidural anesthesia; and Spinal anesthesia.
- Directs the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules;
- Authorized the DOH to deny future office surgery registrations for five years to any person named in office surgery registration documents, including owners and

operators, of an office surgery facility that has had a registration revoked by the DOH;

- Authorizes the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a specific findings;
- Authorizes the DOH to develop rules to administer the registration, inspection, and safety of an office performing office surgery;
- Directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians practicing in an office registered to perform office surgery;
- Directs the BOM and the BOOM to impose a fine of $5,000 per day on a physician who performs office surgical procedures in an office that has not registered;
- Establishes specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH; and
- Directs that any certified registered nurse anesthetist who provide services in a registered office surgery facility work within the framework of an established protocol with an anesthesiologist;

B. Amendments:

None.

859422

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/13/2019	.	
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	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (4) of section 400.9905, Florida Statutes, is amended to read:

400.9905 Definitions.—

(4) "Clinic" means an entity that provides ~~where~~ health care services ~~are provided~~ to individuals and that receives compensation ~~and which tenders charges for reimbursement~~ for

those ~~such~~ services, including a mobile clinic and a portable equipment provider. As used in this part, the term does not include and the licensure requirements of this part do not apply to:

(a) Entities licensed or registered by the state under chapter 395; entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based

health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

(d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based

health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees at least two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

(g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, and that is wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner if one of the owners who is a licensed health care practitioner is supervising the business

activities and is legally responsible for the entity's compliance with all federal and state laws. However, a health care practitioner may not supervise services beyond the scope of the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) which provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

(h) Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.

(j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

(k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.

(l) Orthotic, prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical

facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners where one or more of the persons responsible for the operations of the entity is a health care practitioner who is licensed in this state and who is responsible for supervising the business activities of the entity and is responsible for the entity's compliance with state law for purposes of this part.

(n) Entities that employ 50 or more licensed health care practitioners licensed under chapter 458 or chapter 459 where the billing for medical services is under a single tax identification number. The application for exemption under this subsection shall contain information that includes: the name, residence, and business address and phone number of the entity that owns the practice; a complete list of the names and contact information of all the officers and directors of the corporation; the name, residence address, business address, and medical license number of each licensed Florida health care practitioner employed by the entity; the corporate tax identification number of the entity seeking an exemption; a listing of health care services to be provided by the entity at the health care clinics owned or operated by the entity and a

859422

certified statement prepared by an independent certified public accountant which states that the entity and the health care clinics owned or operated by the entity have not received payment for health care services under personal injury protection insurance coverage for the preceding year. If the agency determines that an entity which is exempt under this subsection has received payments for medical services under personal injury protection insurance coverage, the agency may deny or revoke the exemption from licensure under this subsection.

Notwithstanding this subsection, an entity shall be deemed a clinic and must be licensed under this part in order to receive reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730-627.7405, unless exempted under s. 627.736(5)(h).

Section 2. Subsection (4) of section 400.991, Florida Statutes, is amended to read:

400.991 License requirements; background screenings; prohibitions.—

(4) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the clinic is in compliance with this part and applicable rules, including:

(a) A listing of services to be provided either directly by the applicant or through contractual arrangements with existing providers;

(b) The number and discipline of each professional staff member to be employed; ~~and~~

(c) Proof of financial ability to operate as required under

859422

s. 408.810(8). As an alternative to submitting proof of financial ability to operate as required under s. 408.810(8), the applicant may file a surety bond of at least $500,000 which guarantees that the clinic will act in full conformity with all legal requirements for operating a clinic, payable to the agency. The agency may adopt rules to specify related requirements for such surety bond; and

(d) Proof that the clinic maintains the financial responsibility in the manner set forth in s. 458.320(2) or s. 459.0085(2), as applicable, to pay claims and costs ancillary thereto arising out of the rendering of or the failure to render medical care and services, for physicians and osteopathic physicians who perform liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II office surgery, or Level III office surgery as those terms are defined in ss. 458.305(8) and 459.003(9), in an office setting.

Section 3. Paragraph (j) is added to subsection (1) of section 400.9935, Florida Statutes, to read:

400.9935 Clinic responsibilities.—

(1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:

(j) If the clinic is registered with the department to perform office surgery, ensure that the clinic complies with the standards of practice for office surgery adopted by rule under ss. 458.309(4) and 459.005(3).

Section 4. Subsection (4) of section 400.995, Florida Statutes, is amended to read:

400.995 Agency administrative penalties.—

(4) Any licensed clinic whose owner, medical director, or clinic director concurrently operates an unlicensed clinic or a clinic that is not registered with the department where any liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed or where any Level II office surgery or Level III office surgery, as those terms are defined in ss. 458.305(8) and 459.003(9), is performed, is ~~shall be~~ subject to an administrative fine of $5,000 per day.

Section 5. Subsection (12) is added to section 456.004, Florida Statutes, to read:

456.004 Department; powers and duties.—The department, for the professions under its jurisdiction, shall:

(12) Deny or revoke the registration of, or impose any penalty set forth in s. 456.072(2) against, any facility where office surgery, as defined in ss. 458.305(8) and 459.003(9), is performed for failure of any of its physicians, owners, or operators to comply with rules adopted under ss. 458.309(3) and 459.005(2). Section 456.073 applies to enforcement actions brought against such facilities. If a facility's registration is revoked, the department may deny any person named in the registration documents of the facility, including the persons who own or operate the facility, individually or as part of a group, from registering a facility to perform surgical procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5 years after the revocation date.

Section 6. Subsection (6) is added to section 456.074, Florida Statutes, to read:

456.074 Certain health care practitioners; immediate

859422

suspension of license.—

(6) The department may issue an emergency order suspending or restricting the registration of a facility in which liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II office surgery, or Level III office surgery as those terms are defined in ss. 458.305(8) and 459.003(9), are performed upon a finding of probable cause that the facility or its surgeons are not in compliance with the standards of practice for office surgery adopted by the boards pursuant to s. 458.309(4) or s. 459.005(3), as applicable, or are in violation of s. 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance constitutes an immediate danger to the public.

Section 7. Section 458.305, Florida Statutes, is amended to read:

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

(1) "Board" means the Board of Medicine.

(2) "Deep sedation and analgesia" means a drug-induced depression of consciousness during which all of the following apply:

(a) The patient cannot be easily aroused but responds by purposefully following repeated or painful stimulation.

(b) The patient's ability to independently maintain ventilatory function may be impaired.

(c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

(d) The patient's cardiovascular function is usually maintained.

(e) The patient's reflex withdrawal from painful stimulus

859422

is not considered a purposeful response.

(3) ~~(2)~~ "Department" means the Department of Health.

(4) "Epidural anesthesia" means anesthesia produced by the injection of an anesthetic agent into the space on or around the dura mater of the spinal cord.

(5) "General anesthesia" means a drug-induced loss of consciousness administered by a qualified general anesthesia provider during which all of the following apply:

(a) The patient is not able to be aroused, even by painful stimulation.

(b) The patient's ability to independently maintain ventilatory function is often impaired.

(c) The patient has a level of depressed neuromuscular function.

(d) The patient may require assistance in maintaining a patent airway, and positive pressure ventilation may be required.

(e) The patient's cardiovascular function may be impaired.

(6) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes and respiratory and cardiovascular functions are unaffected.

(7) "Moderate sedation and analgesia" or "conscious sedation" means drug-induced depression of consciousness and a state of consciousness during which all of the following apply:

(a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) Interventions are not required to maintain a patent

859422

airway, and spontaneous ventilation is adequate.

(c) Cardiovascular function is maintained.

(d) Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(8) "Office surgery" means a surgery that is performed in a physician's office or any facility that is not licensed under chapter 390 or chapter 395.

(a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is limited to minimal sedation.

(b) "Level II office surgery" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

(10) ~~(3)~~ "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.

(11) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.

(12) "Surgeon" means a physician who performs surgery.

(13) "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or


859422

defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(9) ~~(4)~~ "Physician" means a person who is licensed to practice medicine in this state.

Section 8. Subsection (3) of section 458.309, Florida Statutes, is amended and subsection (4) is added to that section, to read:

458.309 Rulemaking authority.—

(3) A physician who performs any liposuction procedure ~~procedures~~ in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery ~~level 2 procedures lasting more than 5 minutes~~, or any Level III office surgery ~~and all level 3 surgical procedures~~ in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who

performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 458.320.

(4) The department may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery. The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (3) in an office that is not registered with the department.

Section 9. Paragraph (vv) is added to subsection (1) of section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(vv) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 458.309(3).

Section 10. Section 459.003, Florida Statutes, is amended to read:

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

(1) "Board" means the Board of Osteopathic Medicine.

(2) "Deep sedation and analgesia" means a drug-induced depression of consciousness during which all of the following apply:

859422

(a) The patient cannot be easily aroused but responds by purposefully following repeated or painful stimulation.

(b) The patient's ability to independently maintain ventilatory function may be impaired.

(c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

(d) The patient's cardiovascular function is usually maintained.

(e) The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(3) ~~(2)~~ "Department" means the Department of Health.

(5) "Epidural anesthesia" means anesthesia produced by the injection of an anesthetic agent into the space on or around the dura mater of the spinal cord.

(6) "General anesthesia" means a drug-induced loss of consciousness administered by a qualified general anesthesia provider during which all of the following apply:

(a) The patient is not able to be aroused, even by painful stimulation.

(b) The patient's ability to independently maintain ventilatory function is often impaired.

(c) The patient has a level of depressed neuromuscular function.

(d) The patient may require assistance in maintaining a patent airway, and positive pressure ventilation may be required.

(e) The patient's cardiovascular function may be impaired.

(7) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although

859422

cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected.

(8) "Moderate sedation and analgesia" or "conscious sedation" means drug-induced depression of consciousness and a state of consciousness during which all of the following apply:

(a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

(c) Cardiovascular function is maintained.

(d) Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(9) "Office surgery" means a surgery that is performed in a physician's office or any facility that is not licensed under chapter 390 or chapter 395.

(a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is limited to minimal sedation.

(b) "Level II office surgery" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

(11) ~~(3)~~ "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human

859422

disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

(12) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.

(13) "Surgeon" means a physician who performs surgery.

(14) "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(10) ~~(4)~~ "Osteopathic physician" means a person who is licensed to practice osteopathic medicine in this state.

(4) ~~(5)~~ "Doctor of Osteopathy" and "Doctor of Osteopathic Medicine," when referring to degrees, shall be construed to be equivalent and equal degrees.

Section 11. Subsection (2) of section 459.005, Florida Statutes, is amended and subsection (3) is added to that

section, to read:

459.005 Rulemaking authority.—

(2) A physician who performs any liposuction procedure ~~procedures~~ in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery ~~level 2 procedures lasting more than 5 minutes~~, or any Level III office surgery ~~and all level 3 surgical procedures~~ in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 459.0085.

(3) The department may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery. The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (2) in an office that is not registered with the department.

Section 12. Paragraph (xx) is added to subsection (1) of section 459.015, Florida Statutes, to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(xx) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 459.005(2).

Section 13. Paragraph (b) of subsection (4) of section 464.012, Florida Statutes, is amended to read:

464.012 Licensure of advanced practice registered nurses; fees; controlled substance prescribing.—

(4) In addition to the general functions specified in subsection (3), an advanced practice registered nurse may perform the following acts within his or her specialty:

(b) The certified registered nurse anesthetist may, to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed, perform any or all of the following:

1. Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.

2. Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.

3. Order under the protocol preanesthetic medication.

4. Perform under the protocol procedures commonly used to

render the patient insensible to pain during the performance of surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.

5. Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.

6. Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.

7. Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.

8. Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.

9. Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.

10. Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.

11. Provide the services identified in subsections 1.-10. in an office registered to perform office surgery pursuant to s. 458.309(3) or s. 459.005(2) within the framework of an established protocol with an anesthesiologist licensed under chapter 458 or chapter 459.

Section 14. Paragraph (a) of subsection (1) of section

766.101, Florida Statutes, is amended to read:

766.101 Medical review committee, immunity from liability.—

(1) As used in this section:

(a) The term "medical review committee" or "committee" means:

1.a. A committee of a hospital or ambulatory surgical center licensed under chapter 395 or a health maintenance organization certificated under part I of chapter 641;

b. A committee of a physician-hospital organization, a provider-sponsored organization, or an integrated delivery system;

c. A committee of a state or local professional society of health care providers;

d. A committee of a medical staff of a licensed hospital or nursing home, provided the medical staff operates pursuant to written bylaws that have been approved by the governing board of the hospital or nursing home;

e. A committee of the Department of Corrections or the Correctional Medical Authority as created under s. 945.602, or employees, agents, or consultants of either the department or the authority or both;

f. A committee of a professional service corporation formed under chapter 621 or a corporation organized under part I of chapter 607 or chapter 617, which is formed and operated for the practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~, and which has at least 25 health care providers who routinely provide health care services directly to patients;

g. A committee of the Department of Children and Families which includes employees, agents, or consultants to the

department as deemed necessary to provide peer review, utilization review, and mortality review of treatment services provided pursuant to chapters 394, 397, and 916;

h. A committee of a mental health treatment facility licensed under chapter 394 or a community mental health center as defined in s. 394.907, provided the quality assurance program operates pursuant to the guidelines that have been approved by the governing board of the agency;

i. A committee of a substance abuse treatment and education prevention program licensed under chapter 397 provided the quality assurance program operates pursuant to the guidelines that have been approved by the governing board of the agency;

j. A peer review or utilization review committee organized under chapter 440;

k. A committee of the Department of Health, a county health department, healthy start coalition, or certified rural health network, when reviewing quality of care, or employees of these entities when reviewing mortality records; or

l. A continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465,

which committee is formed to evaluate and improve the quality of health care rendered by providers of health service, to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care, or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area; or

2. A committee of an insurer, self-insurer, or joint

859422

underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106.

Section 15. This act shall take effect upon becoming a law.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to clinics and office surgery; amending s. 400.9905, F.S.; revising the definition of the term "clinic"; amending s. 400.991, F.S.; requiring a clinic to provide proof of its financial responsibility to pay certain claims and costs along with its application for licensure to the Agency for Health Care Administration; amending s. 400.9935, F.S.; requiring a medical director or a clinic director to ensure that the clinic complies with specified rules; amending s. 400.995, F.S.; requiring the agency to impose a specified administrative fine on an unregistered clinic that performs certain office surgeries; amending s. 456.004, F.S.; requiring the Department of Health to deny or revoke the registration of or impose certain penalties against a facility where certain office surgeries are performed under certain circumstances; specifying provisions that apply enforcement actions against such facilities; authorizing the department to deny certain persons associated with an office of which the


859422

registration was revoked from registering a new office to perform certain office surgery; amending s. 456.074, F.S.; authorizing the department to issue an emergency order suspending or restricting the registration of a certain office if it makes certain findings; amending s. 458.305, F.S.; defining terms; amending s. 458.309, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the department to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring the Board of Medicine to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 458.331, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 459.003, F.S.; defining terms; amending s. 459.005, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the department to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring the Board of Osteopathic Medicine to adopt


859422

rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 459.015, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 464.012, F.S.; authorizing a certified registered nurse anesthetist to provide specified services in a an office registered to perform office surgery within the framework of an established protocol with a licensed anesthesiologist; amending s. 766.101, F.S.; conforming a cross-reference; providing an effective date.

By Senator Flores

39-00277A-19 2019732__

A bill to be entitled

An act relating to office surgery; amending s. 395.002, F.S.; revising the definition of the term "ambulatory surgical center" to remove the exclusion of physician offices; amending ss. 458.309 and 459.005, F.S.; deleting provisions related to the registration and inspection of certain offices by the Department of Health and the payment for such registration and inspection, for the purpose of relocating the requirements; creating ss. 458.3266 and 459.0138, F.S.; defining terms; relocating the requirements that a person who seeks to operate an office surgery center must register with the department and pay registration costs; providing an exception; requiring each office surgery center to identify to the department a designated physician upon registration or within a specified timeframe after the resignation or termination of a designated physician; authorizing the department to suspend a center's certificate of registration under certain circumstances; requiring the department to issue a certificate of registration to qualified applicants and prohibiting the department from issuing a certificate to certain centers; requiring the department to revoke a certificate upon making a certain determination; requiring a designated physician of a center to perform certain actions upon the revocation or suspension of the center's certificate and providing for the disposition of

medicinal drugs; authorizing the department to prescribe a certain period of suspension when suspending the certificate of an office surgery center; prohibiting persons named in the registration documents of a center whose certificate was revoked from applying to operate a center for a specified time; prohibiting a registration from being transferred to a new owner and requiring a new owner to register the center with the department before beginning operation under the new ownership; prohibiting a physician from practicing medicine in a center that is not registered with the department; prohibiting a physician from performing certain procedures in a facility or office surgery center; requiring a physician who practices in a center to immediately notify the department of certain noncompliance; requiring a physician to notify the Board of Medicine or Board of Osteopathic Medicine, respectively, within a specified timeframe after beginning or ending his or her practice at a center; providing for disciplinary action; providing requirements for designated physicians; providing facility and infection control requirements for centers; specifying health and safety requirements; prohibiting performance of a level III procedure in a center unless an anesthesiologist is present and available; specifying that level III procedures may be performed only in a center on patients who meet certain conditions; establishing requirements for a

surgeon to perform a level III procedure in a center; relocating the requirement that the department inspect each center for compliance annually unless the center is accredited by certain organizations; relocating the requirement that the person who registered and operates the center pay costs of inspection; requiring the Department of Health to attempt to resolve violations during the inspection of a center; requiring the owner or designated physician to document actions taken to resolve violations; requiring the department to verify correction of the violation during a subsequent inspection; authorizing the department to revoke a center's certificate of registration and prohibit associated physicians from practicing at the center for failure to comply with certain provisions; authorizing the department to impose an administrative fine on a center for violations of specified provisions; requiring the department to consider specified factors in determining whether to impose a penalty or determining the amount of a fine to be imposed on a center; providing that each day a violation continues after the department orders its correction constitutes an additional violation; requiring the department to impose specified fines on an owner or a designated physician for operating an unregistered center; authorizing the department to adopt rules relating to the registration, inspection, and safety of centers; requiring the board to adopt rules specifying training

requirements for certain center practitioners; republishing ss. 458.351 and 459.026, F.S., relating to reports of adverse incidents in office practice settings; providing an effective date.

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

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

395.002 Definitions.—As used in this chapter:

(3) "Ambulatory surgical center" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy~~, an office maintained by a physician for the practice of medicine,~~ or an office maintained for the practice of dentistry may not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003.

Section 2. Subsection (3) of section 458.309, Florida Statutes, is amended to read:

458.309 Rulemaking authority.—

~~(3) A physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, level 2 procedures lasting more than 5 minutes, and all~~

~~level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.~~

Section 3. Section 458.3266, Florida Statutes, is created to read:

458.3266 Office surgery centers.—

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

(a) "Deep sedation with analgesia" means a drug-induced depression of consciousness during which all of the following apply:

1. The patient cannot be easily aroused but responds purposefully following repeated or painful stimulation.

2. The patient's ability to independently maintain ventilatory function may be impaired.

3. The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

4. The patient's cardiovascular function is usually maintained.

5. The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(b) "Designated physician" means a physician licensed under this chapter or chapter 459 who practices at an office surgery center and who has assumed responsibility for the center's

compliance with this section and related board rules.

(c) "General anesthesia" means a drug-induced loss of consciousness administered by an anesthesiologist or a certified registered nurse anesthetist during which all of the following apply:

1. The patient is not able to be aroused, even by painful stimulation.

2. The patient's ability to independently maintain ventilatory function is often impaired.

3. The patient has a level of depressed neuromuscular function.

4. The patient may require assistance in maintaining a patent airway, and positive pressure ventilation is required.

5. The patient's cardiovascular function may be impaired.

(d) "Level I procedure" includes procedures in which the patient's level of sedation is that of minimal sedation, and controlled substances, as defined in ss. 893.02 and 893.03, are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. The term includes:

1. Minor procedures such as excision of skin lesions, moles, warts, cysts, and lipomas; repair of lacerations; or surgery limited to the skin and subcutaneous tissue performed under topical or regional anesthesia not involving drug-induced alteration of consciousness other than minimal preoperative tranquilization of the patient.

2. The incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of

urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations, including, but not limited to, finger and toe joints.

(e) "Level II procedure" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. The term includes, but is not limited to: hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 1,000 cubic centimeters of supernatant fat.

(f) "Level III procedure" includes any surgery in which the patient's level of sedation is that of deep sedation with analgesia, general anesthesia, and spinal, regional, or epidural anesthesia.

(g) "Minimal sedation" includes anxiolysis and means a drug-induced state during which all of the following apply:

1. The patient may respond normally to verbal commands.

2. The patient's cognitive function and physical coordination may be impaired, while his or her airway reflexes, ventilation, and cardiovascular functions are unaffected.

(h) "Moderate sedation with analgesia" or "conscious sedation" are both drug-induced depressions of consciousness and mean a state of consciousness during which all of the following apply:

1. The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

2. Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

3. Cardiovascular function is maintained.

4. Reflex withdrawal from a painful stimulus is not

considered a purposeful response.

(i) "Office surgery" means any manual or operative procedure, including by use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ, including both a closed and open reduction of a fracture; extraction of tissue, including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(j) "Office surgery center" means any facility or office surgery setting, other than a facility licensed under chapter 390 or chapter 395, where a physician performs any of the following surgical procedures:

1. A level I procedure;

2. A level II procedure lasting more than 5 minutes; or

3. A level III procedure.

(k) "Regional anesthesia" is a drug-induced loss of sensation in a circumscribed region of the body, produced by the application of a regional anesthetic, usually by injection. The term includes, but is not limited to, spinal, epidural, and specific nerve blocks.

(l) "Surgery" or "surgical" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health,

diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes. The term includes, but is not limited to, all of the following: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ, including both a closed and an open reduction of a fracture; extraction of tissue, including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local, regional, or general anesthetic.

(2) CERTIFICATE OF REGISTRATION.—

(a) A person who seeks to operate an office surgery center must register the center with the department unless the center is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(b) Each office surgery center must be registered separately, regardless of whether it is operated under the same business name or management as another center. The actual costs of registration, as determined by the department, must be paid by the person seeking to register and operate the center.

(c) At the time of registration and thereafter, each office surgery center shall identify to the department a designated physician. Within 10 days after the resignation or termination of its designated physician, a center shall identify to the department the new designated physician. The department may suspend a center's certificate of registration for failure to comply with this paragraph.

(d) The department shall issue a certificate of registration to a qualified applicant who is required to register under this section. The department may not issue a certificate of registration to an office surgery center that is:

1. Not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians licensed under this chapter or chapter 459;

2. Not a health care center licensed under part X of chapter 400; or

3. Owned by or in any contractual or employment relationship with a physician licensed under this chapter or chapter 459 who:

a. Has had his or her hospital privileges revoked in the last 5 years;

b. Does not have a clear and active license with the department; or

c. Has been the subject of disciplinary action in this state or in another jurisdiction in the last 5 years for an offense related to standard of care.

(e) If the department determines that an office surgery center does not meet the requirements of paragraph (c) or is owned, directly or indirectly, by a physician whose privileges, license, or disciplinary status is identified in sub-subparagraph (d)3.a., sub-subparagraph (d)3.b., or sub-subparagraph (d)3.c., the department shall revoke the center's certificate of registration.

(f) If the center's certificate of registration is revoked or suspended, the designated physician of the center shall ensure that, as appropriate, the owner or lessor of the center

property, the manager, or the proprietor, as of the effective date of the suspension or revocation:

1. Ceases to operate the facility as an office surgery center; and

2. Removes any signs and symbols identifying the premises as an office surgery center.

(g) Upon the effective date of the suspension or revocation, the designated physician of the office surgery center shall advise the department of the disposition of the medicinal drugs located on the premises. Such disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a center that is not registered may be deemed adulterated for purposes of s. 499.006.

(h) When the department suspends the registration of an office surgery center, it shall prescribe an appropriate period of suspension, not to exceed 2 years.

(i) If the office surgery center's registration is revoked, any person named in the registration documents of the center, including the persons who own or operate the center, may not apply, individually or as part of a group, to operate an office surgery center for a period of 5 years after the revocation date.

(j) An office surgery center registration may not be transferred to a new owner. If the ownership of a registered office surgery center changes, the new owner must register the center with the department before beginning operation under the new ownership.

(3) OFFICE SURGERY CENTER PHYSICIANS; DESIGNATED

PHYSICIANS; PROHIBITION; REQUIREMENTS.—

(a)1. A physician may not practice medicine in an office surgery center that is not registered with the department in compliance with this section.

2. A physician may not perform surgical procedures in an office surgery center which may:

a. Result in blood loss of more than 10 percent of estimated blood volume in a patient having a normal hemoglobin level;

b. Require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; or

c. Involve major blood vessels, when such procedure is performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or are generally emergent or life threatening in nature.

3. If a physician who practices in an office surgery center determines that the center is not in compliance with subsection (4), he or she must immediately notify the department of such noncompliance.

4. A physician who practices in an office surgery center shall notify the board in writing within 10 days after beginning or ending his or her practice at the office surgery center.

A physician who violates this paragraph is subject to disciplinary action by the board.

(b) The designated physician of an office surgery center shall:

1. Ensure that the center maintains an ongoing quality

assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies at the facility, alerts the designated physician to identify and resolve recurring problems, and provides opportunities for the center to improve its performance and enhance and improve the quality of care provided to the public.

2. Establish and document compliance with the quality assurance program which includes at least the following components:

a. Identification, investigation, and analysis of the frequency and causes of incidents;

b. Identification of trends or patterns of adverse incidents; and

c. Development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.

3. Review, at least quarterly, the quality assurance program.

4. Report all adverse incidents to the department as provided in s. 458.351.

5. Notify the applicable board in writing of his or her termination of employment within 10 days after such termination.

(4) OFFICE SURGERY CENTERS; REQUIREMENTS.—An office surgery center must comply with the following requirements:

(a) *Facility requirements.*—The office surgery center must:

1. Be located and operated at a publicly accessible, fixed location.

2. Display a sign that clearly identifies the name, hours

of operation, and street address of the center. The sign must be prominently displayed in public view.

3. Maintain and publicly list a telephone number.

4. Provide emergency lighting and for emergency communications.

5. Have a reception and waiting area.

6. Have a restroom.

7. Have an administrative area, including room for storage of medical records, supplies, and equipment.

8. Have private patient examination rooms.

9. Have treatment rooms, if treatment is being provided to the patients.

10. Publicly display a visible printed sign in a conspicuous place in each waiting room which includes the name and contact information of the center's designated physician and the names of all physicians practicing at the center.

11. Comply with ss. 499.0121 and 893.07, if the center stores and dispenses prescription drugs.

(b) *Infection control requirements.*—The center must:

1. Maintain equipment and supplies to support infection prevention and control.

2. Identify infection risks based on the following:

a. Geographic location, community, and population served.

b. The nature of the provided care, treatments, and services.

c. An analysis of the center's infection surveillance and control data.

3. Maintain written infection prevention policies and procedures that address prioritized risks and limit the

following:

a. Unprotected exposure to pathogens.

b. The transmission of infections associated with procedures performed at the center.

c. The transmission of infections associated with the center's use of medical equipment, devices, and supplies.

(c) *Health and safety requirements.*—The center must:

1. Maintain its structurally sound buildings and keep its grounds free from health and safety hazards.

2. Keep its furniture, appliances, and equipment clean, safe, and in good repair.

3. Have evacuation procedures in the event of an emergency. The procedures must provide for the evacuation of patients with disabilities and center employees.

4. Have a written facility-specific disaster plan that specifies actions to be taken in the event of the center closing due to unforeseen disasters. The plan must provide for the protection of medical records and any controlled substances.

5. Have at least one employee on the premises during patient care hours who is certified in basic life support and trained in reacting to accidents and medical emergencies.

6. Have written emergency policies and procedures related to serious anesthesia complications which must be formulated, reviewed annually, practiced, updated, and posted in a conspicuous location. Such procedures must address all of the following conditions:

a. Airway blockage and foreign body obstruction;

b. Allergic reactions;

c. Bradycardia;

d. Bronchospasm;

e. Cardiac arrest;

f. Chest pain;

g. Hypoglycemia;

h. Hypotension;

i. Hypoventilation;

j. Laryngospasm;

k. Local anesthetic toxicity reaction; and

l. Malignant hyperthermia.

(d) *Equipment and supplies.*—The center must:

1. Have the equipment and medications to properly manage and treat a cardiac incident or arrest, including a full and current crash cart with a defibrillator, and, at a minimum, the intravenous or inhaled medications recommended by the American Heart Association Guidelines for CPR & Emergency Cardiovascular Care, as published November 2018, at the location where the anesthetizing is being carried out.

2. Store medicines per the manufacturer's recommendations and note the date on multidose vials once they are opened.

3. Maintain dantrolene on site if halogenated anesthetics or succinylcholine are used.

4. In terms of general preparation, equipment, and supplies, be comparable to a freestanding ambulatory surgical center, including, but not limited to, patient recovery capability and provisions for proper recordkeeping.

5. Have blood pressure monitoring equipment, EKG, end-tidal CO2 monitor, pulse oximeter, emergency intubation equipment, and a temperature monitoring device.

6. Have at least one table capable of trendelenburg,

lithotomy, and other positions necessary to facilitate the surgical procedure.

(e) *Level III office surgery requirements.*—

1. A level III procedure may not be performed in an office surgery center unless an anesthesiologist, as defined in s. 458.3475 or s. 459.023, is physically present at the center and available at the time of the procedure.

2. For a center in which level III procedures are performed, either:

a. The center must have a written patient transfer agreement with a hospital within reasonable proximity to the center which includes the transfer of the patient's medical records held by the center and the treating physician to the licensed hospital; or

b. The surgeon performing the level III procedure must have admitting privileges at a hospital within reasonable proximity to the center.

3. Level III procedures may be performed only on a patient who is classified under the American Society of Anesthesiologists' (ASA) Physical Status Classification System, as approved on October 15, 2014, as Class I or II.

4. All ASA Class II patients above the age of 50 undergoing a level III office surgery procedure shall have a complete medical workup performed by the surgeon before the performance of level III surgery. If the patient has a cardiac history or has other complicating health conditions, he or she must have a preoperative EKG and be referred to an appropriate consultant for medical optimization of the complicating conditions. The referral to a consultant may be waived after evaluation by the

anesthesiologist to administer or supervise the patient's anesthesia.

5. To perform a level III procedure in an office surgery center, the surgeon must have staff privileges at a licensed hospital to perform the same level III procedure in the hospital or must be able to document satisfactory completion of training, such as board certification or board qualification by a board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine.

(5) INSPECTION.—

(a) The department shall inspect each office surgery center annually, including a review of patient records, to ensure that the center complies with this section and board rule, unless the center is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the board. The department also may inspect an office surgery center as necessary to investigate a notification of noncompliance made by a physician pursuant to subparagraph (3)(a)3.

(b) The actual costs of inspection must be paid by the person who registered and operates the office surgery center.

(c) During an onsite inspection, the department shall make a reasonable attempt to resolve each violation with the owner or designated physician of the office surgery center before issuing a formal written notification.

(d) Any action taken to resolve a violation must be documented in writing by the owner or designated physician of the office surgery center and submitted to the department. The department must verify any correction of the violation in a

subsequent inspection.

(6) ENFORCEMENT.—

(a) The department may revoke an office surgery center's certificate of registration and prohibit all physicians associated with the center from practicing at the center for failure to comply with this section and rules adopted hereunder.

(b) The department may impose an administrative fine of up to $5,000 per violation on an office surgery center for violations of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or department rule.

(c) In determining whether to impose a penalty on an office surgery center, and in determining the amount of any fine, the department shall consider all of the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the center's actions or the actions of the physician; the gravity of the action or potential harm; and the nature of the violations of applicable laws or rules.

2. Any actions taken by the owner or designated physician to correct the violation.

3. Whether any previous violations were committed at the center.

4. Any financial benefits derived by the center from committing or continuing to commit the violation.

(d) Each day a violation continues after the date on which the department orders a correction of the violation constitutes an additional, separate, and distinct violation.

(e) The department may impose a fine and, in the case of an owner-operated office surgery center, revoke or deny a center's registration if the center's designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

(f) The department shall impose a fine of $5,000 per day on an owner or designated physician of an office surgery center registered under this section who concurrently operates an unregistered center.

(g) The department shall impose a fine of $10,000 on a new owner of an office surgery center that requires registration who fails to register the center upon the change of ownership and who operates the unregistered center.

(7) RULEMAKING.—

(a) The department may adopt rules to administer the registration, inspection, and safety of office surgery centers.

(b) The board shall adopt rules specifying training requirements for all licensed or certified office surgery center health care practitioners and other health care practitioners who are not regulated by any board.

Section 4. Section 458.351, Florida Statutes, is republished to read:

458.351 Reports of adverse incidents in office practice settings.—

(1) Any adverse incident that occurs on or after January 1, 2000, in any office maintained by a physician for the practice

of medicine which is not licensed under chapter 395 must be reported to the department in accordance with the provisions of this section.

(2) Any physician or other licensee under this chapter practicing in this state must notify the department if the physician or licensee was involved in an adverse incident that occurred on or after January 1, 2000, in any office maintained by a physician for the practice of medicine which is not licensed under chapter 395.

(3) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.

(4) For purposes of notification to the department pursuant to this section, the term "adverse incident" means an event over which the physician or licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

(a) The death of a patient.

(b) Brain or spinal damage to a patient.

(c) The performance of a surgical procedure on the wrong patient.

(d)1. The performance of a wrong-site surgical procedure;

2. The performance of a wrong surgical procedure; or

3. The surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process

if it results in: death; brain or spinal damage; permanent disfigurement not to include the incision scar; fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory function; or any condition that required the transfer of the patient.

(e) A procedure to remove unplanned foreign objects remaining from a surgical procedure.

(f) Any condition that required the transfer of a patient to a hospital licensed under chapter 395 from an ambulatory surgical center licensed under chapter 395 or any facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395.

(5) The department shall review each incident and determine whether it potentially involved conduct by a health care professional who is subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board under which the health care professional is licensed.

(6)(a) The board shall adopt rules establishing a standard informed consent form that sets forth the recognized specific risks related to cataract surgery. The board must propose such rules within 90 days after the effective date of this subsection.

(b) Before formally proposing the rule, the board must consider information from physicians licensed under this chapter or chapter 459 regarding recognized specific risks related to cataract surgery and the standard informed consent forms adopted for use in the medical field by other states.

(c) A patient’s informed consent is not executed until the

patient, or a person authorized by the patient to give consent, and a competent witness sign the form adopted by the board.

(d) An incident resulting from recognized specific risks described in the signed consent form is not considered an adverse incident for purposes of s. 395.0197 and this section.

(e) In a civil action or administrative proceeding against a physician based on his or her alleged failure to properly disclose the risks of cataract surgery, a patient's informed consent executed as provided in paragraph (c) on the form adopted by the board is admissible as evidence and creates a rebuttable presumption that the physician properly disclosed the risks.

(7) The board may adopt rules to administer this section.

Section 5. Section 459.005, Florida Statutes, is amended to read:

459.005 Rulemaking authority.—

~~(1)~~ The board has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

~~(2) A physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or~~

~~accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.~~

Section 6. Section 459.0138, Florida Statutes, is created to read:

459.0138 Office surgery centers.—

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

(a) "Deep sedation with analgesia" means a drug-induced depression of consciousness during which all of the following apply:

1. The patient cannot be easily aroused but responds purposefully following repeated or painful stimulation.

2. The patient's ability to independently maintain ventilatory function may be impaired.

3. The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

4. The patient's cardiovascular function is usually maintained.

5. The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(b) "Designated physician" means a physician licensed under this chapter or chapter 458 who practices at an office surgery center and who has assumed responsibility for the center's compliance with this section and related board rules.

(c) "General anesthesia" means a drug-induced loss of consciousness administered by an anesthesiologist or a certified registered nurse anesthetist during which all of the following apply:

1. The patient is not able to be aroused, even by painful

stimulation.

2. The patient's ability to independently maintain ventilatory function is often impaired.

3. The patient has a level of depressed neuromuscular function.

4. The patient may require assistance in maintaining a patent airway, and positive pressure ventilation is required.

5. The patient's cardiovascular function may be impaired.

(d) "Level I procedure" includes procedures in which the patient's level of sedation is that of minimal sedation, and controlled substances, as defined in ss. 893.02 and 893.03, are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. The term includes:

1. Minor procedures such as excision of skin lesions, moles, warts, cysts, and lipomas; repair of lacerations; or surgery limited to the skin and subcutaneous tissue performed under topical or regional anesthesia not involving drug-induced alteration of consciousness other than minimal preoperative tranquilization of the patient.

2. The incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations, including, but not limited to, finger and toe joints.

(e) "Level II procedure" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. The term includes, but is not

limited to: hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 1,000 cubic centimeters of supernatant fat.

(f) "Level III procedure" includes any surgery in which the patient's level of sedation is that of deep sedation with analgesia, general anesthesia, and spinal, regional, or epidural anesthesia.

(g) "Minimal sedation" includes anxiolysis and means a drug-induced state during which all of the following apply:

1. The patient may respond normally to verbal commands.

2. The patient's cognitive function and physical coordination may be impaired, while his or her airway reflexes, ventilation, and cardiovascular functions are unaffected.

(h) "Moderate sedation with analgesia" or "conscious sedation" are both drug-induced depressions of consciousness and mean a state of consciousness during which all of the following apply:

1. The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

2. Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

3. Cardiovascular function is maintained.

4. Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(i) "Office surgery" means any manual or operative procedure, including by use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or

any elective procedure for aesthetic, reconstructive, or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ, including both a closed and open reduction of a fracture; extraction of tissue, including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(j) "Office surgery center" means any facility or office surgery setting, other than a facility licensed under chapter 390 or chapter 395, where a physician performs any of the following surgical procedures:

1. A level I procedure;

2. A level II procedure lasting more than 5 minutes; or

3. A level III procedure.

(k) "Regional anesthesia" is a drug-induced loss of sensation in a circumscribed region of the body, produced by the application of a regional anesthetic, usually by injection. The term includes, but is not limited to, spinal, epidural, and specific nerve blocks.

(l) "Surgery" or "surgical" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes. The term includes, but is not limited to, all of the following: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ, including both a

closed and an open reduction of a fracture; extraction of tissue, including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local, regional, or general anesthetic.

(2) CERTIFICATE OF REGISTRATION.—

(a) A person who seeks to operate an office surgery center must register the center with the department unless the center is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(b) Each office surgery center must be registered separately, regardless of whether it is operated under the same business name or management as another center. The actual costs of registration, as determined by the department, must be paid by the person seeking to register and operate the center.

(c) At the time of registration and thereafter, each office surgery center shall identify to the department a designated physician. Within 10 days after the resignation or termination of its designated physician, a center shall identify to the department the new designated physician. The department may suspend a center's certificate of registration for failure to comply with this paragraph.

(d) The department shall issue a certificate of registration to a qualified applicant who is required to register under this section. The department may not issue a certificate of registration to an office surgery center that is:

1. Not fully owned by a physician licensed under this chapter or chapter 458 or a group of physicians licensed under

this chapter or chapter 458;

2. Not a health care center licensed under part X of chapter 400; or

3. Owned by or in any contractual or employment relationship with a physician licensed under this chapter or chapter 458 who:

a. Has had his or her hospital privileges revoked in the last 5 years;

b. Does not have a clear and active license with the department; or

c. Has been the subject of disciplinary action in this state or in another jurisdiction in the last 5 years for an offense related to standard of care.

(e) If the department determines that an office surgery center does not meet the requirements of paragraph (c) or is owned, directly or indirectly, by a physician whose privileges, license, or disciplinary status is identified in sub-subparagraph (d)3.a., sub-subparagraph (d)3.b., or sub-subparagraph (d)3.c., the department shall revoke the center's certificate of registration.

(f) If the center's certificate of registration is revoked or suspended, the designated physician of the center shall ensure that, as appropriate, the owner or lessor of the center property, the manager, or the proprietor, as of the effective date of the suspension or revocation:

1. Ceases to operate the facility as an office surgery center; and

2. Removes any signs and symbols identifying the premises as an office surgery center.

(g) Upon the effective date of the suspension or revocation, the designated physician of the office surgery center shall advise the department of the disposition of the medicinal drugs located on the premises. Such disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a center that is not registered may be deemed adulterated for purposes of s. 499.006.

(h) When the department suspends the registration of an office surgery center, it shall prescribe an appropriate period of suspension, not to exceed 2 years.

(i) If the office surgery center's registration is revoked, any person named in the registration documents of the center, including the persons who own or operate the center, may not apply, individually or as part of a group, to operate an office surgery center for a period of 5 years after the revocation date.

(j) An office surgery center registration may not be transferred to a new owner. If the ownership of a registered office surgery center changes, the new owner must register the center with the department before beginning operation under the new ownership.

(3) OFFICE SURGERY CENTER PHYSICIANS; DESIGNATED PHYSICIANS; PROHIBITION; REQUIREMENTS.—

(a)1. A physician may not practice medicine in an office surgery center that is not registered with the department in compliance with this section.

2. A physician may not perform surgical procedures in an office surgery center which may:

a. Result in blood loss of more than 10 percent of estimated blood volume in a patient having a normal hemoglobin level;

b. Require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; or

c. Involve major blood vessels, when such procedure is performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or are generally emergent or life threatening in nature.

3. If a physician who practices in an office surgery center determines that the center is not in compliance with subsection (4), he or she must immediately notify the department of such noncompliance.

4. A physician who practices in an office surgery center shall notify the board in writing within 10 days after beginning or ending his or her practice at the office surgery center.

A physician who violates this paragraph is subject to disciplinary action by the board.

(b) The designated physician of an office surgery center shall:

1. Ensure that the center maintains an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies at the facility, alerts the designated physician to identify and resolve recurring problems, and provides opportunities for the center to improve its performance

and enhance and improve the quality of care provided to the public.

2. Establish and document compliance with the quality assurance program which includes at least the following components:

a. Identification, investigation, and analysis of the frequency and causes of incidents;

b. Identification of trends or patterns of adverse incidents; and

c. Development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.

3. Review, at least quarterly, the quality assurance program.

4. Report all adverse incidents to the department as provided in s. 459.026.

5. Notify the applicable board in writing of his or her termination of employment within 10 days after such termination.

(4) OFFICE SURGERY CENTERS; REQUIREMENTS.—An office surgery center must comply with the following requirements:

(a) *Facility requirements.*—The office surgery center must:

1. Be located and operated at a publicly accessible, fixed location.

2. Display a sign that clearly identifies the name, hours of operation, and street address of the center. The sign must be prominently displayed in public view.

3. Maintain and publicly list a telephone number.

4. Provide emergency lighting and for emergency communications.

5. Have a reception and waiting area.

6. Have a restroom.

7. Have an administrative area, including room for storage of medical records, supplies, and equipment.

8. Have private patient examination rooms.

9. Have treatment rooms, if treatment is being provided to the patients.

10. Publicly display a visible printed sign in a conspicuous place in each waiting room which includes the name and contact information of the center's designated physician and the names of all physicians practicing at the center.

11. Comply with ss. 499.0121 and 893.07, if the center stores and dispenses prescription drugs.

(b) *Infection control requirements.*—The center must:

1. Maintain equipment and supplies to support infection prevention and control.

2. Identify infection risks based on the following:

a. Geographic location, community, and population served.

b. The nature of the provided care, treatments, and services.

c. An analysis of the center's infection surveillance and control data.

3. Maintain written infection prevention policies and procedures that address prioritized risks and limit the following:

a. Unprotected exposure to pathogens.

b. The transmission of infections associated with procedures performed at the center.

c. The transmission of infections associated with the center's use of medical equipment, devices, and supplies.

(c) *Health and safety requirements.*—The center must:

1. Maintain its structurally sound buildings and keep its grounds free from health and safety hazards.

2. Keep its furniture, appliances, and equipment clean, safe, and in good repair.

3. Have evacuation procedures in the event of an emergency. The procedures must provide for the evacuation of patients with disabilities and center employees.

4. Have a written facility-specific disaster plan that specifies actions to be taken in the event of the center closing due to unforeseen disasters. The plan must provide for the protection of medical records and any controlled substances.

5. Have at least one employee on the premises during patient care hours who is certified in basic life support and trained in reacting to accidents and medical emergencies.

6. Have written emergency policies and procedures related to serious anesthesia complications which must be formulated, reviewed annually, practiced, updated, and posted in a conspicuous location. Such procedures must address all of the following conditions:

a. Airway blockage and foreign body obstruction;

b. Allergic reactions;

c. Bradycardia;

d. Bronchospasm;

e. Cardiac arrest;

f. Chest pain;

g. Hypoglycemia;

h. Hypotension;

i. Hypoventilation;

j. Laryngospasm;

k. Local anesthetic toxicity reaction; and

l. Malignant hyperthermia.

(d) *Equipment and supplies.*—The center must:

1. Have the equipment and medications to properly manage and treat a cardiac incident or arrest, including a full and current crash cart with a defibrillator, and, at a minimum, the intravenous or inhaled medications recommended by the American Heart Association Guidelines for CPR & Emergency Cardiovascular Care, as published November 2018, at the location where the anesthetizing is being carried out.

2. Store medicines per the manufacturer's recommendations and note the date on multidose vials once they are opened.

3. Maintain dantrolene on site if halogenated anesthetics or succinylcholine are used.

4. In terms of general preparation, equipment, and supplies, be comparable to a freestanding ambulatory surgical center, including, but not limited to, patient recovery capability and provisions for proper recordkeeping.

5. Have blood pressure monitoring equipment, EKG, end-tidal CO2 monitor, pulse oximeter, emergency intubation equipment, and a temperature monitoring device.

6. Have at least one table capable of trendelenburg, lithotomy, and other positions necessary to facilitate the surgical procedure.

(e) *Level III office surgery requirements.*—

1. A level III procedure may not be performed in an office surgery center unless an anesthesiologist, as defined in s. 458.3475 or s. 459.023, is physically present at the center and

available at the time of the procedure.

2. For a center in which level III procedures are performed, either:

a. The center must have a written patient transfer agreement with a hospital within reasonable proximity to the center which includes the transfer of the patient's medical records held by the center and the treating physician to the licensed hospital; or

b. The surgeon performing the level III procedure must have admitting privileges at a hospital within reasonable proximity to the center.

3. Level III procedures may be performed only on a patient who is classified under the American Society of Anesthesiologists' (ASA) Physical Status Classification System, as approved on October 15, 2014, as Class I or II.

4. All ASA Class II patients above the age of 50 undergoing a level III office surgery procedure shall have a complete medical workup performed by the surgeon before the performance of level III surgery. If the patient has a cardiac history or has other complicating health conditions, he or she must have a preoperative EKG and be referred to an appropriate consultant for medical optimization of the complicating conditions. The referral to a consultant may be waived after evaluation by the anesthesiologist to administer or supervise the patient's anesthesia.

5. To perform a level III procedure in an office surgery center, the surgeon must have staff privileges at a licensed hospital to perform the same level III procedure in the hospital or must be able to document satisfactory completion of training,

such as board certification or board qualification by a board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine.

(5) INSPECTION.—

(a) The department shall inspect each office surgery center annually, including a review of patient records, to ensure that the center complies with this section and board rule, unless the center is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the board. The department also may inspect an office surgery center as necessary to investigate a notification of noncompliance made by a physician pursuant to subparagraph (3)(a)3.

(b) The actual costs of inspection must be paid by the person who registered and operates the office surgery center.

(c) During an onsite inspection, the department shall make a reasonable attempt to resolve each violation with the owner or designated physician of the office surgery center before issuing a formal written notification.

(d) Any action taken to resolve a violation must be documented in writing by the owner or designated physician of the office surgery center and submitted to the department. The department must verify any correction of the violation in a subsequent inspection.

(6) ENFORCEMENT.—

(a) The department may revoke an office surgery center's certificate of registration and prohibit all physicians associated with the center from practicing at the center for failure to comply with this section and rules adopted hereunder.

(b) The department may impose an administrative fine of up to $5,000 per violation on an office surgery center for violations of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or department rule.

(c) In determining whether to impose a penalty on an office surgery center, and in determining the amount of any fine, the department shall consider all of the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the center's actions or the actions of the physician; the gravity of the action or potential harm; and the nature of the violations of applicable laws or rules.

2. Any actions taken by the owner or designated physician to correct the violation.

3. Whether any previous violations were committed at the center.

4. Any financial benefits derived by the center from committing or continuing to commit the violation.

(d) Each day a violation continues after the date on which the department orders a correction of the violation constitutes an additional, separate, and distinct violation.

(e) The department may impose a fine and, in the case of an owner-operated office surgery center, revoke or deny a center's registration if the center's designated physician knowingly and

intentionally misrepresents actions taken to correct a violation.

(f) The department shall impose a fine of $5,000 per day on an owner or designated physician of an office surgery center registered under this section who concurrently operates an unregistered center.

(g) The department shall impose a fine of $10,000 on a new owner of an office surgery center that requires registration who fails to register the center upon the change of ownership and who operates the unregistered center.

(7) RULEMAKING.—

(a) The department may adopt rules to administer the registration, inspection, and safety of office surgery centers.

(b) The board shall adopt rules specifying training requirements for all licensed or certified office surgery center health care practitioners and other health care practitioners who are not regulated by any board.

Section 7. Section 459.026, Florida Statutes, is republished to read:

459.026 Reports of adverse incidents in office practice settings.—

(1) Any adverse incident that occurs on or after January 1, 2000, in any office maintained by an osteopathic physician for the practice of osteopathic medicine which is not licensed under chapter 395 must be reported to the department in accordance with the provisions of this section.

(2) Any osteopathic physician or other licensee under this chapter practicing in this state must notify the department if the osteopathic physician or licensee was involved in an adverse

incident that occurred on or after January 1, 2000, in any office maintained by an osteopathic physician for the practice of osteopathic medicine which is not licensed under chapter 395.

(3) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.

(4) For purposes of notification to the department pursuant to this section, the term "adverse incident" means an event over which the physician or licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

(a) The death of a patient.

(b) Brain or spinal damage to a patient.

(c) The performance of a surgical procedure on the wrong patient.

(d)1. The performance of a wrong-site surgical procedure;

2. The performance of a wrong surgical procedure; or

3. The surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process

if it results in: death; brain or spinal damage; permanent disfigurement not to include the incision scar; fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory function; or any condition that required the transfer of the patient.

(e) A procedure to remove unplanned foreign objects

remaining from a surgical procedure.

(f) Any condition that required the transfer of a patient to a hospital licensed under chapter 395 from an ambulatory surgical center licensed under chapter 395 or any facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395.

(5) The department shall review each incident and determine whether it potentially involved conduct by a health care professional who is subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board under which the health care professional is licensed.

(6)(a) The board shall adopt rules establishing a standard informed consent form that sets forth the recognized specific risks related to cataract surgery. The board must propose such rules within 90 days after the effective date of this subsection.

(b) Before formally proposing the rule, the board must consider information from physicians licensed under chapter 458 or this chapter regarding recognized specific risks related to cataract surgery and the standard informed consent forms adopted for use in the medical field by other states.

(c) A patient’s informed consent is not executed until the patient, or a person authorized by the patient to give consent, and a competent witness sign the form adopted by the board.

(d) An incident resulting from recognized specific risks described in the signed consent form is not considered an adverse incident for purposes of s. 395.0197 and this section.

(e) In a civil action or administrative proceeding against

a physician based on his or her alleged failure to properly disclose the risks of cataract surgery, a patient's informed consent executed as provided in paragraph (c) on the form adopted by the board is admissible as evidence and creates a rebuttable presumption that the physician properly disclosed the risks.

(7) The board may adopt rules to administer this section.

Section 8. 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 26, 2019

I respectfully request that **Senate Bill #732**, relating to Office Surgery, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Anitere Flores

Senator Anitere Flores
Florida Senate, District 39

2015 AGENCY LEGISLATIVE BILL ANALYSIS

BILL INFORMATION	
BILL NUMBER:	SB 486
BILL TITLE:	**Relating to Health Care Clinic Act**
BILL SPONSOR:	Senator Sobel
EFFECTIVE DATE:	July 1, 2015

COMMITTEES OF REFERENCE
1) Health Policy
2) Appropriations Subcommittee on Health and Human Services
3) Fiscal Policy
4)
5)

CURRENT COMMITTEE
Health Policy

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

IDENTICAL BILLS	
BILL NUMBER:	**HB 533**
SPONSOR:	**Rep. Jacobs**

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

Is this bill part of an agency package?
No

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	
LEAD AGENCY ANALYST:	Tom Jones, HQA/HFR/Health Care Clinic Unit, Manager
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

This bill is an act relating to the Health Care Clinic Act and amends the definition of "clinic" to include any entity that provides health care services and "*receives remuneration*" for those services, which would include services paid by cash (not through a third-party payer).

The bill amends the definition of "applicant" for background screening purposes to require an applicant with any interest in a clinic to have a level two (2) background screening. Also, for background screening purposes, in addition to the disqualifying offenses already listed in ss. 435.04 and 408.809, F.S., the bill adds that an applicant may not have an arrest awaiting final disposition for, or have been convicted of, a felony or crime punishable by imprisonment of one year or more. The bill also requires the Agency for Health Care Administration (AHCA) to deny a clinic license or clinic license renewal for an applicant who committed an act that resulted in the suspension or revocation of a clinic license.

The bill adds an administrative fine of $5,000 per day if the medical or clinic director violates s. 400.9935(1)(b), F.S., which requires the medical director to ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license.

This bill adds an exception from the licensing requirement for rehabilitation agencies, certified under 42 C.F.R. Part 485, subpart H.. The bill provides for an effective date of July 1, 2015.

Because the bill expands the definition of health care clinic, additional clinics will require licensure. It is anticipated that the number of licensed health care clinics will increase by ten percent requiring four (4) full-time equivalent (FTE) positions to license, inspect and handle legal actions. The revenues generated by the additional licensees will pay the majority of the additional staffing costs.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The AHCA licenses "health care clinics" as facilities that meet the definition of "clinic" in s. 400.9905(4), F.S. Unless exempt from licensure, an entity is deemed a "clinic" and must be licensed, if it meets the definition of "clinic", as follows: "Clinic means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider." The AHCA interprets "…and which tenders charges for reimbursement for such services…" to only include entities that bill third parties (e.g., Medicare, Medicaid, insurance companies, etc.). Entities that provide health care services and accept "cash only" for services are excluded from the definition and are not subject to health care clinic licensure. An applicant with at least five percent or more interest in a clinic is required to have a level two (2) background screening. Currently, to receive reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730 - 627.7405, F.S. (PIP), an entity excluded from the definition of clinic is required to obtain a health care clinic license.

2. EFFECT OF THE BILL:

The definition of "health care clinic" is revised to include any entity that receives remuneration for providing health care services, which will include those clinics that currently accept "cash only." These clinics would be required to apply for a health care clinic license.

Section 1. This section amends subsection (4) of s. 400.9905, F.S., (Definitions) to remove language indicating that a clinic must tenders charges for reimbursement for health care services and adds language indicating that a clinic must receive remuneration for health care services.

Section 2. This section, which concerns background screening of clinic personnel, revises paragraphs (a) and (b) of subsection (5) of s. 400.991, F.S., and presents subsection (7). A new subsection (6) is added. In subsection (5)(a)(1) language is removed indicating that an "applicant" means an individual owning or controlling at least five percent or more of an interest in the clinic and language is added indicating that an applicant means an individual who owns or controls any interest in a clinic. Subsection (5)(a)(2) is added to define "convicted" as a finding of guilt, regardless of adjudication, the acceptance of a plea of nolo contender or guilty by a court, or an adjudication of delinquency if the record has not been sealed or expunged. Subsection (5)(b) adds that, in addition to the list of disqualifying offenses listed in ss. 435.04 and 408.809, F.S., an applicant may not have an arrest awaiting final

disposition for, or have been convicted of, a felony or a crime punishable by imprisonment of one year or more under state or federal law or the law of any other country. Subsection (6) adds language requiring the AHCA to deny the application for a clinic license or clinic license renewal by an applicant who has been previously found by a state or federal regulatory agency or court to have committed an act that resulted in the suspension or revocation of a clinic license or its equivalent. The bill applies the definitions of "applicant" and "conviction," as defined in subsections (5)(a) and (5)(b), only to subsections (5) and (6).

Section 3. This section adds an administrative fine of $5,000 per day if the medical or clinic director violates s. 400.9935(1)(b), F.S., which requires the medical director to ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license.

Section 4. This section amends paragraph (h) of subsection (5) of s. 627.736, F.S. The bill adds subsection (5)(h)(7) which creates an exception from the licensing requirement for rehabilitative agencies, defined in 42 C.F.R. part 485, subpart H, for purposes of receiving reimbursement under ss. 627.730 - 627.7405, F.S., (PIP).

3. DOES THE LEGISLATION DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? No

If yes, explain:	N/A
What is the expected impact to the agency's core mission?	None
Rule(s) impacted (provide references to F.A.C., etc.):	N/A

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

List any known proponents and opponents:	None known
Provide a summary of the proponents' and opponents' positions:	None known

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? No

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

6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC. REQUIRED BY THIS BILL? No

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. WHAT IS THE FISCAL IMPACT TO LOCAL GOVERNMENT? None

Revenues:	None are projected.
Expenditures:	None are projected.
Does the legislation increase local taxes or fees?	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. WHAT IS THE FISCAL IMPACT TO STATE GOVERNMENT?

The licensure workload is expected to increase by ten percent requiring four (4) FTE positions to manage the program. The licensure fees will substantially cover the cost of the additional staff. Existing resources can absorb the difference.

Revenues:	Revenues for AHCA are calculated at $2,000 per license application and $100 per exemption application – an estimated 250 clinics that will be required to be licensed over a two year period – a ten percent increase from revenues currently as follows: Year 1 - $177,900 Year 2 - $175,800 Year 3 - $177,900
Expenditures:	Costs for AHCA will increase as follows: Year 1 - $234,499 Year 2 - $217,447 Year 3 - $217,447
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

FISCAL IMPACT:					Year 1 (FY 2015-16)	Year 2 (FY 2016-17)	Year 3 (FY 2017-18)
1. Non-Recurring Impact:							
Expenditures:							
Expense (Agency Standard Expense Package)							
Professional Staff	4.00	@	$ 4,263		$ 17,052		
Total Non-Recurring Expense	**4.00**				**$ 17,052**		
Operating Capital Outlay (Agency Standard Operating Capital Outlay Package)							
Total Operating Capital Outlay					**$ -**		
Total Non-Recurring Expenditures					**$ 17,052**		
2. Recurring Impact:							
Revenues:							
License fee					$ 177,900	$ 175,800	$ 177,900
Total Recurring Revenues					**$ 177,900**	**$ 175,800**	**$ 177,900**
Expenditures:							
Salaries	**Class Code**	**FTEs**	**Pay Grade**	**Rate**			
Health Services & Facility Consu	5894	1.50	24	61,659	$ 75,330	$ 75,330	$ 75,330
Health Facility Evaluator II	5620	2.00	21	69,268	84,627	84,627	84,627
Senior Attorney	7738	0.50	230	25,913	31,658	31,658	31,658
Total Salary and Benefits		**4.00**		**156,840**	**$ 191,615**	**$ 191,615**	**$ 191,615**
OPS		**FTEs**					
Total OPS		**0.00**			**$ -**	**$ -**	**$ -**
Expenses							
Professional Staff		4.00	@	$ 6,104	$ 24,416	$ 24,416	$ 24,416
Total Expenses					**$ 24,416**	**$ 24,416**	$ 24,416
Human Resources Services							
FTE Positions		4.00	@	$ 354	$ 1,416	$ 1,416	$ 1,416
Total Human Resources Services					**$ 1,416**	**$ 1,416**	**$ 1,416**
Special Categories/Contracted Services							
Total Special Categories/Contracted Services					**$ -**	**$ -**	**$ -**
Total Recurring Expenditures					**$ 217,447**	**$ 217,447**	**$ 217,447**
3. Total Revenues and Expenditures:							
Sub-Total Recurring Revenues					$ 177,900	$ 175,800	$ 177,900
Total Revenues					**$ 177,900**	**$ 175,800**	**$ 177,900**
Sub-Total Non-Recurring Expenditures					$ 17,052	$ -	$ -
Sub-Total Recurring Expenditures					217,447	217,447	217,447
Total Expenditures					**$ 234,499**	**$ 217,447**	**$ 217,447**
Net Impact (Total Revenues minus Total Expenditures)					**$ (56,599)**	**$ (41,647)**	**$ (39,547)**
4. Net Impact (By Fund)							
Health Care Trust Fund (2003)					$ (56,599)	$ (41,647)	$ (39,547)
-					-	-	-
Net Impact (By Fund)					**$ (56,599)**	**$ (41,647)**	**$ (39,547)**

3. WHAT IS THE FISCAL IMPACT TO THE PRIVATE SECTOR?

Revenues:	None are projected
Expenditures:	License fee of $2,000
Other:	N/A

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

Does the bill increase taxes, fees or fines?	The bill requires licensure (and a license fee of $2,000) for facilities that meet the definition of health care clinic.
Does the bill decrease taxes, fees or fines?	No
What is the impact of the increase or decrease?	$2,000 per entity
Bill Section Number:	Section 1

TECHNOLOGY IMPACT

Does the legislation impact the agency's technology systems (i.e., IT support, licensing software, data storage, etc.)?	No
If yes, describe the anticipated impact to the agency including any fiscal impact.	N/A

FEDERAL IMPACT

Does the legislation have a federal impact (i.e. federal compliance, federal funding, federal agency involvement, etc.)?	No
If yes, describe the anticipated impact including any fiscal impact.	N/A

ADDITIONAL COMMENTS

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments and recommended action:	• None

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

732
Bill Number (if applicable)

859422
Amendment Barcode (if applicable)

Topic _____

Name Chris Nland

Job Title _____

Address 1000 Riverside Ave #240
Street

Jacksonville, FL 32204
City *State* *Zip*

Phone 904-233-3051

Email nlandlaweacl.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Society of Plastic Surgeons

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

732
Bill Number (if applicable)

859422
Amendment Barcode (if applicable)

Topic Office Surgery

Name Chris Lyon

Job Title

Address 315 S. Calhoun St. Ste. 830 (*Street*)

Phone 850/222-5702

Tallahassee (*City*) FL (*State*) 32301 (*Zip*)

Email clyon@llw-law.com

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Association of Nurse Anesthetists

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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3/11/19
Meeting Date

732
Bill Number (if applicable)

859422
Amendment Barcode (if applicable)

Topic Office Surgery

Name Mary Thomas

Job Title Assistant Gen. Counsel

Address 1430 Piedmont Dr
Street

Phone 850 224 6496

TLH FL 32308
City *State* *Zip*

Email MThomas@flmedical.org

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

Bill Number (if applicable)

859422
Amendment Barcode (if applicable)

Topic Office Surgery

Name Stephen Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Dr
Street

Phone 878-7364

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

732
Bill Number (if applicable)

as amended
Amendment Barcode (if applicable)

Topic Office Surgery

Name Stephen Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Dr
Street

Phone 878-7364

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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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

732
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Niland

Job Title 1000 Riverside Ave #240

Address Jacksonville, FL
Street

Phone 904-233-3051

FL 32204
City *State* *Zip*

Email _____

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Society of Plastic 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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/2019
Meeting Date

S 732
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Office Surgery

Name Brence Sell, M.D.

Job Title Anesthesiologist

Address 4770 Buckhead Ct
Street
Tallahassee, FL 32309
City *State* *Zip*

Phone (850) 668-0653

Email DrSell@comcast.net

Speaking: ☑ For ☐ Against ☐ Information

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

Representing the Florida Society of Anesthesiologists

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Meeting Date	Bill Number (if applicable)
	732

Topic Surgery Center

Amendment Barcode (if applicable)

Name Michael Saxman

Job Title Plastic Surgeon

Address 11 Phone

Street

Email

City State Zip

Speaking: ☒ For ☐ Against ☐ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1124
INTRODUCER:	Senator Harrell
SUBJECT:	Dispensing Medicinal Drugs
DATE:	March 8, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Favorable**
2.			IT	
3.			RC	

I. Summary:

SB 1124 amends s. 465.019, F.S., to authorize individuals licensed to prescribe medicinal drugs to dispense a 48-hour supply, rather than a 24-hour supply, of medicinal drugs to any patient of a hospital emergency department, including a discharged patient, that operates a Class II or Class III institutional pharmacy with a community pharmacy permit from the Department of Health (DOH), under certain circumstances.

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

II. Present Situation:

Medicinal Prescribing and Dispensing Practitioners

There are several professions in Florida that have prescriptive authority at various levels, including:

- Allopathic physicians;
- Osteopathic physicians;
- Podiatrists;
- Dentists;
- Advanced registered nurse practitioners;[1]
- Physician assistants;[2] and
- Pharmacists.[3]

[1] See s. 464.012(3)(a), F.S.
[2] *See* ss. 458.347 (4)(e)4., and 459.022(4)(e)4., F.S.
[3] *See* s. 465.186, F.S. and Fla. Admin. Code R. 64B8-36.001 (2019).

A person may not dispense medicinal drugs unless licensed as a pharmacist, except that a practitioner authorized by law to prescribe drugs may dispense medicinal drugs to his or her patients in the regular course of her or his practice.[4] A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether directly or indirectly, must:

- Register with her or his professional licensing board as a dispensing practitioner and pay a board-established fee at the time of such registration and upon each renewal of his or her license;
- Comply with, and be subject to, all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, chs. 456, 499 and 893, F.S., and all applicable federal laws and federal regulations; and
- Give each patient a written prescription and, orally or in writing, advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy, before dispensing any drug.[5]

Pharmacy

The practice of pharmacy and the licensure of pharmacies are regulated by ch. 465, F.S. The "practice of the profession of pharmacy" includes:

- Compounding, dispensing, and consulting the consumer concerning the contents, therapeutic values, and uses of any medicinal (prescription)[6] drug; and
- Other pharmaceutical services.[7,8]

The Board of Pharmacy

The Board of Pharmacy (Board) is created within the DOH and is authorized to make rules to regulate the practice of professional pharmacy in pharmacies meeting minimum requirements for safe practice.[9] All pharmacies must obtain a permit before operating, unless exempt by law. This is true whether opening a new establishment or simply changing locations or owners.[10]

The Practice of Pharmacy

There are seven types of pharmacies eligible for various operating permits issued by the DOH:

[4] Section 465.0276, F.S.
[5] Section 465.0276(2), F.S.
[6] Under s. 465.003(8), F.S., "medicinal drugs" means substances commonly known as "prescription" or "legend" drugs required by law to be dispensed by prescription only.
[7] Section 465.003(13), F.S.
[8] In the context of pharmacy practice, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chs. 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. The "practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, expressly permits a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients, and includes the administration of vaccines to adults. Section 465.003(13), F.S.
[9] Sections 465.002, and 465.0155, F.S.
[10] *See* Fla. Admin. Code R. 64B16-28.100(1) (2019).

- Community pharmacy;[11]
- Institutional pharmacy;[12]
- Nuclear pharmacy;[13]
- Special pharmacy;[14]
- Internet pharmacy;[15]
- Non-resident sterile compounding pharmacy;[16] and
- Special sterile compounding pharmacy.[17]

Institutional Pharmacies

An "institutional pharmacy" includes any pharmacy located in a health care institution, which includes a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[18] Institutional pharmacy permits are required for any pharmacy located in any health care institution.[19]

All institutional pharmacies must designate a consultant pharmacist[20] who is responsible for maintaining all drug records required by law, and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical tests when such tests are necessary for the proper performance of his or her responsibilities.[21] Such laboratory or clinical tests may be ordered only with regard to patients residing in a nursing home, and then only when authorized by the facility's medical director. The consultant pharmacist must complete additional training and demonstrate additional qualifications in the practice of institutional pharmacy, as required by the board, and be licensed as a registered pharmacist.[22,23]

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[11] The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. *See* ss. 465.003(11)(a)1. and 465.018, F.S.
[12] *See* ss. 465.003(11)(a)2. and 465.019, F.S.
[13] The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, but does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals. *See* ss. 465.003(11)(a)3. and 465.0193, F.S.
[14] The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined by law. *See* ss. 465.003(11)(a)4. and 465.0196, F.S.
[15] The term "internet pharmacy" includes locations not otherwise licensed or issued a permit under ch. 465, F.S., whether or not in Florida, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. *See* ss. 465.003(11)(a)5. and 465.0197, F.S.
[16] The term "nonresident sterile compounding pharmacy" includes a pharmacy that ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida, and a nonresident pharmacy registered under s. 465.0156, F.S., or an outsourcing facility, must hold a nonresident sterile compounding permit. *See* s. 465.0158, F.S.
[17] *See* Fla. Admin. Code R. 64B16-28.100 and 64B16-28.802 (2019). An outsourcing facility is considered a pharmacy and must hold a special sterile compounding permit if it engages in sterile compounding.
[18] Section 465.003(11)(a)2., F.S.
[19] *See* Fla. Admin. Code R. 64B16-28.100(3) (2019).
[20] *See* ss. 465.003(11), and 465.0125, F.S.
[21] *Id*.
[22] Section 465.0125, F.S.
[23] As required by Fla. Admin. Code R. 64B16-28.501(1), (2), and (3) (2019), the consultant pharmacist must also "conduct Drug Regimen Reviews required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly, . . . monitor the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review,

Currently there are four types of institutional pharmacy permits issued by the Board to institutional pharmacies: Institutional Class I, Class II, Modified Class II, and Class III.[24]

Institutional Class I Pharmacy

A Class I institutional pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to an individual patient; and in which medicinal drugs are not dispensed on the premises, except licensed nursing homes[25] may purchase medical oxygen for administration to residents.[26]

Institutional Class II Pharmacy

A Class II institutional pharmacy is a pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of the institution, for use on the premises of the institution.[27] A Class II institutional pharmacy is required to be open sufficient hours to meet the needs of the hospital facility.[28] The consultant pharmacist of record is responsible for establishing a written policy and procedure manual.[29] An institutional Class II pharmacy may elect to participate in the Cancer Drug Donation Program within the Department of Business and Professional Regulation.[30]

Modified Institutional Class II Pharmacy Permits

Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.[31] Modified Class II Institutional pharmacies are designated as Type A, Type B, and Type C according to the specialized type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and the quantity of the medicinal drug formulary at the facility.[32]

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and may utilize additional consultant pharmacists to assist in this review and in the monthly facility inspection." A licensed consultant pharmacist may "remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations." The Board must be notified in writing within ten days of any change in the consultant pharmacist of record, pursuant to Fla. Admin. Code R. 64B16-28.100(3)(b) (2019).

[24] Section 465.019, F.S.

[25] *See* part II, ch. 400, F.S., relating to nursing homes.

[26] Section 465.019(2)(a), F.S.

[27] *See* s. 565.019(2)(b), F.S. Exceptions apply when there is a state of emergency and for single doses of a drug ordered by physicians under limited circumstances.

[28] *See* Fla. Admin. Code R. 64B16-28.603 (2019).

[29] *See* s. 465.019(5), F.S.

[30] *See* s. 499.029, F.S., relating to the Cancer Drug Donation Program Act.

[31] *See* s. 465.019(2)(c), F.S.

[32] *See* Fla. Admin. Code R. 64B16-28.702(2), (2019). Modified Class II Institutional Pharmacies and provide the following pharmacy services: 1) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist provides on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual; 2) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the

All Modified Class II institutional pharmacies must be under the control and supervision of a certified consultant pharmacist. The consultant pharmacist of record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection.[33]

Institutional Class III Pharmacies

Class III institutional pharmacies are those pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Class III institutional pharmacies may also:

- Dispense, distribute, compound, and fill prescriptions for medicinal drugs;
- Prepare prepackaged drug products;
- Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under ch. 465, F.S., to possess medicinal drugs; and
- Provide the services in Class I institutional pharmacies, Class II institutional pharmacies, and Modified Class II institutional pharmacies which hold an active health care clinic establishment permit.[34,35]

A Class III institutional pharmacy must also maintain policies and procedures addressing the following:

- Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products; and
- Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.[36]

Class III Institutional pharmacies are permitted to dispense medicinal drugs to outpatients only when that institution has been issued a community pharmacy permit from the DOH. An individual licensed to prescribe medicinal drugs may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines the following:

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facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist provides on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual; and 3) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist provides onsite consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

[33] See Florida Board of Pharmacy, *Institutional Pharmacy Permit* http://floridaspharmacy.gov/licensing/institutional-pharmacy-permit/ (last visited Feb. 19, 2019).

[34] Section 465.019(2)(d)1., F.S.

[35] *See* s. 499.01(2)(r), F.S.

[36] Section 465.019(d)2., F.S.

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible, geographically or otherwise, to the patient.[37]

Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for the drug for use after the initial 24-hour period.[38]

III. Effect of Proposed Changes:

The bill permits an individual, licensed to prescribe medicinal drugs to dispense up to a 48-hour supply, rather than 24-hour supply, of medicinal drugs to any patient of a hospital emergency department, as well as a patient discharged from the emergency department, that operates a Class II or Class III institutional pharmacy with a community pharmacy permit from the DOH, if the physician treating the patient makes the following determinations:

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible to the patient, geographically or otherwise.

Any dispensing from the emergency department that operates a Class II or Class III institutional pharmacy with a community pharmacy permit, to any patient, including a discharged patient, must be done in accordance with hospital procedures. For any patients prescribed a medicinal drug for a period of longer than 48 hours, the individual prescribing the drug must dispense a 48-hour supply to the patient and also provide the patient with a prescription for the drug for use after the initial 48-hours. The board may adopt rules necessary to carry out these provisions.

This act shall take effect July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[37] Section 465.019(4), F.S.
[38] *Id.*

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.019 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Harrell

25-01771-19 20191124__

A bill to be entitled

An act relating to dispensing medicinal drugs; amending s. 465.019, F.S.; authorizing individuals licensed to prescribe medicinal drugs to dispense a 48-hour supply, rather than a 24-hour supply, of such drugs to any patient, including a discharged patient, under certain circumstances; providing an effective date.

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

Section 1. Subsection (4) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.—

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 48-hour ~~24-hour~~ supply of a medicinal drug to any patient of, or patient discharged from, an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department or the discharged patient determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department to any patient, including a discharged patient, must be in accordance with the procedures of the hospital. For any such patient for whom a

medicinal drug is warranted for a period to exceed 48 ~~24~~ hours, an individual licensed to prescribe such drug must dispense a 48-hour ~~24-hour~~ supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 48-hour ~~24-hour~~ period. The board may adopt rules necessary to carry out the provisions of this subsection.

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/14
Meeting Date

SB 1124
Bill Number (if applicable)

Topic Dispensing Medical Drugs

Amendment Barcode (if applicable)

Name Diane Barker

Job Title Assoc. State Director

Address 200 W. College Ave
Street

Phone 228-6387

Tall FL 32301
City *State* *Zip*

Email dobarker@aarp.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing AARP FL

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1126
INTRODUCER:	Senator Harrell
SUBJECT:	Pediatric Cardiac Technical Advisory Panel
DATE:	March 8, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1126 amends s. 395.1055, F.S., and modifies the authority and duties of the Pediatric Cardiac Technical Advisory Panel (panel) by:

- Authorizing travel reimbursement for panel members.
- Adding three alternate, non-voting panel members affiliated with three different programs.
- Establishing a maximum term limit of two 2-year terms, but allowing a panel member to return after a full 2-year retirement period.
- Providing civil and criminal immunity for panel members relating to events resulting from good faith performance of duties that are assigned to them.
- Requiring the Secretary of the Agency for Health Care Administration (AHCA) to consult with and receive a recommendation from the panel for all certificate of need applications to establish pediatric surgical centers.
- Permitting the AHCA Secretary to request panel members to conduct announced or unannounced site visits to any existing pediatric cardiac facility or a facility seeking such a license, to ensure compliance.
- Allowing panel members, at the request of the AHCA Secretary, to recommend in-state physician experts and up to two out-of-state physician experts for such visits.
- Providing parameters for site visit inspections and contents of site visit reports.
- Requiring Department of Health, State Surgeon General to provide quarterly data on critical congenital heart disease to AHCA Secretary for panel review.

The fiscal impact of the bill is indeterminate and will depend on the number of site visits and inspections requested by the AHCA Secretary and travel requests of the panel Members.

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

II. Present Situation:

Children's Medical Services

Children's Medical Services (CMS) is a group of programs administered by the Department of Health (DOH) that serve children with special health care needs. Within CMS, individual services and health care programs are designed to address specific conditions or family needs, such as the newborn screening program under ss. 383.14 and 383.145, F.S., early intervention screenings under the Early Steps program as established in s. 391.301, F.S., or the more comprehensive CMS Managed Care Plan described in ss. 391.055 and 409.974(4), F.S. To be eligible for these programs, children must meet designated eligibility criteria that usually include both a clinical determination and a financial eligibility requirement.

CMS is created under ch. 391, F.S., and divided into three parts: Part I (General Provisions), Part II (Children's Medical Services Councils and Panels), and Part III (Developmental Evaluation and Intervention Programs).

The State Surgeon General has general authority under s. 391.223, F.S., to establish technical advisory panels to assist with the development of specific policies and procedures for the Children's Medical Services program.

Children's Medical Services Managed Care Plan Advisory Panel

In September 2015, the State Surgeon General created a Children's Medical Services Managed Care Plan Advisory Panel to advise the DOH as it transited from a direct service provider network to a managed care plan.[1] The panel includes pediatricians, pediatric specialists, parents of children with special health care needs, representatives from managed health care plans, and academic health care centers. Members of the panel are appointed to serve one-year terms. The creating document for the panel entitles members to per diem and reimbursement of travel expenses pursuant s. 113.061, F.S., and meetings were to be held upon the call of the Surgeon General, CMS Plan President, or CMS Plan Chief Executive Officer.[2] No meetings of the panel are currently scheduled.[3]

Repeal of the Cardiac Advisory Council

Prior to the 2001 Regular Session, a Cardiac Advisory Council in the Division of Children's Medical Services existed.[4] The council was appointed by the DOH Secretary and included eight members with technical expertise in cardiac medicine who were charged with:

- Recommending standards for personnel and facilities rendering cardiac services.

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[1] Fla. Dep't of Health, *Department of Health announces creation of Children's Medical Services Managed Care Plan Advisory Panel* (Sept. 21, 2015), *available at* http://www.floridahealth.gov/newsroom/2015/09/092115-cms-tap.html (last visited Mar. 5, 2019).
[2] Fla. Dep't of Health, *Creation of the Children's Medical Services Managed Care Plan Technical Advisory Panel* (Sept. 21, 2015), *available at* http://www.floridahealth.gov/_documents/cms-plan-tap.pdf (last visited Mar. 5, 2019).
[3] Fla. Dep't of Health, *CMS Plan Technical Advisory Panel,* http://www.floridahealth.gov/programs-and-services/childrens-health/cms-plan/tap/index.html (last visited Mar. 5, 2019).
[4] *See* s. 391.222, F.S. (2000).

- Receiving reports of the periodic review of cardiac personnel and facilities to determine if established standards of care for cardiac care are met.
- Making recommendations to the director as to the approval or disapproval of reviewed personnel and facilities.
- Providing input on all aspects of the Children's Medical Services Network cardiac program, including the rulemaking process.[5]

The statute was repealed effective June 30, 2001, as part of an exhaustive review of more than three dozen boards, committees, committees, and councils to determine whether to continue or abolish each entity.[6] The DOH recommended the repeal of the council and indicated it would absorb the council's functions in 2001.[7]

Department of Health Repeal of Rule 64C-4.003, F.A.C.

Rule 64C-4.003, F.A.C., established and incorporated by reference quality assurance standards and criteria for the approval and operation of CMS pediatric cardiac facilities. On October 12, 2015, the DOH proposed the repeal of that rule after determining that it did not have the statutory authority to establish the standards, inspect the facilities, or prepare inspection reports for the technical advisory panel to review as provided for under the rule.[8] A group of CMS participants who require cardiac care services believed the repeal of the rule would affect their interests and were concerned that without the standards created in the rule, the quality of care available to them under the CMS program would be reduced. Several affected parties filed an administrative challenge through the Division of Administrative Hearings (DOAH).[9]

A final administrative hearing was held on November 20 and 23, 2015, and a Final Order was issued on December 16, 2015. On January 9, 2017, the DOH published *A Notice of Disposition* in the *Florida Administrative Register* adopting the ruling in the DOAH Final Order. The notice stated that in the case of *W.D., C.V., K.E., and K.M. vs. Department of Health, Case No. 15-6009RP; Rule 64C-4.003.*

> Petitioners lacked standing to challenge the proposed repeal of a rule that would deregulate certain cardiac facilities, because no real or immediate injury was shown, and because common good such as quality health care is not within the zone of interest.[10]

The Petitioners appealed DOAH's final order in both the First and Third District Courts of Appeal. The case was voluntarily dismissed at the First District Court of Appeal on February 15, 2016, and, in the Third District Court of Appeal, the court affirmed the findings of the DOAH administrative law judge and dismissed the petition for lack of jurisdiction.[11] The rule was

[5] *Id.*
[6] Chapter 2001-89, s. 27, Laws of Fla.
[7] Senate Committee on Governmental Oversight and Productivity, *CS/SB 1410 Staff Analysis and Fiscal Impact Statement,* (March 28, 2001), pg. 9, http://archive.flsenate.gov/data/session/2001/Senate/bills/analysis/pdf/2001s1410.go.pdf (last visited Mar. 6, 2019).
[8] Vol. 43, Fla. Admin. Register 145 (Aug. 28, 2017).
[9] *See W.D., C.V., and K.M. v. Dep't of Health,* Case No. 15-6009RP (Fla. DOAH 2015).
[10] Vol. 43, Admin. Register 145 (Jan. 9, 2017).
[11] *K.M. v. Dep't of Health*, 237 So. 3d 1084 (Fla. 3d DCA 2017).

effectively repealed March 20, 2018, 90 days after the disposition date from the Third District Court of Appeal.

Current Standards for Pediatric Cardiac Services

Hospital facilities are regulated by the AHCA under ch. 395, F.S., and the general licensure provisions of ch. 408, F.S. Hospitals are also subject to the certificate of need (CON) provisions in Part I of ch. 408, F.S.

A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Certain specialty programs offered within a hospital may also be subject to a CON process as prescribed by statute. Under s. 408.036, F.S., all health-care-related projects described in that section are subject to review and must file a CON application with the AHCA unless specifically exempted from the process. Examples of covered health-care-related projects include hospice services, skilled nursing facilities, intermediate care facilities for the developmentally disabled, organ transplantation, and neonatal intensive care unit level II and level III. Programs for both pediatric cardiac catheterization and pediatric open heart surgery fall under paragraph (1)(f) of the section: *the establishment of tertiary health services, including inpatient comprehensive rehabilitation services.*[12]

The AHCA has four batching cycle per calendar year for CON, and the cycles are segmented into cycles for just hospital beds and cycles for Other Beds and Programs.[13] If requested, a public hearing may be held on a CON application if either the applicant or other interested parties request such a hearing.

For some CON projects, the AHCA will publish a Fixed Need Pool for the service which projects the expected need over a specified period of time in a designated area.[14] The minimum base filing fee for an application is $10,000. In addition to the base filing fee, the fee shall also include $0.015 of each dollar of any proposed expenditure, except that no fee shall exceed $50,000.[15] Applications are reviewed on a comparative basis.

Pediatric Open Heart Surgery Programs

Pediatric open heart surgery programs are regulated through the CON process and an existing rule governs the program under Rule 59C-1.033, F.AC. The administrative rule establishes five service areas, defines the pediatric patient as those patients under 15 years of age, and what services are included in a pediatric open heart surgery program. To be considered for an open heart surgery program, the rule requires that a facility must be able to, at a minimum:

- Repair or replace heart valves.
- Repair congenital heart defects.
- Perform cardiac revascularization.

[12] *See* s. 408.036(1)(f), F.S. (2018) and Rule 59C-1.004, F.A.C.
[13] Agency for Health Care Administration, *Certificate of Need Program Overview*, https://ahca.myflorida.com/MCHQ/CON_FA/index.shtml (last visited Mar. 7, 2019).
[14] Rule 59C-1.008(2), F.A.C.
[15] Rule 59C-1.008(3), F.A.C.

- Repair or reconstruct intrathoracic vessels.
- Treat cardiac trauma.

A health care facility that performs pediatric open heart surgery must also provide these additional services:

- Cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases.
- Pathology, including anatomical, clinical blood bank and coagulation laboratory services.
- Anesthesiology, including respiratory therapy.
- Radiology, including diagnostic nuclear medicine and magnetic resonance imaging studies.
- Neurology.
- Inpatient cardiac catheterization.
- Non-invasive cardiographics, including electrocardiography, exercise stress testing, transthoracic and transesophageal echocardiography.
- Intensive care.
- Emergency care available 24 hours per day for cardiac emergencies.
- Extracorporeal life support (ECLS).

The pediatric open heart surgery team must be available for elective open heart surgery eight hours per day, five days per week and be available for rapid mobilization for emergency cases 24 hours a day, seven days per week. Rapid mobilization means a waiting period for surgery of a maximum of two hours.[16]

For pediatric open heart surgery, any CON applicant must document an adequate number of the following properly trained personnel that can perform during surgery:

- A cardiovascular surgeon, board certified by the American Board of Thoracic Surgery, or board eligible.
- A physician to assist the operating surgeon.
- A board certified or board eligible anesthesiologist trained in open heart surgery.
- A registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties.
- A perfusionist to perform extracorporeal perfusion, or a physician or specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.[17]

Follow-up care after open heart surgery must be provided in an intensive care unit that provides 24 hour nursing coverage with a nurse-to-patient ratio of no less than one nurse for every two patients for the first hours of post-operative care. The facility must have at least one board-certified or board-eligible pediatric cardiac surgeon on the staff of the hospital seeking the CON for a pediatric open heart surgery.[18] Back-up personnel must be available for consultation to the surgical team, including a clinical cardiologist, cardiologist, anesthesiologist, pathologist, thoracic surgeon, and radiologist.

[16] Rule 59C-1.033(4)(b), F.A.C.
[17] Rule 59C-1.033(5)(a), F.A.C.
[18] Rule 59C-1.033(5)(b), F.A.C.

Pediatric Cardiac Catheterization and Angioplasty Institutional Health Services

As with the requirements for the pediatric open heart surgery program, the pediatric cardiac catheterization program requires a hospital to have a CON before it may operate its program. A cardiac catheterization is a medical procedure requiring the passage of a catheter into one or more cardiac chambers with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow. Cardiac catheterization also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.[19]

A facility must demonstrate as part of the CON approval process that it is capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording to evaluate valvular disease or heart failure.[20] The facility must also make this range of services available within the health facility:

- Hematology studies or coagulation studies
- Electrocardiography
- Chest X-ray
- Blood gas studies
- Clinical pathology studies and blood chemistry analysis[21]

The program must also include:

- A special procedure X-ray room
- A film storage and darkroom for proper processing of films
- X-ray equipment with the capability in cineangiocardiography[22], or equipment with similar capabilities
- An image intensifier
- An automatic injector
- A diagnostic X-ray examination table for special procedures
- An electrocardiograph
- A blood gas analyzer
- A multi-channel polygraph
- Emergency equipment, including but not limited to, a temporary pacemaker unit with catheters, ventilatory assistance devices, and a DC defibrillator
- Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40mL/s
- One or more crash carts containing the necessary medication and equipment for ventilatory support, which must be located in each pediatric cardiac catheterization procedure room.[23]

[19] Rule 59C-1.032(2), F.A.C.
[20] Rule 59C-1.032(3)(a), F.A.C.
[21] Rule 59C-1.032(3)(b), F.A.C.
[22] According to the Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, cineangiocardiography is the photographic recording of fluoroscopic images of the heart and great vessels by motion picture techniques.
[23] Rule 59C-1.032(3)(b), F.A.C.

The cardiac catheterization team must be capable of rapidly mobilizing within 30 minutes, 24 hours a day, seven days a week for emergency procedures.[24] The team must be capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording for monitoring and to evaluate valvular disease, or heart failure.[25] The team must be able to document these standards.

In addition to documentation of the required staff[26] that is available to perform the pediatric cardiac catheterization and angiographic processes, the CON applicant facility is also required to have a department, service, or other similar unit organized, directed, staffed, and integrated with the other units and departments of the hospital to assure the provision of quality of care.[27] A pediatric catheterization program must also be co-located at a facility where pediatric open heart surgeries are being performed.[28]

Pediatric cardiac facilities granted CONs under either program are also required to provide the AHCA with quarterly utilization reports within 45 days of the end of each quarter showing the number of pediatric procedures under both programs.

Facility Standards

State Facility Standards and Inspections

Hospitals must maintain a current state license to operate as a hospital under the provisions of ch. 395, part I, F.S. and ch. 408, part II, F.S. Hospitals may elect to be Medicare certified and may choose to be accredited by one of several accrediting organizations. If a hospital is accredited, the AHCA will accept the reports of the accrediting agency in lieu of a state licensure inspection.[29] A facility may still be subject to a licensure inspection if the hospital has been denied accreditation and has not submitted an acceptable corrective plan of action; received full accreditation but has not authorized release of the report to the AHCA; or has not ensured that the AHCA received the accrediting organization's report prior to the AHCA's scheduling of a licensure inspection.[30]

The AHCA is authorized to conduct investigations based upon investigatory findings, complaints, or non-conformance with accreditation standards. Sanctions can also be imposed on facilities by the AHCA in accordance with s. 395.1065, F.S.,[31] where a corrective plan of action

[24] Rule 59C-1.032(4)(a), F.A.C.
[25] Rule 59C-1.032(3)(a), F.A.C.
[26] The staff required for these programs are listed in Rule 59C-1.032(b), F.A.C.
[27] Rule 59C-1.032(5)(a), F.A.C.
[28] Rule 59C-1.032(6), F.A.C.
[29] Rule 59A 3.253(3), F.A.C.
[30] Rule 59A 3.253(3)(a), F.A.C.
[31] Section 395.1065, F.S., authorizes the AHCA to impose administrative fines for operating a facility without a license of up to $500 per day for a first offense and no more than $1,000 for each subsequent offense. Administrative fines, not to exceed $1,000 per violation, per day, may also be imposed by the AHCA for violations of part I or part II of chapter 408 based on the severity of the violation, probability that death or serious harm to the health or safety of any one person will result or has resulted, the severity of any actual or potential harm, the actions taken by the licensee to correct the violations or to remedy the complaints, and any previous violations of the licensee. The AHCA may also impose a moratorium on elective admissions to any licensed facility when the AHCA determines that any condition in the facility presents a threat to public

is not submitted or actions are not implemented to correct deficiencies identified by either an accrediting organization or the AHCA.[32] Inspections may also be conducted by the AHCA, as it deems necessary, for:

- Inspections directed by the federal Centers for Medicare & Medicaid Services.
- Validation inspections.
- Lifesafety inspections.
- Licensure complaint investigations, including full licensure investigations with a review of all licensure standards as outlined in the administrative rules. Complaints received by the AHCA from individuals, organizations, or other sources are subject to review and investigation by the AHCA.
- Emergency access investigations.[33]

Accreditation by the Joint Commission[34] requires the organization to demonstrate that it will continually assess and improve the quality of its care, treatment, and services. The hospital must provide services that can be evaluated by Joint Commission standards and can provide review records equal to ten percent of the average daily census for the initial survey. Tests, treatments or interventions provided at the hospital must be prescribed or ordered by a licensed independent practitioner in accordance with state and federal requirements.[35]

One of the newest accreditation organizations is the Center for Improvement in Healthcare Quality Accreditation program (CIHQ).[36] The program received initial approval in July 2013.[37] Currently, 62 hospitals nationally have achieved accreditation under this standard, including one Florida hospital.[38] Standards for accreditation under CIHQ track to the required components of the federal Code of Federal Regulations.

Florida also recognizes accreditation for hospitals by DNV GL which was introduced in 2008.[39] The DNV GL program provides accreditation for acute care, critical access, ancillary, and psychiatric hospitals. The program also offers clinical specialty certifications in several areas:

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health or safety. The AHCA may also rely on the findings and investigations of the Department of Health in lieu of conducting its own investigation.

[32] Rule 59A 3.253(9), F.A.C.

[33] Section 395.0161, F.S.

[34] *See* The Joint Commission, https://www.jointcommission.org/accreditation/hospital_audience.aspx (last visited Mar. 6, 2019).

[35] The Joint Commission, *Eligibility for Hospital Accreditation* (January 15, 2015), https://www.jointcommission.org/eligibility_hospital_accreditation/ (last visited Mar. 6, 2019).

[36] Center for Improvement in Healthcare Quality, https://cihq.org/hospital_accreditation_division.asp (last visited Mar. 6, 2019).

[37] Centers for Medicare and Medicaid Services, *Annual Report to Congress: Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program* (Fiscal Year 2015), pg. 64, *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last visited Mar. 6, 2019).

[38] The one Florida hospital with this accreditation is Landmark Hospital of Southwest Florida, LLC located in East Naples, Florida. Full accreditation was achieved on September 30, 2018. *See* https://cihq.org/hospital_list.asp (last visited Mar. 6, 2019).

[39] DNV GNL, *Accreditation, Certification & Training,* https://www.dnvgl.us/assurance/healthcare/ac.html (last visited Mar. 6, 2019).

hip & knee, heart failure, and ventricular assist devices.[40] Rather than multi-year surveys, the DNV GL standards are based on an annual survey of the facility's processes.

Medicare Accreditation

With all of these accreditation programs discussed above, if a hospital achieves accreditation under one of these programs, the hospital could also be deemed in compliance with all of the applicable Medicare conditions. The federal Centers for Medicare & Medicaid Services is authorized under Section 1865(a) of the Social Security Act to recognize and approve national accrediting organizations that demonstrate that their health and safety standards and survey and oversight processes meet or exceed those used to determine a health care provider's compliance with Medicare's Conditions for Certification or requirements.[41] To be eligible to receive Medicare reimbursement, certain types of health care facilities must demonstrate compliance with Medicare's conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification.[42]

General Participation Requirements

Under 42 CFR §482.11, to participate in Medicare, a hospital must be in compliance with all applicable federal laws related to the health and safety of patients. Additionally, the hospital must be licensed and approved as meeting the standards established by the licensing state or other regulatory bodies. The federal regulations set out the standards of care for patients, and for the hospital administration, chief executive officer, the institutional plan and budget, contracted services, and emergency services.[43] The hospital is also required to protect and promote each patient's rights which includes establishing a process for the prompt resolution of grievances, allowing patients to participate in the development and implementation of his or her plan of care, permitting patients to make informed decisions about their care, acknowledging each patient's right to privacy and right to confidentiality of their records, and providing patients the right to be free from restraint or seclusion.[44] Other areas that indicate compliance with the general participation requirements for hospitals are found in the following table:

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[40] *Id.*

[41] Centers for Medicare and Medicaid Services, State Operations Manual, *Chapter 2-The Certification Process, Section 2003C – Deemed Status Providers/Suppliers, Excluding CLIA*, pg. 25, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf (last visited Mar. 6, 2019).

[42] Centers for Medicare and Medicaid Services, *Annual Report to Congress: Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program* (Fiscal Year 2015), pg. 7, *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last visited Mar. 6, 2019).

[43] 42 CFR §482.12 – Condition of participation: Governing body.

[44] 42 CFR §482.13.

General Participation Requirements for Hospitals Code of Federal Regulations – Sampling of Citations							
Citation	**Title**	**Citation**	**Title**	**Citation**	**Title**	**Citation**	**Title**
482.11	Compliance with Federal, State, and Local Laws	**482.23**	Nursing Services	**482.30**	Utilization Review	**482.53**	Nuclear medicine
482.12	Governing Body	**482.24**	Medical Record Services	**482.41**	Physical environment	**482.54**	Outpatient services
482.13	Patient's Right	**482.25**	Pharmaceutical Services	**482.42**	Infection control	**482.55**	Emergency services
482.15	Emergency Preparedness	**482.26**	Radiological Services	**482.43**	Discharge planning	**482.56**	Rehabilitation services
482.21	Quality Assessment and Performance Improvement Program	**482.27**	Laboratory Services	**482.51**	Surgical services	**482.57**	Respiratory care services
482.22	Medical Staff	**482.28**	Food and dietetic services	**482.52**	Anesthesia services		

Additionally, for a hospital to be eligible for reimbursement under the Florida Medicaid program, for either inpatient or outpatient services, federal and state regulations require, among other requirements, that the hospital meet the Medicare conditions of participation and be licensed or formally approved by the state licensing entity.[45,46]

If a facility is not meeting the conditions for participation and such failures are significant, the federal government may determine that the findings constitute "an immediate or serious threat to patient health and safety." The federal regulations define "immediate jeopardy" as:

> *As situation in which the provider's noncompliance with one or more requirements of participation has, or is likely to cause, serious injury, harm, impairment, or death, to a resident.*[47]

Under the requirements, only one individual needs to be at risk, and the serious harm, injury, impairment, or death does not have to occur before considering immediate jeopardy. There needs only to be a high potential in the near future for these outcomes to occur. Additionally, the serious harm can result from both abuse and neglect, and psychological harm is considered just as serious as physical harm.[48] Common triggers include:

- Failure to protect from abuse.
- Failure to prevent neglect.
- Failure to protect from psychological harm.

[45] 42 CFR 440.10 and 42 CFR 440.20.
[46] Rule 59G-4.150, F.A.C.
[47] 42 CFR 489.3
[48] Centers for Medicare and Medicaid Services, State Operations Manual, *Appendix Q – Guidelines for Determining Immediate Jeopardy* (Rev. 102, Issued 02-14-14), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf (last visited Mar. 7, 2019).

- Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed.
- Failure to provide adequate nutrition and hydration to support and maintain health.
- Failure to protect from widespread nosocomial infection; e.g.; failure to practice standard precautions, failure to maintain sterile techniques during invasive procedures and/or failure to identify and treat nosocomial infections.
- Failure to correctly identify individuals.
- Failure to safely administer blood products and safely monitor organ transplantation.
- Failure to provide safety from fire, smoke and environment hazards and/or failure to educate staff in handling emergency situations.
- Failure to provide initial medical screening, stabilization of emergency medical conditions and safe transfer for individuals and women in active labor seeking emergency treatment (Emergency Medical Treatment and Active Labor Act).[49]

In November 2018, the *Tampa Bay Times* began a series of articles on the rising infection and mortality rates in the pediatric heart surgical program at Johns Hopkins All Children's Hospital (All Children's) in St. Petersburg, Florida.[50] In June 2015, a similar series of stories by CNN on a pediatric heart program at St. Mary's Medical Center in West Palm Beach led to the closure of that hospital's program.[51] By January 2019, federal and state inspectors visited All Children's for inspections, and, shortly thereafter, the federal Centers for Medicare & Medicaid Services issued an "immediate jeopardy" warning and gave All Children's until February 10, 2019, to file a corrective action plan.[52] The report indicated widespread issues from communication, infection control, and physician competency issues. The hospital had a Joint Commission survey visit on February 22, 2019, which had no findings, and still maintains its accreditation.[53] The "immediate jeopardy" label has also been removed from the hospital and the corrective action plan was accepted, according to newspaper reports.[54]

Technical Advisory Panel for Pediatric Cardiac Programs

During the 2018 Legislative Session, a Technical Advisory Panel (panel) for Pediatric Cardiac Programs was established to develop procedures and standards for measuring outcomes of pediatric catheterization programs and pediatric cardiac cardiovascular programs; and to make recommendations about regulatory guidelines for pediatric open heart surgery programs. The panel is housed administratively at the AHCA, and appointments to the panel are made by the AHCA Secretary in accordance with the statutory guidelines.

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[49] *Id.*
[50] Kathleen McCrory and Neil Bedi, *Heartbroken: Johns Hopkins Promised to Elevate All Children's Heart Institute. Then Patients Start to Die at an Alarming Rate.* TAMPA BAY TIMES, Nov. 28, 2018, Special Report, http://www.tampabay.com/projects/2018/investigations/heartbroken/all-childrens-heart-institute/ (last visited Mar. 7, 2019).
[51] Margie Menzel, *Pediatric Cardiac Surgery Standards Eyed,* HEALTH NEWS FLORIDA, Oct. 13, 2015, https://health.wusf.usf.edu/post/pediatric-cardiac-surgery-standards-eyed (last visited Mar. 7, 2019).
[52] Agency for Health Care Administration, Statement of Deficiencies – Reports(January 11, 2019), http://apps.ahca.myflorida.com/dm_web/DMWeb_Docs/9379109.pdf (last visited Mar. 7, 2019).
[53] Johns Hopkins All Children's Hospital, Inc. *Quality Report, https://www.qualitycheck.org/quality-report/?bsnId=6908* (last visited Mar. 7, 2019).
[54] Kathleen McCrory and Neil Bedi, *New Federal Report Details Widespread Problems at All Children's,* TAMPA BAY TIMES, Feb. 22, 2019, Investigations, http://www.tampabay.com/investigations/2019/02/22/federal-investigators-found-systemic-failures-at-all-childrens/ (last visited Mar. 7, 2019).

To be eligible as a voting member on the Panel, a hospital must maintain its pediatric CON and the individual member must have technical expertise in pediatric cardiac medicine. Members serve without compensation and are not reimbursed for any travel costs or per diem.[55]

The AHCA Secretary appoints three at-large members, one of whom is a cardiologist who is board certified in caring for adults with congenital heart disease and two board-certified pediatric cardiologists. None of the three at-large members may be employed by any of the named facilities who have specific representation on the panel. The panel has 10 other members who are appointed by the chief executive officer of their respective hospitals, plus an alternate member. The named member, either the voting member or the alternate, must be a pediatric cardiologist or pediatric cardiovascular surgeon.

The Panel Membership comprises the following:

Cardiac Program Technical Advisory Panel Membership[56]			
Members\Type of Members:	**Voting**	**Alternate**	**Non-Voting**
Johns Hopkins All Children's in St. Petersburg	■	■	
Arnold Palmer Hospital in Hollywood	■	■	
Nicklaus Children's Hospital in Miami	■	■	
St. Joseph's Children's Hospital in Tampa	■	■	
University of Florida Health Shands Hospital in Gainesville	■	■	
University of Miami Holtz Children's Hospital in Miami	■	■	
Wolfson Children's Hospital in Jacksonville	■	■	
Florida Hospital for Children in Orlando	■	■	
Nemours Children's Hospital in Orlando	■	■	
AHCA Secretary may appoint following nonvoting members:			
Agency for Health Care Administration Secretary			■
Surgeon General			■
Deputy Secretary of Children's Medical Services			■
Any current or past Director of Children's Medical Services			■
A parent of a child with congenital heart disease			■
An adult with congenital heart disease			■
3- At Large Members			
1 Cardiologist- Board Certified in caring for adults with congenital health disease	■		
1 Pediatric Cardiologist – Board Certified	■		
1-Pediatric Cardiologist Board Certified	■		
A representative from each of the following organizations:			
Florida Chapter of the American Academy of Pediatrics			■
Florida Chapter of the American College of Cardiology			■
Greater Southeast Affiliate of the American Heart Association			■
Adult Congenital Heart Association			■
March of Dimes			■
Florida Association of Children's Hospitals			■
Florida Society of Thoracic and Cardiovascular Surgeons			■

[55] Section 395.1055(9)(a) and (b), F.S.
[56] Section 395.1055(9)(b) and (c), F.S.

The panel is required to meet at least biannually, or more frequently, upon the call of the AHCA Secretary. Meetings may be held telephonically or by other electronic means. The panel has held at least 26 meetings since its inception in 2017 and has been working towards proposed rules and policies on cardiology, surgery, public reporting and transparency, and facility standards.

At a minimum, the statute requires the panel to make recommendations for rules and standards for pediatric cardiac programs which must include:

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

Records of the panel's meetings and those of its subcommittees, including draft standards, meeting minutes, and handouts, are posted on the AHCA's website.[57] The most recent draft of pediatric and congenital cardiovascular center standards are dated September 2018 and were last edited at a telephonic meeting held on January 29, 2019. The most recently posted draft meeting minutes on the panel's website are from the panel's December 13, 2018 meeting. Those draft minutes and draft standards include recommendations for the panel being consulted for CON applications for new programs, a requirement that programs maintain a two-star rating as determined by the Society of Thoracic Surgeons (STS), and that if a program drops below a two-star rating, the program can be subject to a corrective action plan as determined by the panel.[58]

The draft proposal also includes recommendations that pediatric centers must:

- Be located in a healthcare facility that maintains accreditation by the Joint Commission on the Accreditation of Healthcare Organizations, also known as the Joint Commission (JCAHO), or the National Committee for Quality Assurance (NCQA).[59]
- Be compliant with the Health Insurance Portability and Accountability Act (HIPAA).[60]

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[57] *See* Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel,* http://ahca.myflorida.com/SCHS/PCTAP/index.shtml (last visited Mar. 5, 2019).

[58] Agency for Health Care Administration, Pediatric Cardiology Technical Advisory Panel, *Pediatric and Congenital Cardiovascular Center Standards* (September 2018), pg. 1, *available at* http://ahca.myflorida.com/SCHS/PCTAP/docs/121318/DraftPCTAPWorkingDocument120418Revised.pdf (last viewed Mar. 6, 2018).

[59] The National Committee for Quality Assurance (NCQA) was formed in 1990 as a nonprofit organization that focused on measuring and then accrediting health plans. The NCQA now also measures the quality of care delivered at the provider and practice level. *See* https://www.ncqa.org/about-ncqa/ (last visited Mar. 7, 2019).

[60] The Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191) included administrative simplifications provisions which required the federal Department of Health and Human Services to adopt national standards on health care standards for electronic health care transactions and security. There are several parts to the Act: the Privacy Rule which set national standards to protect individually identifiable health information across different entities and the Security Rule which set national standards to protect the confidentiality, integrity, and availability of electronic protected

- Provide limited English proficiency services the meet federal guidelines.
- Set guidelines for medical records reviews and onsite reviews.
- Establish draft volume standards.
- Have quality assurance and quality improvement processes.
- Actively participate in the required STS databases.
- Collect and submit quality assurance data annually
- Implement electronic medical records.
- Have providers meet specified standards based on their roles within the center.
- Provide equipment and facility space based on designated specifications.[61]

By January 1, 2020, an annual report must be provided to the Governor, President of the Senate, the Speaker of the House of Representatives, the AHCA Secretary, and the Surgeon General which summarizes the panel's activities during the preceding fiscal year. The report must include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.[62]

The current statute already provides some minimal standards for cardiac programs. For example, a pediatric cardiac program must:

- Be affiliated with a hospital licensed under chapter 395.
- Have a pediatric cardiac catheterization laboratory and pediatric cardiovascular surgical program located in the hospital.
- Have a risk adjusted surgical procedure protocol which follows the guidelines established by the STS.[63]

The AHCA is authorized to adopt rules to implement this section. Once the panel has developed its recommendations for pediatric cardiac care, the panel expects to forward those recommendations to the AHCA for adoption through the formal administrative rulemaking process.[64]

Liability for Good Faith Actions

Currently, the volunteer physicians and other members of the panel are not covered by any liability or immunity clauses in the panel's implementing statute. During panel meetings, the members have had discussions relating to sovereign immunity for panel members when they are

health information. A third rule, the Enforcement Rule, provides the Standards for the enforcement of all the administrative simplification rules.

[61] *Supra* note 15, at 3 - 17.

[62] Section 395.1055(9)(f), F.S.

[63] The Society for Thoracic Surgeons National Database was established in 1989 as a quality improvement initiative. It has four components: Adult Cardiac, General Thoracic, Congenital Heart Surgery, and the Interagency Registry for Mechanically Assisted Circulatory Support (Intermacs) Databases. The Database has participants in all 50 states and 13 countries with approximately 6.7 million surgical records and more than 90 percent of the groups that perform cardiac surgery in the United States. In 2011, the STS Research Center was launched to provide scientific evidence and research to held cardiothoracic surgeons and other interested parties improve surgical outcome and patient quality of care. *See* The Society of Thoracic Surgeons, https://www.sts.org/about-sts (last visited Mar. 5, 2019).

[64] *See* s. 395.1055(10)(a-c) and (12), F.S.

engaged in activities related to the panel.[65] Members on other panels, board of directors or volunteers in programs by the Legislature have been granted similar provisions of immunity for their official actions, such as individuals in the Division of Rehabilitation and Liquidation of the Department of Financial Services,[66] guardians ad litem,[67] and employees and board of directors of the Health Maintenance Organization Consumer Assistance Plan.[68]

III. Effect of Proposed Changes:

The bill modifies the composition of the Pediatric Cardiac Technical Advisory Panel (panel) as established in the Agency for Health Care Administration (AHCA) by:

- Authorizing the appointment of three alternate, at-large members from affiliations different than those of the voting at-large members.
- Adding a two-year term limit to voting panel members; however, members may be re-appointed to the panel after a two-year retirement period.
- Allowing members of the panel to be reimbursed for travel and per diem.
- Providing Panel members immunity from criminal and civil liability for any good faith performance of duties assigned to them by the AHCA Secretary.
- Requiring the AHCA Secretary to consult with the panel for an advisory recommendation on all CON applications to establish pediatric cardiac surgical centers.
- Authorizing the AHCA Secretary to request announced or unannounced site visits to any existing pediatric cardiac surgical center or a facility seeking licensure as a pediatric cardiac surgical center through the CON process to ensure compliance with the process.
- Permitting the panel, at the request of the AHCA Secretary, to make recommendations for in-state physician experts to conduct site visits and up to two out-of-state physician experts.
- Establishing the procedures for the on-site inspection of a hospital's pediatric medical and surgical programs and providing the required contents of the written inspection reports, advisory opinion, and suggested actions for correction, which include:
  - An inspection of the program's physical facilities, clinics and laboratories.
  - Interviews with support staff and hospital administration.
  - A review of medical records and reports, clinical outcome data from STS, mortality reports, and program volumes.
- Requiring the Surgeon General to provide quarterly reports to the AHCA Secretary data from CMS' critical congenital heart disease screening program for review by the panel.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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[65] Agency for Health Care Administration, Pediatric Cardiology Technical Advisory Panel Meeting Minutes (Oct. 2, 2018), pg. 3, http://ahca.myflorida.com/SCHS/PCTAP/docs/102518/PCTAPDraftMinutes100218.pdf (last visited Mar. 7, 2019).
[66] *See* s. 631.391, F.S.
[67] *See* s. 61.405, F.S.
[68] *See* s. 631.825, F.S.

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:

The panel is composed of private and public medical providers reviewing medical data about other private and public medical providers. Changes in the bill will permit panel members, at the request of the AHCA Secretary only, to conduct site visits on private health care facilities. Such site visits may be beneficial to the public once completed; however, they may also be time consuming to the health care facility. The outcome of the inspection and review may also result in licensing action by the AHCA.

C. Government Sector Impact:

SB 1126 directs the AHCA Secretary to consult with the panel for advisory recommendations if there is a CON application process to establish pediatric cardiac surgical centers. The AHCA Secretary is not required to follow the panel's advisory recommendation but is required to consult with the panel as part of the CON process for pediatric surgical centers.

The bill also provides the AHCA Secretary with the authority to request that the panel conduct announced or unannounced site visits upon pediatric cardiac centers or facilities and provides the parameters for the site visit teams and the contents of the inspection reports. While the AHCA Secretary currently has the authority to direct her/his own staff to inspect any facility, this provision provides another set of technical experts for such tasks. Such site visits and inspections; however, will likely have a fiscal impact, and no estimate of the bill's fiscal impact has been provided by the AHCA. The costs of such visits and inspections would likely depend on the location of the facility, the number of technical experts sent to the location, where the experts were located, and if any out-of-state experts were also included.

To the extent that any publicly owned hospitals also have a pediatric cardiac care facility that may be subject to an announced or unannounced inspection, such facilities would be impacted by hosting those inspections and by any findings from the reports.

The DOH and the State Surgeon General will be required to produce a quarterly report for the AHCA Secretary that shows the data from the Children's Medical Services critical congenital heart disease screening program. This data will be reviewed by the panel. It is unknown at this time whether there is a fiscal impact to the DOH to produce to this data.

The bill also allows for panel members to receive travel reimbursement.

The total fiscal impact of the bill is indeterminate and will dependent on the number of site visits and inspections requested by the AHCA Secretary and travel requests of the panel members. At the time the total fiscal impact is not known.

VI. Technical Deficiencies:

SB 1126 modifies the travel reimbursement provision to allow panel members to be reimbursed for travel and per diem; however, the provision does not include the statutory cross reference to s. 112.061, F.S., that limits travel reimbursement for those who travel on public business. Without the cross reference to the state guidelines, a different travel reimbursement schedule might be implemented for the panel members.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 395.1055 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Harrell

25-01272-19 20191126__

A bill to be entitled

An act relating to the Pediatric Cardiac Technical Advisory Panel; amending s. 395.1055, F.S.; authorizing the reimbursement of per diem and travel expenses to members of the pediatric cardiac technical advisory panel, established within the Agency for Health Care Administration; revising panel membership to include certain alternate at-large members; providing term limits for voting members; providing immunity from civil and criminal liabilities to members of the panel; requiring the Secretary of Health Care Administration to consult the panel for advisory recommendations on certain certificate of need applications; authorizing the secretary to request announced or unannounced site visits to any existing pediatric cardiac surgical centers or facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process; providing a process for the appointment of physician experts to a site visit team; requiring each member of a site visit team to submit a report to the panel; requiring the panel to discuss such reports and present an advisory opinion to the secretary; providing requirements for an on-site inspection; requiring the Surgeon General of the Department of Health to provide specified reports to the secretary; providing an effective date.

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

Section 1. Present subsections (9) through (12) of section 395.1055, Florida Statutes, are amended, and new subsections (10), (13), and (14) are added to that section, to read:

395.1055 Rules and enforcement.—

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

(a) Members of the panel must have technical expertise in pediatric cardiac medicine, shall serve without compensation, and may ~~not~~ be reimbursed for per diem and travel expenses.

(b) Voting members of the panel shall include: 3 at-large members, and 3 alternate at-large members with different program affiliations, including 1 cardiologist who is board certified in caring for adults with congenital heart disease and 2 board-certified pediatric cardiologists, neither of whom may be employed by any of the hospitals specified in subparagraphs 1.-10. or their affiliates, each of whom is appointed by the Secretary of Health Care Administration, and 10 members, and an alternate for each member, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following hospitals:

1. Johns Hopkins All Children’s Hospital in St. Petersburg.

2. Arnold Palmer Hospital for Children in Orlando.

3. Joe DiMaggio Children’s Hospital in Hollywood.

4. Nicklaus Children’s Hospital in Miami.

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

6. University of Florida Health Shands Hospital in Gainesville.

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

8. Wolfson Children's Hospital in Jacksonville.

9. Florida Hospital for Children in Orlando.

10. Nemours Children's Hospital in Orlando.

Appointments made under subparagraphs 1.-10. are contingent upon the hospital's maintenance of pediatric certificates of need and the hospital's compliance with this section and rules adopted thereunder, as determined by the Secretary of Health Care Administration. A member appointed under subparagraphs 1.-10. whose hospital fails to maintain such certificates or comply with standards may serve only as a nonvoting member until the hospital restores such certificates or complies with such standards. A voting member may serve a maximum of two 2-year terms and may be reappointed to the panel after being retired from the panel for a full 2-year term.

(c) The Secretary of Health Care Administration may appoint nonvoting members to the panel. Nonvoting members may include:

1. The Secretary of Health Care Administration.

2. The Surgeon General.

3. The Deputy Secretary of Children's Medical Services.

4. Any current or past Division Director of Children's Medical Services.

5. A parent of a child with congenital heart disease.

6. An adult with congenital heart disease.

7. A representative from each of the following

organizations: the Florida Chapter of the American Academy of Pediatrics, the Florida Chapter of the American College of Cardiology, the Greater Southeast Affiliate of the American Heart Association, the Adult Congenital Heart Association, the March of Dimes, the Florida Association of Children's Hospitals, and the Florida Society of Thoracic and Cardiovascular Surgeons.

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

(e) The duties of the panel include recommending to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services.

(f) Beginning on January 1, 2020, and annually thereafter, the panel shall submit a report to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General. The report must summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.

(g) Members of the panel are immune from any civil or criminal liability for events resulting from the good faith performance of duties assigned to them by the Secretary of Health Care Administration.

(10) The Secretary of Health Care Administration shall consult the pediatric cardiac technical advisory panel for an advisory recommendation on all certificate of need applications

to establish pediatric cardiac surgical centers.

(11)~~(10)~~ Based on the recommendations of the pediatric cardiac technical advisory panel ~~in subsection (9)~~, the agency shall adopt rules for pediatric cardiac programs which, at a minimum, include:

(a) Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures.

(b) Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.

(c) Specific steps to be taken by the agency and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.

(12)~~(11)~~ A pediatric cardiac program shall:

(a) Have a pediatric cardiology clinic affiliated with a hospital licensed under this chapter.

(b) Have a pediatric cardiac catheterization laboratory and a pediatric cardiovascular surgical program located in the hospital.

(c) Have a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons.

(d) Have quality assurance and quality improvement processes in place to enhance clinical operation and patient satisfaction with services.

(e) Participate in the clinical outcome reporting systems operated by the Society of Thoracic Surgeons and the American College of Cardiology.

(13)(a) The Secretary of Health Care Administration may request announced or unannounced site visits to any existing pediatric cardiac surgical centers or facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process, to ensure compliance with this section and rules adopted hereunder.

(b) At the request of the Secretary of Health Care Administration, the pediatric cardiac technical advisory panel shall recommend in-state physician experts to conduct an on-site visit. The Secretary may also appoint up to two out-of-state physician experts.

(c) A site visit team shall conduct an on-site inspection of the designated hospital's pediatric medical and surgical programs, and each member shall submit a written report of its findings to the panel. The panel shall discuss the written reports and present an advisory opinion to the Secretary of Health Care Administration which includes recommendations and any suggested actions for correction.

(d) Each on-site inspection must include all of the following:

1. An inspection of the program's physical facilities, clinics, and laboratories.

2. Interviews with support staff and hospital administration.

3. A review of:

a. Randomly selected medical records and reports,

including, but not limited to, advanced cardiac imaging, computed tomography, magnetic resonance imaging, cardiac ultrasound, cardiac catheterization, and surgical operative notes.

b. The program's clinical outcome data submitted to the Society of Thoracic Surgeons and the American College of Cardiology pursuant to s. 408.05(3)(k).

c. Mortality reports from cardiac-related deaths that occurred in the previous year.

d. Program volume data from the preceding year for interventional and electrophysiology catheterizations and surgical procedures.

(14) The Surgeon General shall provide quarterly reports to the Secretary of Health Care Administration consisting of data from the Children's Medical Services' critical congenital heart disease screening program for review by the advisory panel.

(15) ~~(12)~~ The agency may adopt rules to administer the requirements of part II of chapter 408.

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

SB-1126
Bill Number (if applicable)

Topic Pediatric Cardiac Technical Bd

Amendment Barcode (if applicable)

Name Marnie George

Job Title Sr Advisor Buchanan Ingersoll & Rooney

Address 101 N. Monroe St, Suite 1090
Street

Phone 850-510-8566

Tallahassee FL 32303
City *State* *Zip*

Email marnie.george@bipc.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL. Chapter, Am College of Cardiology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/11/19
Meeting Date

SB 1126
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic PEDIATRIC CARDIAC TECHNICAL ADVISORY PANEL

Name DR. WILLIAM B. BLANCHARD, M.D.

Job Title PEDIATRIC CARDIOLOGIST

Address 3248 BAYOU LANE
Street
PENSACOLA FL 32503
City *State* *Zip*

Phone 850-554-3818

Email bcblanchard@cox.net

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

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

Representing PEDIATRIC CARDIAC TECHNICAL ADVISORY PANEL – FORMER AT-LARGE MEMBER

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

Lobbyist registered with Legislature: [ ] Yes [X] 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)

Alternatives to Opioids Pain Management and Addiction Prevention Program

The Journey: Implementation Plan and Future Recommendations

Presented by
Kevin DiLallo, FACHE, Manatee Memorial Hospital
Dr. Candace Smith, PhD, RN, NEA-BC, Manatee Memorial Hospital

GET the FACTS …

2006-2015- 144% Increase in individuals treated and released from the ED for opioid-related care- prescriptions quadrupled.

2006-2015- 64% Increase in individuals admitted to the hospital for opioid-related care.

Opioid-Related Costs Taking Toll on Overall Economy

$55.6B	$1T	$500B
Estimated cost of opioids In lost economic productivity (2016)	Estimated total opioid-related costs to the American economy (2001-2017)	Projected future opioid-related costs to the American economy (2017-2020)

Yet….

There was no overall increase in pain reported by Americans

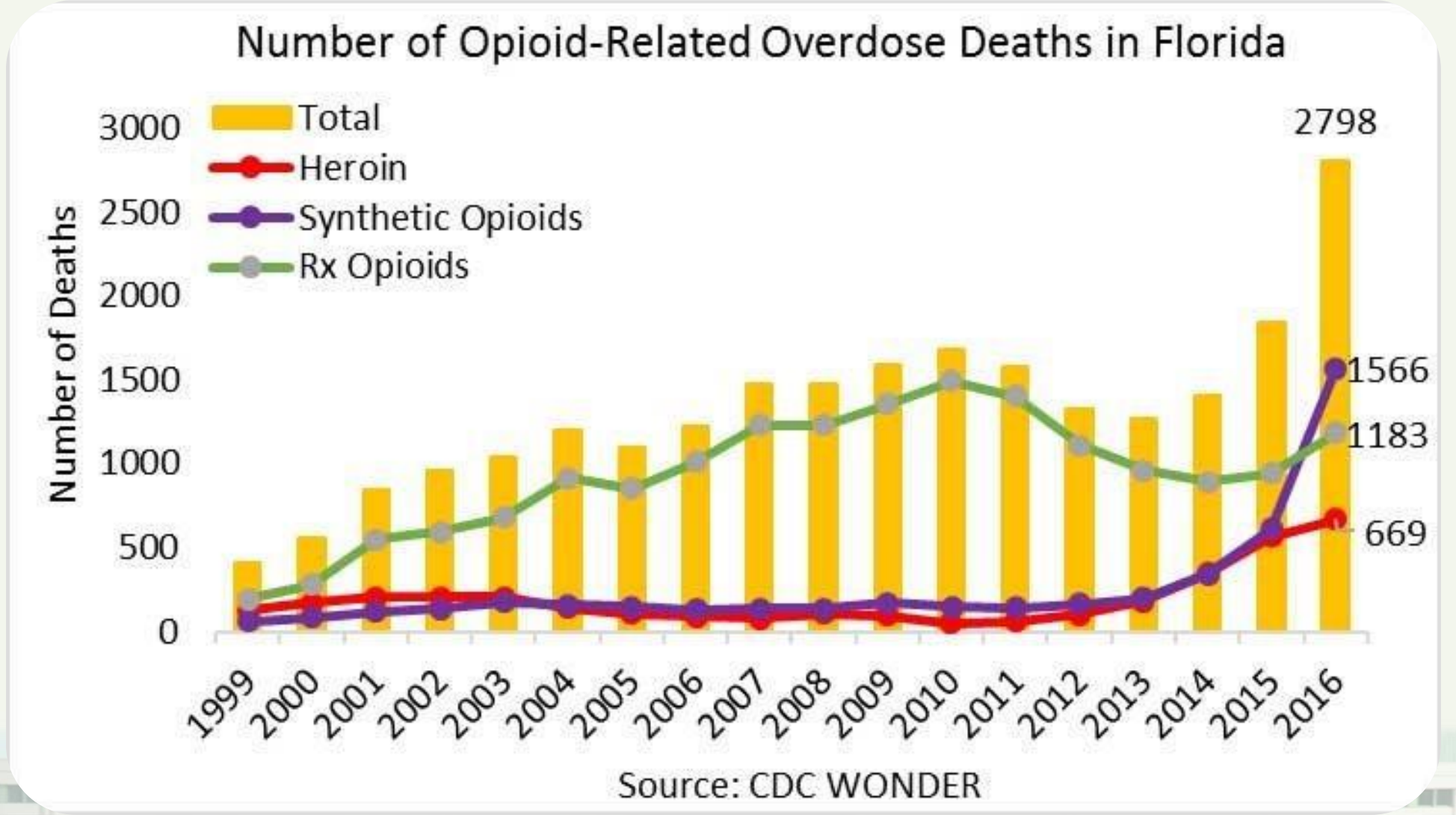
Source: NICHM, "The Opioid Crisis at a Glance," January 2018; Katz J., "Drug Deaths in American are Rising Faster Than Ever," The New York Times. June 5, 2017; Boyles S., " Opioid Overdose ICU Admissions Increasing, "MedPage Today, August 13, 2017; Politico Pulse, September 17, 2017; American Society for Addiction Medicine, "Opioid Addition 2016 Facts & Figures," 2016; STAT Forecast Opioids Could Kill Nearly 500,000 Americans in the Next Decade, " June 27, 2017; Rhyan C., " Burden of Opioid Crisis Reached $95 Billion in 2016; Private Sector Hit Hardest, " Altarum, November 16, 2017; Health Care Advisory Board interviews and analysis .

Opioid Overview

A List of Common Opioids in Increasing Strength

- **Codeine**
- **Hydrocodone (Vicodin, Hycodan, Norco)**
- **Morphine (MS Contin, Kadian)**
- **Oxycodone (Oxycontin, Percocet)**
- **Hydromorphone (Dilaudid)**
- **Fentanyl (Duragesic)**

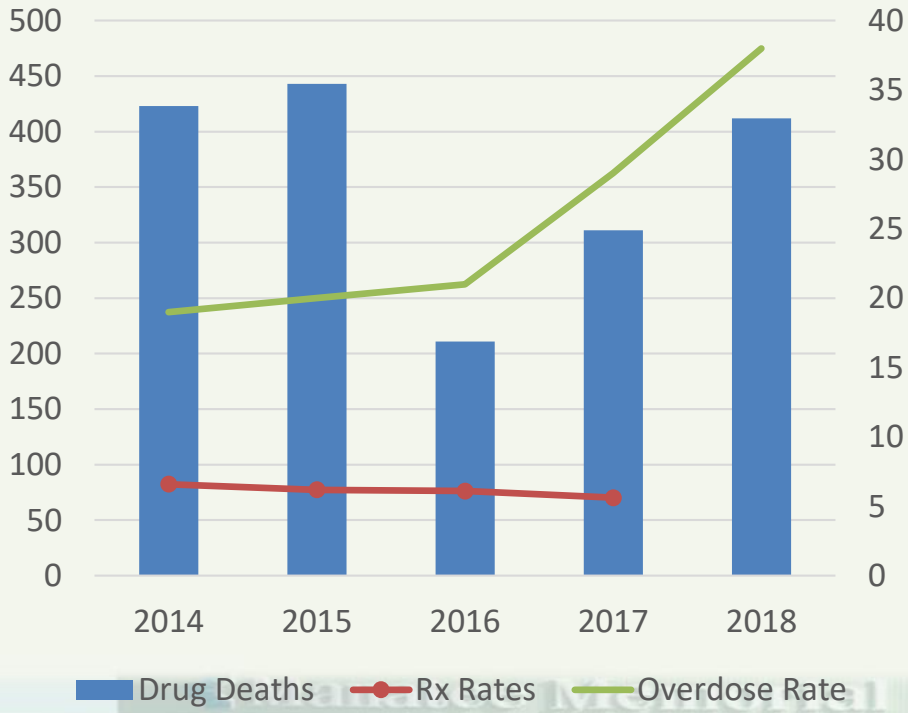
Florida Opioid Deaths



Drug Overdose & Rx Mortality

Drug Overdose Data

Manatee County Drug Overdose and Opioid Rx Rates



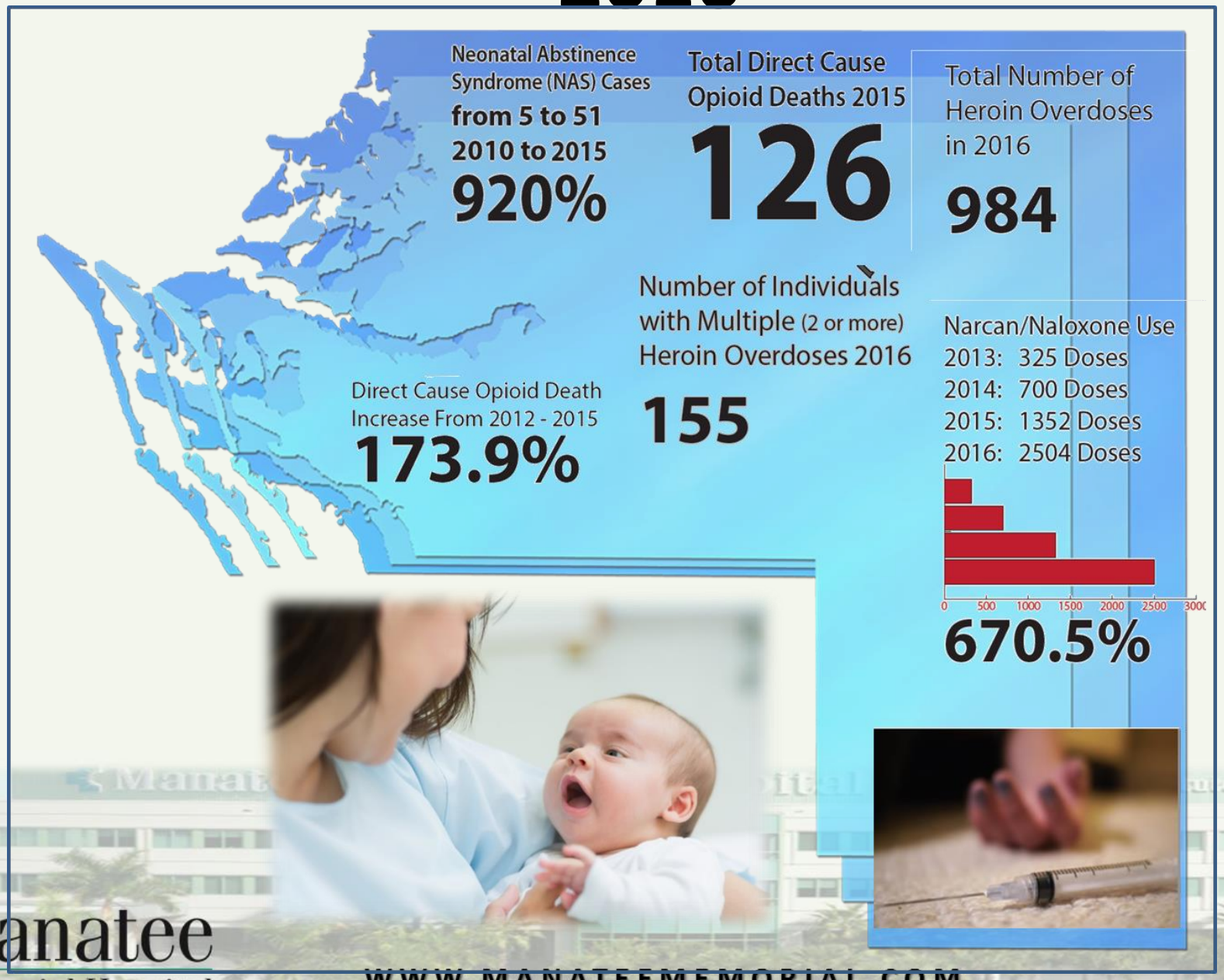
(Source: County Health Rankings and CDC)

Overdose EMS Reversals: 2016

Narcan = 2,521 ~$109,650	REPEATS = 1247 49.5% >7 Repeats = Age 25-41 (31 adj.)	
GENDER	MALES	65.8%
RACE	WHITE	89.9%
34207 34205 34208	605 502 359	58.2%
Days	Wednesday Friday	32.4%
Hours	3PM – 8PM	41.4% (170 – 186)

Source: Manatee County Paramedicine, Overdose Repeat Patients, Demographics, and Volume (2016)
**Note: Repeat-data is attributable value*

Manatee County: 363,000 Population 2016



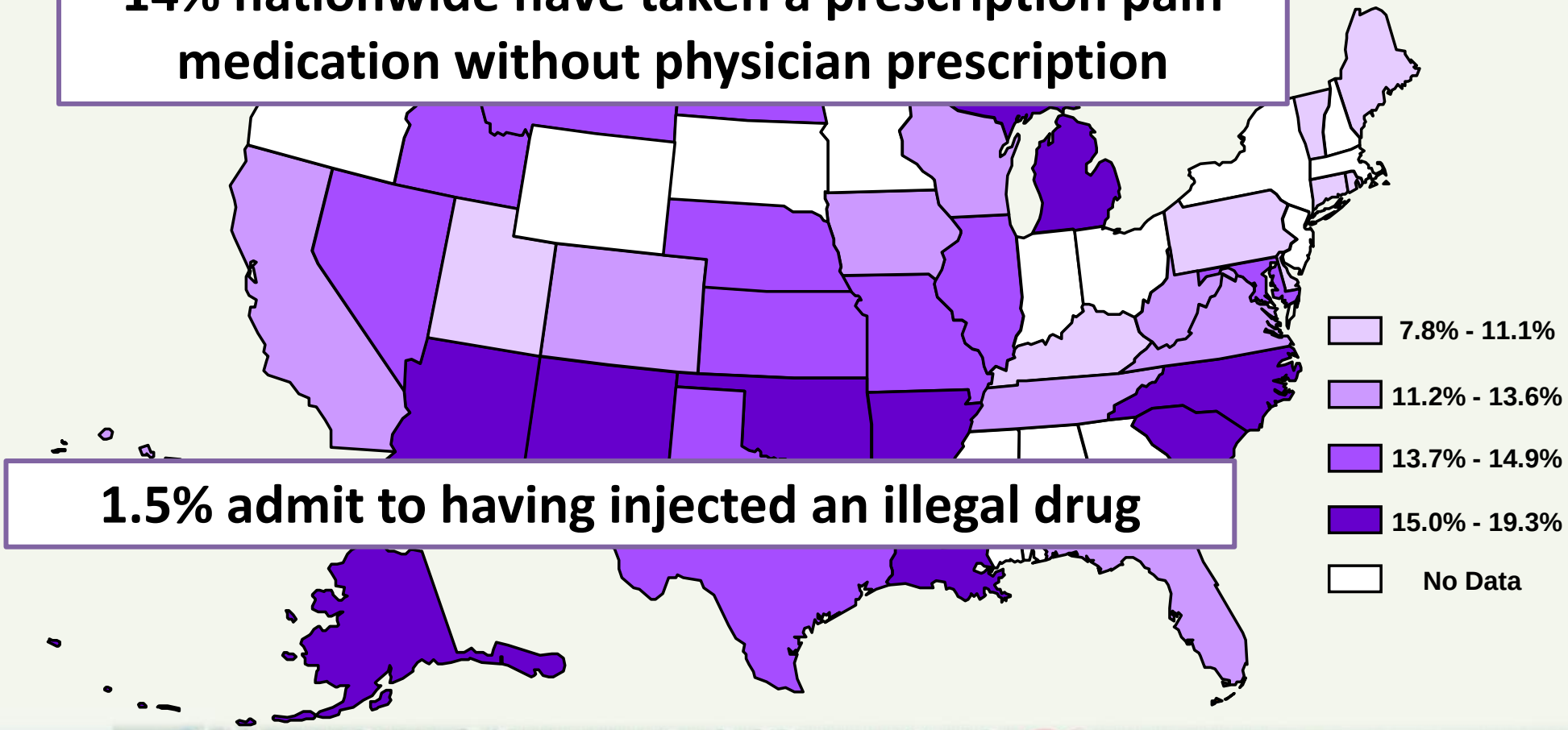
Neonatal Abstinence Syndrome

Withdrawal symptoms in a newborn who was exposed to opioids in utero

	2016			2017			2018		
	NAS	Total Births	NAS Rate	NAS	Total Births	NAS Rate	NAS	Total Births	NAS Rate
Hospital A	70	1,763	4.0%	71	1,852	3.8%	62	1,938	3.1%
Hospital B	114	3,722	3.1%	71	3,631	2.0%	112	3,762	3.0%

CDC High School Student Survey

14% nationwide have taken a prescription pain medication without physician prescription

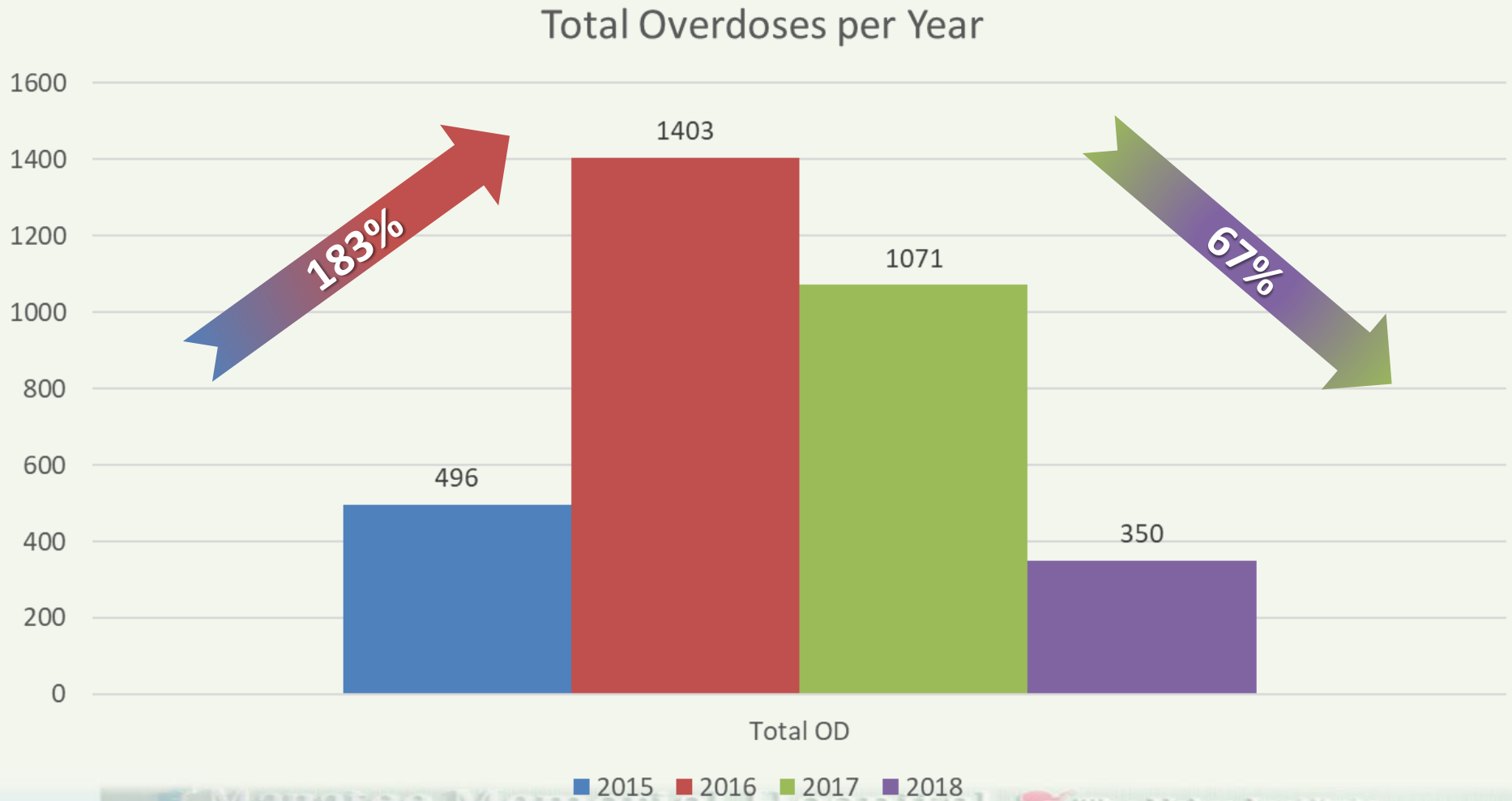


1.5% admit to having injected an illegal drug

State Youth Risk Behavior Surveys, 2017

www.cdc.gov/healthyyouth/data/yrgs/results.htm

THIS IS WHY ALTO



Understanding the Case for Alternatives to Opioids: The Facts

CDC Recommends:

- Opioids are not first-line or routine therapy for chronic pain.
- Discussion of benefits, risks, and availability of non-opioid therapies with patients.

CDC Guidelines for prescribing Opioids are underutilized

http://www.cdc.gov/drugoverdose.pdf/Guidelines_Factsheet-a.pdf

MMH Develops the ALTO Toolkit

- Charter
- Stakeholders
- Work Plan
- Communication Plan
- Community Information Sessions
- Data Management
- Patient Education Plan
- Tools for Success
- Pharmacists in the ECC
- EMR alerts and notifications
- IP SWAT Team
- Post Hospitalization Support and Care Transitions
- Sustain and Maintain Program
- Recommendations

Toolkit now available!

Key Elements of the Plan:
1. Patient Education

- **Informing** patients of outcomes and procedures
- **Educating** on opioids and side effects
- **Demonstrating** how to counteract the outbursts

Discussing Pain Management with Patients

- MMH is committed to providing excellent care for patients while hospitalized including keeping patients comfortable
  - Avoiding all pain is not always possible or to be expected
  - Minimizing pain and keeping it at a tolerable is the goal
- Pain can be treated in a variety of ways
  - Non-medication (ice, heat, rest, elevation, physical therapy, massage)
  - Non-opioid medications
    - Acetaminophen (Tylenol®)
    - NSAIDs –ibuprofen, ketorolac
    - Topical analgesics (lidocaine patches)
    - Gabapentin, pregabalin (Lyrica®)
  - Opioids
    - CDC recommends to be used as second line agents for chronic pain
    - Use only when risks outweigh benefits
    - Use the lowest dose possible for the shortest course possible
    - Oral agents provide the same analgesia as IV agents
- It is important to ensure that patients receive appropriate education regarding pain control. Informing patients of shortages of opioids is not appropriate messaging.

2. Hospital Prescriber Interventions

- Use of Alternative Agents
  - Focus on renal colic, low back pain, headache, muscle strain, fracture
- Limit discharge prescriptions to 3 days
- Use of eFORCSE system
- Enhanced patient education regarding prescriptions
- Use of Health Information Exchange (HIE)

3. Inpatient Substance Withdrawal Action Team (SWAT)

- Screenings done on presentation
- Patient admissions based on a consequence of their drug use are placed in program

- *The implementation of a risk screening tool is advised and should be incorporated into the electronic medical record.*

4. Post Hospitalization Support

- Community paramedicine program
- Case management
- Peer to Peer Counseling

- Post Hospitalization support- Care Transitions
  - Understand Behavioral Health component
  - Methadone Clinic or other MAT clinic
  - Mental Health Counselors in Urgent Care Centers and FEDs

What every Hospital in Florida should do

MMH Opioid Stewardship

Revised 2/20/2019

Monthly Summary 2018-2019

ECC Opioid Stewardship Initiative

Baseline Opioid Utilization 13%

	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan 2019	YTD
Opioid Doses	1,034	899	741	670	690	654	698	586	745	686	728	828	10,294
All Med Doses	9,131	9,499	8,947	8,655	8,002	7,555	8,213	7,767	9,062	8,810	9,404	10,235	118,014
Opioid %	11.32%	9.46%	8.28%	7.74%	8.62%	8.66%	8.50%	7.54%	8.22%	7.79%	7.74%	8.09%	8.72%
NSAID/APAP Doses	1,697	1,732	1,756	1,742	1,557	1,498	1,679	1,713	1,967	1,910	1,963	2,119	23,424
NSAID/APAP %	18.59%	18.23%	19.63%	20.13%	19.46%	19.83%	20.44%	22.05%	21.71%	21.68%	20.87%	20.70%	19.85%
Opioid dc Rx #	394	257	210	156	140	139	132	126	118	124	143	129	2068
OP Patient Visits	5,634	5,695	5,429	5,343	4,781	5,032	5,060	5,466	5,591	5,377	5,660	5,801	71166
Opioid dc Rx %	7.0%	4.5%	3.9%	2.9%	2.9%	2.8%	2.6%	2.3%	2.1%	2.3%	2.5%	2.2%	2.9%
Total Visits	6,841	7,069	6,704	6,621	6,023	6,205	6,237	6,589	6,917	6,662	7,087	7,270	87888

Inpatient Opioid Stewardship Initiative

	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan 2019	
Morphine Equivalents/ad	9.52	9.75	8.81	7.73	8.09	9.45	9.53	10.06	7.76	7.89	10.71	9.2	9.04
Methadone MME/APD	0.88	6.36	8.87	8.36	0.95	4.9	7.46	7.03	2.64	6.3	2.36	0.92	5.38
Adjusted Pt days	10,834	11,723	11,253	11,328	10,864	9,991	10,179	9,746	10,664	10,483	11,122	11,667	129,854
All Providers; ED Orders Only													
Opioid Doses	1,167	1,040	867	740	787	714	778	713	845	770	807	992	11,555
All Med Doses	10,889	11,437	10,524	9,522	9,272	8,255	9,047	9,170	9,961	9,707	10,311	11,876	132,705
Opioid %	10.72%	9.09%	8.24%	7.77%	8.49%	8.65%	8.60%	7.78%	8.48%	7.93%	7.83%	8.35%	8.71%
NSAID/APAP Doses	1,435	1,953	1,911	1,889	1,670	1,627	1,849	1,965	2,142	2,101	2,118	2,291	25,042
NSAID/APAP %	13.18%	17.08%	18.16%	19.84%	18.01%	19.71%	20.44%	21.43%	21.50%	21.64%	20.54%	19.29%	18.87%
Naloxone Use (doses)	37	66	33	39	38	30	33	21	28	44	34	18	421

Opioids include hydrocodone, hydromorphone, morphine, and oxycodone containing products
The focus is to review medications typically used for pain and not for procedural sedation (fentanyl)

Reduced Emergency Care Center Opioid Use by 40%
Reduced ECC Discharge Prescriptions by 64%

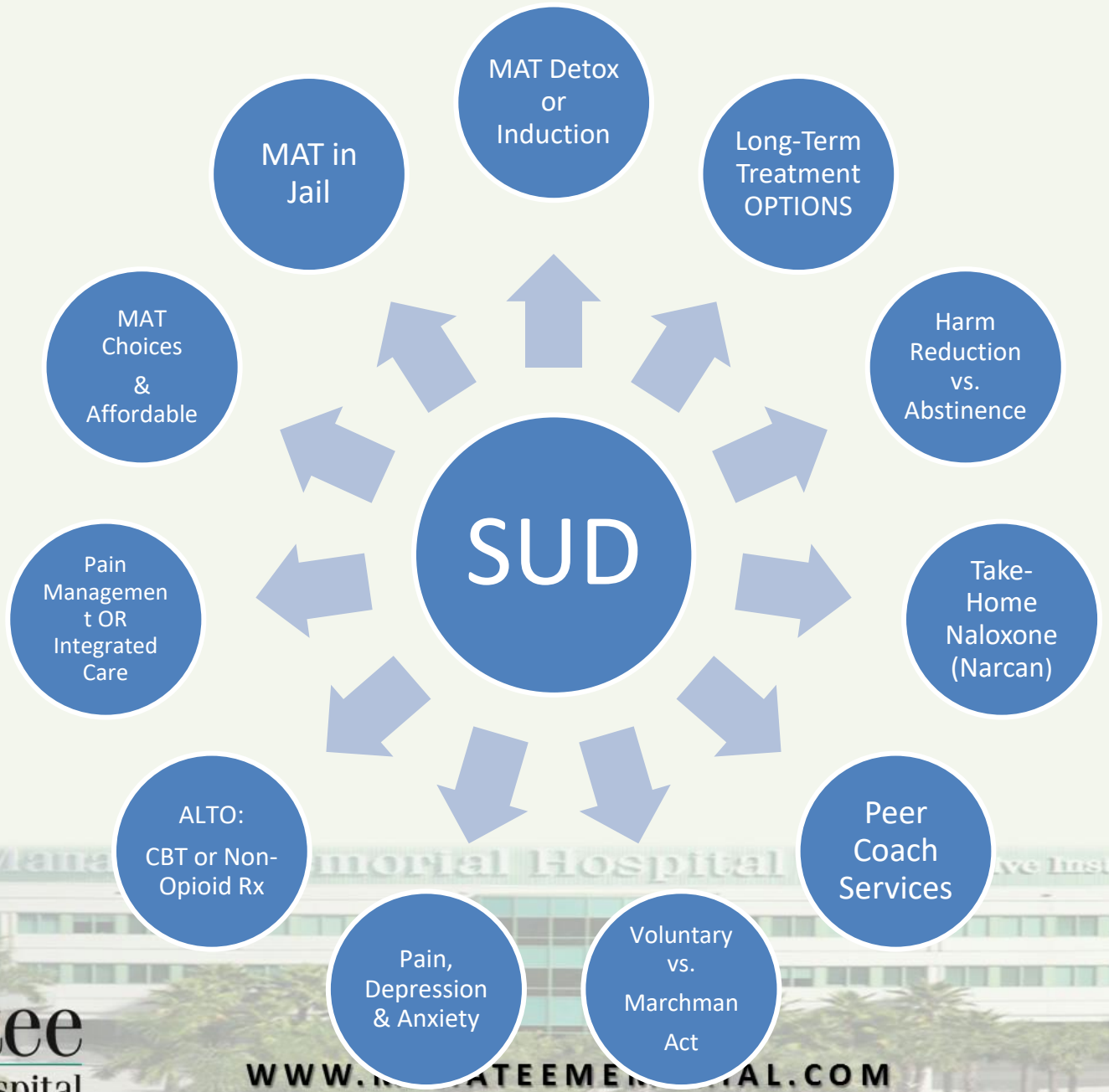
Future Considerations

- Consider adoption of process for timely disclosure of data from PDMP with transparency for providers to encourage accountability within organizations
- Consider leveraging data regarding opioid utilization within organizations to drive best practices
- Consider incentives for adoption of opioid sparing pain management programs by healthcare providers and hospital organizations with support from state agencies
  - State wide roll out plan & toolkit
  - Engagement of dental providers

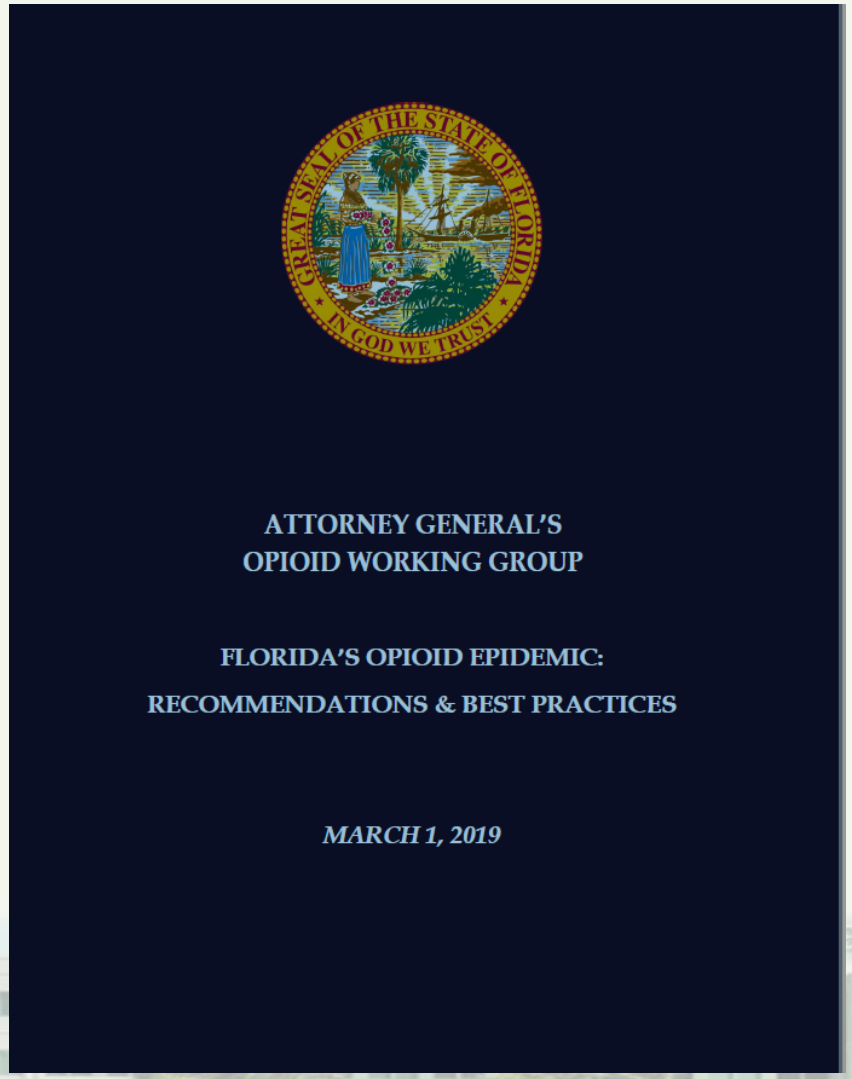
Future Considerations

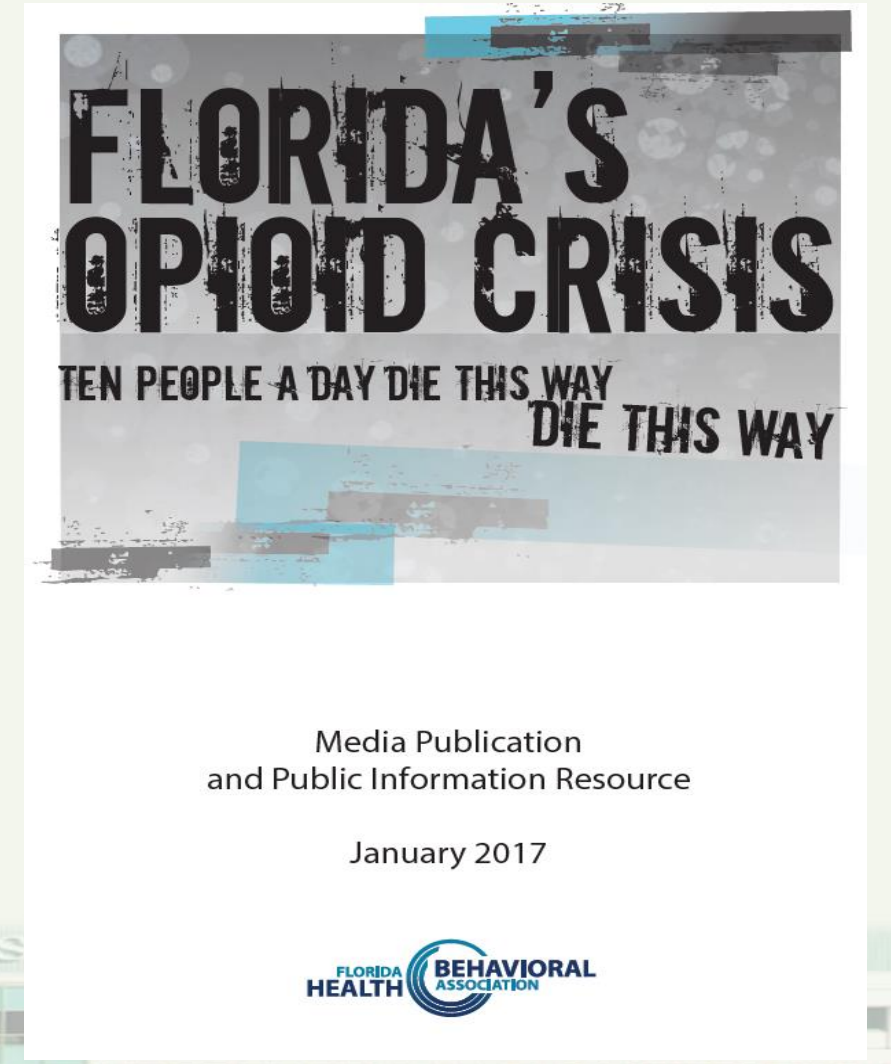
- Consider pharmacist to aid in coordination of programs as a State of Florida Quality Program Manager (**Pharmacist Czar**)
  - Data management
  - Education program development and coordination
  - Aid in facility rollouts & adoption of best practices in hospitals, nursing homes, and physician practices
  - Coordination between agencies
- Consider provision of funding to support services for uninsured and underinsured patients requiring hospitalization and inpatient and outpatient treatment of substance use disorder

Clinical Evidence-Based Practices for Substance Use Disorder



Florida Recommendations





Media Publication
and Public Information Resource
January 2017

1. Initiate Task Force with all disciplines to develop recommendations for a coordinated statewide action plan to combat the crisis

2. Expansion of treatment availability including Medication-Assisted Treatment (MAT); increased funding to accomplish this goal

3. Enhanced penalties for drug trafficking of opioids

5. Expanded training for first responders, law enforcement, addiction treatment professionals, and health professionals in opioid prescribing, overdose prevention, and MAT

6. Create a bridge between patients treated in hospital emergency departments for overdoses and referrals for substance use disorder treatment

7. Continue Public awareness initiatives to inform public and reduce stigma

8. Improve reporting of data/utilization of data to guide state response, better target resources, and improve efficiency

MMH ALTO KIT for ALL COUNTIES

THE HOW Behind ALTO

Manatee Memorial Hospital

Alternatives to Opioids

TOOL KIT

Pain Management and Addiction Prevention

This toolkit is designed to support your organization with the building blocks for a successful pain management and addiction prevention program.

Regional Summit

Manatee Memorial Hospital

Opioid Use Disorder Prevention: A Community Based Approach

Date: Friday, March 22nd

Time: 1:00-4:00 PM

Location: Manatee Memorial Hospital
206 Second Street East, Bradenton FL 34208

Room: Manatee Auditorium

Capacity: 85

Panel discussions including, Law Enforcement, Healthcare Leadership, and County Administrators:

Topics included: ALTO Program, Peer to Peer, Grants, Taskforce, ED Physicians, Surgeons, Pharmacists, Nurses and Leaders sharing the Opioid Prevention Measures and Alternatives

Register online at: https://manatee-memorial-hospital.doodle.com/poll/qi8xxzmf7tcpk2e8

Raise the Bar for Each County in Florida

- **Organize** multiagency taskforce
- **Implement** ALTO program using toolkit to kick start the program
- **Expand funding for** Peer to Peer program
- **Fund** Licensed Therapists in ED's, UCC's, FED's
- **Host** Regional Summits with Panel discussion approach
- **Share** up to date data on number and types of prescriptions by prescriber from hospitals, ED's, Dentist offices, UCC's, FED's, and Private Offices

Questions?

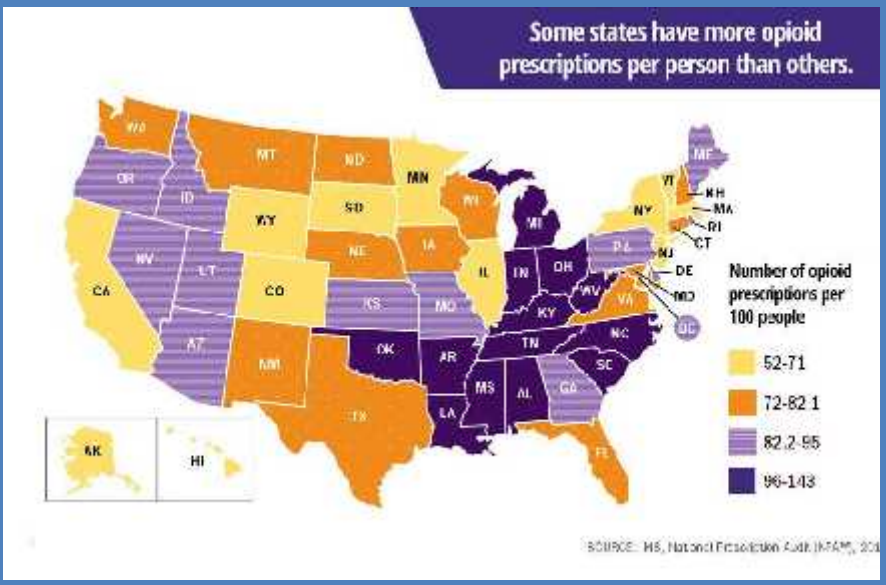
Manatee County is now becoming the EPICENTER for PREVENTION not Addiction

Thank you!

ALTERNATIVES TO OPIOIDS TOOL KIT

(Pain Management and Addiction Prevention)

This tool kit is designed to support your organization with the building blocks for successful pain management and addiction prevention program.



Manatee Memorial Hospital has researched the opioid epidemic and programs to support alternatives to opioids and developed a tool kit for pain management and addiction prevention.

Table of Contents

1. Charter

Opioid overdose deaths involving a prescription opioid are at 40%.[1] Prescription pain reliever misuse occurs in 4.31 out of 100 people.[2] 80% of new heroin users began by misusing prescription pain medications.[3] Up to 10% of patients who are newly prescribed an opioid will become addicted.[4] The Center for Disease Control recommends opioids are not first-line or routine therapy for chronic pain.[5] Most importantly, the discussion of benefits, risks, and availability of non-opioid therapies with patients must occur differently if a change in lifestyle and outcomes is to happen in your respective county. The main objectives for a hospital and community committee for consideration are as follows:

- **Provide** community with education, evidence based protocols, and support with pain management and addiction prevention. (hospitals, providers, payers, schools, faith based organizations)
- **Develop** enhanced Protocols, Medical Assisted Treatments (MAT), Pharmaceutical and Non-Pharmaceutical Interventions intra hospitalization and post hospitalization through collaboration and use of evidence based literature.
- **Improve** use of alternatives for opioids in your county.

2. Stakeholders

Identification of stakeholders across the continuum of care is essential for a successful program that meets the needs of the patient in the hospital and throughout the transitions of care. The hospital must take the initiative to develop a multidisciplinary team to manage prevention and treatment of opioid use disorder (OUD). This process begins with assessing awareness of the issues and developing a common level of understanding within the group of key stakeholders. A developed level of understanding identifies motivating factors of each stakeholder and advances the level of shared knowledge amongst its members to develop prevention and treatment needs. Key stakeholders may include:

- Hospital stakeholders
  - Hospital Administrators
  - Governing Bodies: Medical Committees, Board of Governors
  - Physicians: Emergency Medicine, Surgeons, Pain Management Specialists, Anesthesiologists, Internists, Psychiatrists, Neonatologists, Obstetricians
  - Nurse Leaders and Staff Nurses
  - Pharmacists
  - Social Workers and/or Case Managers
  - Physical Therapists
  - Department of Health Physician leadership

- Marketing and Community Relations
- Information System leaders

- Community Stakeholders
  - Primary Care Physicians
  - Pain Management Specialists
  - Free Standing Emergency Departments (FED)
  - Urgent Care Centers
  - Other Local Health Systems
  - Law Enforcement
  - Emergency Medical Services
  - Community Paramedicine Program
  - Drug Enforcement Agency
  - Community Institutions: Schools, Churches, Community Resource Centers
  - Behavioral Health and Rehabilitation Centers
  - Local Municipal and/or County, State, and Federal Legislators
  - Local and National Not-for Profit Organization
  - Peer to Peer Recovery Program

3. Work Plan

Work plans should be established with the aim to meet goals, provide methods for evaluation, and define stakeholders responsible for components of the plan. Work plans should include specific steps involved, a timeline for development and implementation of the steps, and accountability to the components of the plan.

Strategy	*Responsible Party*	*Action*	*Deliverable*	*Due Date*
Establish Workgroup or Committee		➢ Physician Champions- Emergency department, Surgery, Anesthesia, Pain Management, Internal Medicine ➢ Hospital Leadership – CEO, CNO, CMO ➢ Nurse Leaders ➢ Pharmacist ➢ Quality ➢ Community Liaisons ➢ EMS ➢ Information Technology		
Create timeline for implementation			Timeline with interim goals	
Define Scope		➢ ECC: Target diagnoses	Charter	

		➢ Target Surgical Protocols ➢ Inpatient pain syndromes ➢ Transitions of Care		
Assess IS (Information Services aka- IT) infrastructure needed		➢ Evaluate current state o Electronic order sets and pathways o Clinical decision support available and needed o ➢ Design ideal build ➢ Test and Evaluate	IS workplan and gap analysis	
Establish policy and guidelines				
Education/Training		➢ Workshops o Primary Care o Inpatient providers o Internal Medicine and Family Residents o Nursing and Pharmacy Staff o Hospitals/care networks ➢ Community education o Flyers o Workshops o Other media		
Measuring and Monitoring		➢ Define Key Performance Indicators ➢ Establish reporting structure		
Regulatory Needs Assessment		➢ Nursing practice acts ➢ Pharmacist practice acts ➢ Payer methodology (CMS, commercial) - behavioral health ➢ Controlled substance regulations ➢ Public funding and support		
Risk Screening/assessment and referral		➢ SBIRT ➢ Risk stratification (NIDA screening) ➢ Referral procedure		

4. Communication Plan

Programs should develop an internal and external communication plan for optimal success with opioid alternatives and overall pain management and addiction prevention initiatives. The first step is creating a sense of awareness at leadership and physician attended meetings. This includes but not limited to Board of Governors, Medical Executive Committees, Quality Committee of the Board, Senior Manager Meetings, Supervisor meetings, Pharmacy and Therapeutics, Surgical Services, and all other meetings involving decision makers within your program. The communication plan should describe the problem and a solid analysis of the problem in your respective area, current state, and problem analysis with use of a quality management performance improvement tool (recommend Institute for Healthcare Improvement tools and resources)[6], future state, countermeasures, implementation plan, and sustainability plan with dashboard to track key performance improvement measures. External communication plan should involve the VP of Public Relations and Community Stakeholders, local media previously identified. Communication plans should be tailored to meet facility and community objectives and evolve as objectives are met and as timelines progress.

5. Community Information Sessions with Local Facilities

When a commitment to change has been agreed upon within your organization, it is imperative to host a community wide information session with guest speakers that can support your initiatives and back your current state and future state proposal. The goal of this session is to invite all community stakeholders and local facilities to develop a unified community wide action plan with goals and metrics to ensure a transparent and engaged community. Speakers can be from other counties in the state or other facilities in the country that have managed to achieve solid program outcomes. This session should be planned with senior hospital leaders, senior leaders from local hospitals in the community, local and state government officials, county or community task forces tackling drug free initiatives, behavioral health executives, local media, law enforcement, DEA representatives, and patients and families that have suffered through this addiction crisis. Develop a program with contact information from your facility, speaker biographies, and provide highlights of the initiative within the organization to support this program.

6. Data Management

Programs should establish key performance indicators (KPI) to evaluate the current state, establish a strategic plan, and measure success. KPI should evaluate each component of the plan.[7] Leveraging data obtained from the Electronic Health Record (EHR) is an important component of the monitoring plan and should involve information technology specialists.

- Prevention
  - Initial opioid prescriptions per 1,000 patients or opioid prescription rate
    - Initial opioid prescribed in combination with benzodiazepine (rate)
    - Initial opioid is short acting
    - Initial opioid is for ≤ 50 MME (morphine milligram equivalents)/day
    - Initial prescription is ≤ 3 day supply
    - Rates of past or current substance use identified during screening
  - NSAID, acetaminophen, topical lidocaine, corticosteroid prescription rate
  - CDC guidelines for chronic pain followed[5]
  - Rate of initial prescriptions that convert to chronic opioid use
  - Overdose rate
- Pain Management
  - Rate of ED visits for breakthrough surgical pain
  - Rate of ED visits for breakthrough chronic pain
  - PDMP (prescription drug monitoring program) use- ED and Inpatient
- Opioid Use Disorder Treatment
  - Referral to medication-assisted treatment (MAT) for patients with opioid overdose (OD) or identified opioid use disorder (OUD)
    - Compliance or retention rates in MAT
    - Evidence of naloxone fill among patients with OUD or OD
- Maternal, Infant, Child Health
  - Rate of infants with neonatal abstinence syndrome (NAS)
- Regulatory Compliance
  - Adherence to state prescription drug laws
  - Adherence to Joint Commission and CMS requirements for pain management

7. IP SWAT(Substance Withdrawal Action Team) for patients with known addiction

Programs that have matured are adding the Inpatient SWAT team concept to support patients suffering from opioid use disorder as a cause of admission or at high risk for developing opioid use disorder. The implementation of a validated risk screening tool is advised and should be incorporated into the electronic medical record, screening for opioid addiction or opioid

addiction with co-occurring pain.[8] Screening should be performed on all patient encounters including emergency care centers, urgent care centers, outpatient visits, and inpatient hospital stays. Positive screens should result in the use of a comprehensive assessment.

Teams should be focused on safe care of the patient while hospitalized including consideration of drug screening, camera observation of patient or assigned sitter, evaluation of visitors and belongings, psychiatry consult, pain management consult, spiritual care, nutritional support, and case management consult for discharge planning or ongoing treatment. Initiation of medication assisted treatment should also be considered as licensure permits.[9]

Refer to APPENDIX D for examples of screening tools and treatment algorithms.

Examples of patient screening tools:

- National Institute on Drug Abuse (NIDA): *https://www.drugabuse.gov/sites/default/files/files/QuickScreen_Updated_2013%281%29.pdf*
- Screening, Brief Intervention and Referral to Treatment (SBIRT): https://www.samhsa.gov/sbirt/about
- Clinical Opiate Withdrawal Scale (COWS)[10]

8. Community and Patient Education Plan

Community education should include prevention and awareness, pain management education, and recovery. This should include a comprehensive catalogue of community support available to high, medium, and low risk opioid use disorder patients. Community support may include support groups, peer to peer recovery support, withdrawal management, outpatient services and inpatient treatment services. All patient education materials should be available in Urgent Care Centers and Free Standing Emergency Rooms. Community partners should be engaged to assist with and coordinate community education plans.

Patient education should include resources to discuss opioid alternatives with patients, appropriate storage, disposal, and handling of prescriptions, and reinforcement of behaviors that promote reduced use or abstinence. For high risk patients, additional support and education should be offered. For patients who inject opioids, additional harm-reduction interventions to prevent unintentional overdose or communicable disease should be discussed.

Patient education and community awareness resources can be found:
http://www.floridahealth.gov/provider-and-partner-resources/dpac/_documents/prescription-brochure-commercial.pdf

http://www.drugfreemanatee.org/wp-content/uploads/2016/02/Secure-Monitor-Dispose.pdf

https://www.oasas.ny.gov/admed/sbirt/documents/Opioideffects-UniversityofMo.pdf

https://www.cdc.gov/rxawareness/resources/socialmedia.html

https://www.cdc.gov/drugoverdose/patients/index.html

https://turnthetiderx.org/for-patients/#

https://www.va.gov/PAINMANAGEMENT/docs/TakingOpioidsResponsibly20121017.pdf

http://www.lockyourmeds.org/

9. Tools, Protocols for Success: Provider & Staff Education Plan

Provider Education (Appendix E)

Multimodal education approach is recommended

- Workgroups for protocol development with key physician stakeholders and champions
- Workshops/seminars
- Protocol distribution
  - Electronic notification boards
  - Physician newsletters
  - Computer screen savers
- Web based learning
  - http://www.flhealthsource.gov/FloridaTakeControl
  - https://fl.cme.edu/

Include key information

- Evidence behind protocols developed
- Implementation dates
- Clinical decision support and IS resources available
- Plans for monitoring

Staff Education (Appendix F)

Resident Education on Pain Management

SBIRT (Screening Brief Intervention and Referral for Treatment) Training Certification

Healthstream® or other web-based education plan to include

- Protocols, timeline, clinical decision support, and monitoring plans
- Signs and symptoms of opioid intoxication and withdrawal
- Discharge Education from ECC and how to message patients (Pain Management Talking Points)
- https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio

Discussing Pain Management with Patients

Manatee Memorial Hospital is committed to providing excellent care for patients while hospitalized including keeping patients comfortable

- Avoiding all pain is not always possible or to be expected
- Minimizing pain and keeping it tolerable is the goal

Pain can be treated in a variety of ways

- Non-medication (ice, heat, rest, elevation, physical therapy, massage)
- Behavioral (cognitive behavioral therapy, mindfulness)
- Non-opioid medications
    a. Acetaminophen (Tylenol®)
    b. NSAIDs –ibuprofen, ketorolac
    c. Topical analgesics (lidocaine patches)
    d. Gabapentin, pregabalin (Lyrica®)
- Opioids
    a. CDC recommends to be used as second line agents for chronic pain
    b. Use only when risks outweigh benefits
    c. Use the lowest dose possible for the shortest course possible
    d. Oral agents provide the same analgesia as IV agents

Protocol Development

Key Considerations:

1. Regulatory considerations related to the use of alternative agents such as ketamine and nitrous oxide
2. Training and credentialing considerations related to nerve blocks and trigger point injections, alternative medication administration
3. Medication access and distribution
4. Supply and equipment needs related to intranasal medication administration and nitrous oxide administration

Emergency Care Center[11,12,13,14,15,16,17,18,19,20] (Appendix B)

Consider key pain syndromes:

1. Musculoskeletal Pain: Sprains, strains, opioid-naïve lower back pain, acute neck, joint, soft tissue pain, rotator cuff tendonitis, arthritis of knee, etc.
2. Headache/Migraine
3. Renal Colic
4. Extremity Fracture or Joint Dislocation
5. Acute on chronic back pain

Anesthesia &Surgery[21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39] (Appendix C)

Standardize preoperative medications to include:

Oral acetaminophen

Gabapentin or pregabalin

Intra-procedural use of ketorolac injection and lidocaine and ketamine infusions to minimize opioid use

Standardized post-operative pain management protocols and orders
- Use of nerve blocks, scheduled acetaminophen and NSAIDS
- Topical lidocaine at incision sites
- Using opioids for breakthrough pain only
- Pre-operative teaching and setting realistic pain management expectations and goals

Primary Care Physicians
- Acute pain protocols that mimic ECC pain protocols
- Use of non-pharmacologic therapies
  - Heat, ice, massage, early PT/OT evaluation and treatment, behavioral therapy
- Screening for Opioid Use Disorder and activation of SWAT team
- Utilize CDC guidelines for treatment of chronic pain

10. Pharmacists in the Emergency Care Center

The American Society of Health Systems Pharmacists has defined roles for emergency medicine pharmacists.[40] These pharmacists are important for advancing best practices in pain management and can be involved in collection of accurate pain management histories, allergy histories, providing patient specific pain management recommendations, avoiding medication interactions, identifying patients at high risk for OUD or OD, and patient education. Pharmacists are able to assist in creation of protocols, implementation, and monitoring of protocol compliance, and staff and provider education.

11. Electronic Medical Record (EMR) Alerts/Push Notifications/Defaults/Health Information Exchange (HIE)

Leverage local IS departments to establish evidence based order sets, screening tools, and decision support.

Evaluate current protocols and order sets to optimize pain management options and default to non-opioid options for first line therapy when appropriate. Ensure non-medication options are included in protocols and order sets.

Leverage local Health Information Exchange (HIE) and Prescription Drug Monitoring Programs (PDMP) to evaluate patient histories and prior treatments.

Consider establishing clinical decision support, alerts and notifications as follows:

a. Patients with moderate or high risk substance involvement screening
   i. Consult SWAT team
   ii. Establish referrals
b. Drug-drug and disease interaction warnings for opioids and alternative agents
c. Maximum dose warnings for acetaminophen and NSAIDs
d. Warnings/alerts for long acting opioids in opiate naïve patients

e. Warnings/alerts for co-prescribed benzodiazepines and opioids
f. Warnings/alerts for co-prescribed gabapentinoids and opioids
g. Warnings/alerts for opioid orders and prescriptions for MME >50 mg/day
h. Cascading order set options for treatment of acute pain in patients who are chronic opioid users

12. Post Hospital Support & Care Transitions

Facilities should utilize their established community support catalogue to refer patients for follow up and ensure appropriate care transitions. It is imperative that follow up and care transitions occur timely to avoid relapse soon after discharge. Patients are at highest risk of overdose following a period of abstinence such as a hospitalization. Some of these strategies may include:

a. Community paramedicine programs
b. Behavioral health referrals
c. Methadone clinic or other MAT clinic
d. Mental Health Counselors in Urgent Care Centers and FEDs
e. Peer to peer counseling programs
f. Primary care physicians engaged in treatment of OUD patients
g. Timely outpatient physical and occupational therapy referrals
h. Faith based organizations as appropriate
i. Naloxone distribution centers
j. Onsite behavioral health intake on same day of hospital discharge
k. Coordination of medical or pain treatment with treating psychiatrist of record

13. Maintenance, Sustainability, and Future Recommendations

Sustainability *of the initiative requires continued engagement of all stakeholders. Providing regular feedback regarding key performance indicators and next steps in the plan is key for the success of the program. Additional broad support is also necessary for the success of these programs.*

Advocacy: Engaging legislators at the local, state and national level to maintain focus and provide funding for programs is paramount for optimal benefit of this program.

Research longitudinal studies: Funding for research regarding long term success and strategies is needed. Advocacy for support of research is needed. Local research should focus on local strategies and patient outcomes from the program

Single integration and management of program: Consider development of a Chief Pain Management or Pharmacy Officer to oversee and administer the program.

Regional and state summits and integration of regional programs: County, state, and national success is dependent on programs that are in alignment and seeking to meet similar goals and outcomes.

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Appendix A: Sample Work Plan- Opioid Stewardship

Strategy	*Responsible Party*	*Action*	*Deliverable*	*Due Date*
Establish Workgroup or Committee		➢ Physician Champions- Emergency department, Surgery, Anesthesia, Pain Management, Internal Medicine ➢ Hospital Leadership – CEO, CNO, CMO ➢ Nurse Leaders ➢ Pharmacist ➢ Quality ➢ Community Liaisons ➢ EMS ➢ Information Technology	➢ Team contact list & commitments ➢ Meeting schedule	
Create timeline for implementation			➢ Timeline with interim goals ➢ Establish subgroups to meet interim goals as needed	
Define Scope		➢ ED: Target diagnoses ➢ Target Surgical Protocols ➢ Inpatient pain syndromes ➢ Transitions of Care	➢ Charter ➢ Define key Performance Indicators for measuring/ monitoring	
Assess IS infrastructure needed		➢ Evaluate current state o Electronic order sets and pathways o Clinical decision support available and needed o ➢ Design ideal build ➢ Test and Evaluate	➢ IS workplan ➢ Gap analysis	
Establish policy and guidelines		➢ Create policy based on scope of project ➢ Create clinical pathways, guidelines, resources for implementation	➢ Policy ➢ Clinical pathways or references	
Education/Training		➢ Workshops o Primary Care	➢ Master training/ education	

		○ Inpatient providers ○ Internal Medicine and Family Residents ○ Nursing and Pharmacy Staff ○ hospitals/care networks ➢ Community education ○ Flyers ○ Workshops ○ Other media	schedule ➢ Assignments for development of training/ education ➢ Education interim timeline	
Measuring and Monitoring		➢ Define Key Performance Indicators ➢ Establish reporting structure	➢ Reporting tool (dashboard)	
Regulatory Needs Assessment		➢ Nursing practice acts ➢ Pharmacist practice acts ➢ Payer methodology (CMS, commercial) - behavioral health ➢ Controlled substance regulations ➢ Public funding and support	➢ Strategy for advocacy	
Risk Screening/ assessment and referral		➢ SBIRT ➢ Risk stratification (NIDA screening) ➢ Referral procedure	➢ Screening and referral procedure ➢ Education	

Appendix B: Opioid Alternative Protocol: Emergency Department

Indication	Treatment Options
Renal colic	Ketorolac 15mg IV Acetaminophen 1,000 mg po 0.9% Sodium chloride 1,000 mL bolus Lidocaine 200mg/100 mL infusion 1.5 mg/kg over 10 minutes (max 200 mg)
Musculoskeletal pain (sprains, strains, opiate naïve lower back pain)	Acetaminophen 1,000 mg po Ibuprofen 400mg po OR ketorolac 15 mg IV/IM Muscle relaxant (Choose one) Cyclobenzaprine 5 mg po (age >65 yo or BW <70 kg or concerns for somnolence) OR Cyclobenzaprine 10 mg po Diazepam 5 mg po Lidocaine patch –up to 3 patches to painful areas –remove after 12 hrs Gabapentin 300 mg po (age >65 yo or BW <70 kg or concerns for somnolence/naïve to med) OR gabapentin 600 mg po Bupivacaine 0.5% OR lidocaine 1% 1-2 mL trigger point injection
Acute on Chronic Radicular Lower Back Pain (Opioid tolerant)	Acetaminophen 1,000 mg po Ibuprofen 400mg po OR ketorolac 15 mg IV/IM Muscle relaxant (Choose one) Cyclobenzaprine 5 mg po (age >65 yo or BW <70 kg or concerns for somnolence) OR Cyclobenzaprine 10 mg po Diazepam 5 mg po Lidocaine patch –up to 3 patches to painful areas –remove after 12 hrs Gabapentin 300 mg po (age >65 yo or BW <70 kg or concerns for somnolence/naïve to med) OR gabapentin 600 mg po Dexamethasone 8 mg IV Bupivacaine 0.5% OR lidocaine 1% 1-2 mL trigger point injection Ketamine 500 mg/250 mL: 0.3 mg/kg bolus over 10 minutes, then 1.7 mcg/kg/min infusion
Headache/Migraine	Metoclopramide 10mg PO/IV 0.9% Sodium chloride 1,000 mL bolus Acetaminophen 1,000 mg po Ibuprofen 400mg po OR ketorolac 15 mg IV/IM Bupivacaine 0.5% OR lidocaine 1% 1-2 mL cervical or trapezius trigger point injection Lidocaine 4% Intranasal 0.5 mL If <50% pain relief to above: Magnesium 1gm IV over 60 minutes Valproic acid 500mg IV over 20 minutes Dexamethasone 4-8 mg IV If <50% pain relief to above: Haloperidol 2.5-5 mg IV
Extremity Fracture or Joint Dislocation	Ketamine intranasal (50 mg/mL) 0.5 mg/kg (maximum 50 mg) x 1 Acetaminophen 1,000 mg PO Ultrasound guided regional anesthesia peri-neural infiltration Lidocaine 0.5% (max 5 mg/kg) OR Ropivacaine 0.5% (max 3 mg/kg)

Appendix C: Pain Management Orders: Surgery

Preoperative Orders (1hr prior to surgery):

Acetaminophen 1,000 mg po
Gabapentin 300 mg po

Intraoperative Orders (at conclusion of surgery):

Ketorolac 15-30 mg x 1

Postoperative Orders:

Acetaminophen 1g PO q 8 hours
Ketorolac 15-30 mg IV q 6-8 hours OR Ibuprofen 400 mg q 8 hours
Lidocaine patch every 12 hours near incision site
PRN:
Tramadol 50 mg q 6 hours Prn for mild to moderate pain
Oxycodone 5 mg PO q 4 hours PRN for moderate to severe pain
Hydromorphone 0.5 mg IV q 2hours PRN for breakthrough pain

Colorectal Surgery:

In addition to above, consider intraoperative
Ketamine 10-35 mg IV x 1, then 4-10 mg/hr
Lidocaine 100 mg IV x 1, then 2-3 mg/min

Drug allergies, contraindications, previous treatments, and drug-drug interactions must be considered prior to treatment

Appendix D: Opioid Screening Tools and Protocols for Withdrawal Management

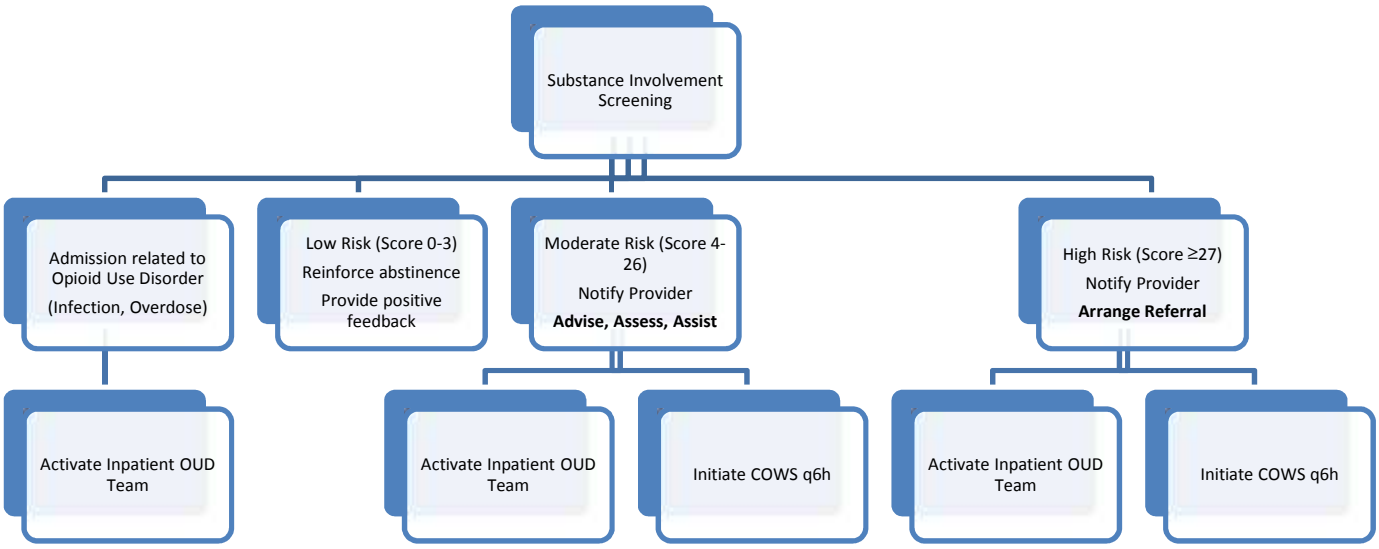
Substance Involvement Screening (National Institute on Drug Abuse) NIDA Modified Scale – To be completed on admission
https://www.drugabuse.gov/sites/default/files/files/QuickScreen_Updated_2013%281%29.pdf

Screening Question:

- ***In the past year, have you used illegal drugs or prescription drugs for non-medical reasons? (Screen in EMR)***
- ***If YES, ask the questions below about each drug***

In your ***LIFETIME*** have you ever used the following **NOT PRESCRIBED BY YOUR DOCTOR**?													
Circle responses – If A is no, move to next drug If A is yes, proceed across with questions	A: Ever used in life-time?	Past 3 months used?		Past 3 months desire to use?		Past 3 months, use has led to health, social, legal, or financial problems?		Past 3 months, failed to do what was expected due to use?		Has a friend or relative expressed concern about use?		Have you ever tried and failed to control, cut down or stop using?	
Substance		Response	Score	Response	Score	Response	Score	Response	Score	Response	Score	Response	Score
Cannabis (marijuana, pot, grass, hash)	Yes / No	No	0	No	0	No	0	No	0	No	0	No	0
		1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Cocaine (coke, crack)	Yes / No	No	0	No	0	No	0	No	0	No	0	No	0
		1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Prescription stimulants (Ritalin, Adderall, diet pills)	Yes / No	No	0	No	0	No	0	No	0	No	0	No	0
		1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Methamphetamine	Yes	No	0	No	0	No	0	No	0	No	0	No	0
		1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3

(speed, crystal, ice)	No	Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Inhalants (nitrous, glue, gas, paint thinner)	Yes	No	0	No	0	No	0	No	0	No	0	No	0
	No	1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Sedatives or sleeping pills (Valium, Xanax, Ativan, GHB, Rohypnol)	Yes	No	0	No	0	No	0	No	0	No	0	No	0
	No	1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Street opioids (heroin, opium)	Yes	No	0	No	0	No	0	No	0	No	0	No	0
	No	1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Prescription opioids (fentanyl, oxy, hydrocodone, methadone, buprenorphine)	Yes	No	0	No	0	No	0	No	0	No	0	No	0
	No	1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstacy)	Yes	No	0	No	0	No	0	No	0	No	0	No	0
	No	1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Other (Specify)	Yes	No	0	No	0	No	0	No	0	No	0	No	0
	No	1-2 x	2	1-2 x	3	1-2 x	4	1-2 x	5	1-2 x	3	1-2 x	3
		Monthly	3	Monthly	4	Monthly	5	Monthly	6	Monthly	3	Monthly	3
		Weekly	4	Weekly	5	Weekly	6	Weekly	7	Weekly	6	Weekly	6
		Daily	6	Daily	6	Daily	7	Daily	8	Daily	6	Daily	6
Total Combined Score													



Referral algorithm using National Institute on Drug Abuse substance involvement screening:

Advise about patient's drug use:	⁾ Recommend quitting ⁾ Explain consequences of drug use
Assess readiness to quit	⁾ Is the patient willing to engage in additional behavioral health therapies? o Yes- requires outpatient MAT or inpatient treatment? ***Arrange*** o Yes- does not require outpatient MAT or inpatient treatment? ***Assist*** o No – offer best advice; revisit and offer additional therapies at each encounter
Assist in making a change	⁾ Formulate a plan ⁾ Offer Community Resources o Manatee County Resources: ▪ Centerstone: Inpatient and Outpatient Treatment (941-782-4617) ▪ Operation PAR (MAT): 941-7453-0877 – walk in treatment M-F 0530-1000; Consultation fee $30, then $84 for initial treatment period. Time to treatment: 1-3 days ▪ First Step: Medically supervised detoxification; inpatient and outpatient services (941-366-5333) ▪ Peer to Peer recovery (free of charge): 941-444-7772 – referral can be made 24 hrs/day ▪ Suncoast Behavioral Health:

	▪ AA/NA Meetings: https://yourlifemattersproject.org/aa-na-meetings/ ❯ Consider necessary support for vocational training, housing, transportation, food, and legal support ❯ Schedule follow up (1-2 weeks)
Arrange specialty treatment	❯ Outpatient medication assisted treatment ❯ Inpatient treatment ❯ Referral Process

Clinical Opiate Withdrawal Scale

The Clinical Opiate Withdrawal Scale combines objective and subjective items and can be administered multiple times in a day.

For each item, write in the number that best describes the patient's signs or symptom. Rate each section on just the apparent relationship to opiate withdrawal, not a known medical diagnosis. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Resting Pulse Rate (Beats per Minute) ❯ *Measured after patient is sitting or lying for one minute*	0=pulse rate 80 or below 1=pulse rate 81-100 2=pulse rate 101-120 4=pulse rate greater than 120	Score:
Sweating ❯ *Over past ½ hour not accounted for by room temperature or patient activity*	0=no report of chills or flushing 1=subjective report of chills or flushing 2=flushed or observable moistness on face 3=beads of sweat on brow or face 4=sweat streaming off face	Score:
Restlessness ❯ *Observation during assessment*	0=able to sit still 1=reports difficulty sitting still, but is able to do so 3=frequent shifting or extraneous movements of legs/arms 5=Unable to sit still for more than a few seconds	Score:
Pupil size (Assessment)	0=pupils pinned or normal size for room light 1=pupils possibly larger than normal for room light 2=pupils moderately dilated 5=pupils so dilated that only the rim of the iris is visible	Score:

Bone or Joint aches • *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored*	0=not present 1=mild diffuse discomfort 2=patient reports severe diffuse aching of joints/ muscles 4=patient is rubbing joints or muscles and is unable to sit still because of discomfort	Score:
Runny nose or tearing • *Not accounted for by cold symptoms or allergies*	0=not present 1=nasal stuffiness or unusually moist eyes 2=nose running or tearing 4=nose constantly running or tears streaming down cheeks	Score:
GI Upset • *Only score over last ½ hour*	0=no GI symptoms 1=stomach cramps 2=nausea or loose stool 3=vomiting or diarrhea x1 5=2 or more episodes of diarrhea or vomiting	Score:
Tremor • *Observation of outstretched hands*	0=No tremor 1=tremor can be felt, but not observed 2=slight tremor observable 4=gross tremor or muscle twitching	Score:
Yawning • *Observation during assessment*	0=no yawning 1=yawning once or twice during assessment 2=yawning three or more times during assessment 4=yawning several times/minute	Score:
Anxiety or Irritability	0=none 1=patient reports increasing irritability or anxiousness 2=patient obviously irritable anxious 4=patient so irritable or anxious that participation in the assessment is difficult	Score:
Gooseflesh skin	0=skin is smooth 3=piloerection of skin can be felt or hairs standing up on arms 5=prominent piloerrection	Score:
Total score (sum of all 11 items):		

Scoring Scale:

- 5-12 = mild

- 13-24 = moderate
- 25-36 = moderately severe
- more than 36 = severe withdrawal

Management of mild opioid withdrawal[41]

- Drink 2-3 liters of water per day during withdrawal to replace fluids lost through perspiration and diarrhea.
- Provide vitamin B and vitamin C supplements.
- Symptomatic treatment and supportive care are usually sufficient for management of mild opioid withdrawal.

Symptomatic medications in withdrawal management

Symptom	Medication	Dose	Route	Frequency	Contraindications
Insomnia	Zolpidem	5 mg	By mouth	As needed, before bed	
Nausea and Vomiting	Ondansetron	4-8mg	By mouth	Every 6 hours as needed	QT prolongation
Diarrhea	Loperamide	4mg initially, then 2mg	By mouth	4mg initially then 2mg after each unformed stool up to a maximum of 16mg per day	
Headache	Acetaminophen	650-1,000 mg	By mouth	4 times per day as needed	
	Ibuprofen	400mg	By mouth	3 times per day as needed	Gastric ulcer Gastritis
Agitation, anxiety and restlessness	Lorazepam	0.5 mg	By mouth	2-3 times per day, reducing over 3-5 days	Benzodiazepine withdrawal
Abdominal cramping	Dicyclomine	10 mg	By mouth	Every 6 hours as needed	Caution with renal or hepatic impairment

Management of moderate to moderately severe opioid withdrawal:

- Continue symptomatic management for mild withdrawal
- Consider addition of clonidine, lofexidine, or opioid medications such as buprenorphine or methadone.
  - Buprenorphine and methadone treatment require additional licensing
  - Clonidine or lofexidine may assist with lessening symptoms if abrupt discontinuation of opioid therapy is required

Management of Opioid withdrawal using clonidine:

Clonidine is an alpha-2 adrenergic agonist. It can provide relief to many of the physical symptoms of opioid withdrawal including sweating, diarrhea, vomiting, abdominal cramps, chills, anxiety, insomnia, and tremor. It can also cause drowsiness, dizziness and low blood pressure. It is recommended as adjunct therapy for patients with a clinical opioid withdrawal score of ≤24. Patients with higher scores will likely require opioids to assist with withdrawal.

1. At anytime during clonidine treatment, blood pressure falls below 90/60 or HR 60 bpm, treatment may be interrupted and/or dose reduction required
2. Obtain baseline blood pressure (sitting and standing) and heart rate before administering clonidine. Do not begin clonidine treatment if blood pressure < 90/60mmHg or HR <60 bpm
3. Day 1: Administer test dose of clonidine 0.1 mg (0.2 mg for patients >90 kg)
   a. Recheck blood pressure & HR 45 minutes after test dose
   b. If blood pressure and HR within parameters, may continue treatment
   c. If clinical opioid withdrawal score remains >8 after test dose, may administer clonidine 0.1 mg every 45 minutes up to 4 doses
   d. Clonidine every 6 hours based on symptoms

Clinical Opioid Withdrawal Score	Clonidine dose
8-12	0.1 mg (0.2 mg if >90 kg)
>12	0.2 mg (0.3 mg if >90 kg)
>24	Consider additional therapy
Maximum total dose (Day 1)	0.8 mg (1.2 mg if >90 kg)

4. Day 2: Add total clonidine administered day 1 and divide evenly between four doses on day 2
5. Day 4-5: Consider beginning clonidine taper as withdrawal symptoms improve – clonidine cannot be immediately discontinued due to risk of rebound hypertension
   a. Reduce dose by 0.1-0.2 mg/day

Follow-up care after Withdrawal Management:

Acute opioid withdrawal is followed by a protracted withdrawal phase that lasts for up to six months and is characterized by a general feeling of reduced well-being and strong cravings for opioids. This craving often leads to relapse to opioid use. To reduce the risk of relapse, patients should be engaged in psychosocial interventions such as described later in these guidelines. Patients who repeatedly relapse following withdrawal management are likely to benefit from mediation assisted treatment (MAT).

All opioid dependent patients who have withdrawn from opioids should be advised that they are at **increased risk of overdose** due to reduced opioid tolerance. Should they use opioids, they should take preventative precautions which include using a smaller amount than usual to reduce the risk of overdose, not use in isolation in the event of unintended overdose, or have access to overdose-reversal medication such as naloxone.

Polysubstance Withdrawal Management:

Assessment for polysubstance withdrawal should be completed based on risk from NIDA screening. Many symptoms overlap with those of opioid withdrawal. Supportive care should be given for patients experiencing cannabis withdrawal and stimulant withdrawal. **Benzodiazepine withdrawal requires medical management.**

Benzodiazepine Withdrawal Management:

Benzodiazepine withdrawal may result in anxiety, tremor, insomnia, nausea, vomiting, hallucinations, seizure, and delirium. Gradual tapering over a period of months is required to avoid adverse events. Converting patients to longer acting benzodiazepines may improve withdrawal symptoms.

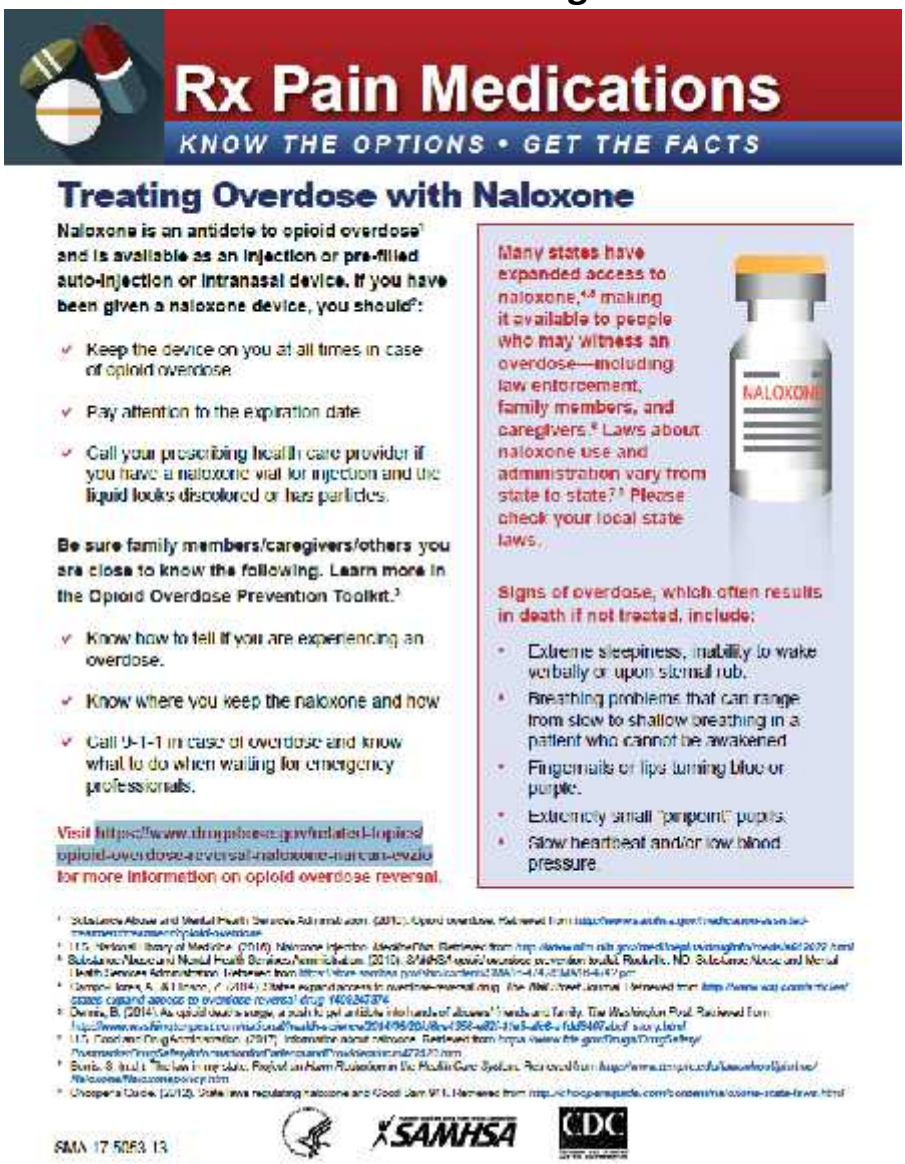
Benzodiazepine equivalencies:

Drug	Half life	Onset of Action	Route of Administration	Equivalent Dosages (Lorazepam Equivalence)
lorazepam (Ativan)	12-14 hrs	2-3 minutes	Oral, IM, IV	1 mg
chlordiazepoxide (Librium)	24-48 hrs	30 -60 min (time to peak)	Oral	25 mg
oxazepam (Serax)	~8.2 hrs	180 min (time to peak)	Oral	30 mg
diazepam (Valium)	~30-40 hrs	4-5 minutes	Oral, IV, IM	5 mg

Appendix E: Provider Education Presentations

Available upon request to authors identified.

Appendix F: Patient Education on Discharge



Rx Pain Medications

KNOW THE OPTIONS • GET THE FACTS

Treating Overdose with Naloxone

Naloxone is an antidote to opioid overdose[1] and is available as an injection or pre-filled auto-injection or intranasal device. If you have been given a naloxone device, you should[2]:

- Keep the device on you at all times in case of opioid overdose
- Pay attention to the expiration date
- Call your prescribing health care provider if you have a naloxone vial for injection and the liquid looks discolored or has particles.

Be sure family members/caregivers/others you are close to know the following. Learn more in the Opioid Overdose Prevention Toolkit.[3]

- Know how to tell if you are experiencing an overdose.
- Know where you keep the naloxone and how
- Call 9-1-1 in case of overdose and know what to do when waiting for emergency professionals.

Visit https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio for more information on opioid overdose reversal.

Many states have expanded access to naloxone,[4-6] making it available to people who may witness an overdose—including law enforcement, family members, and caregivers.[6] Laws about naloxone use and administration vary from state to state.[7] Please check your local state laws.

Signs of overdose, which often results in death if not treated, include:

- Extreme sleepiness, inability to wake verbally or upon sternal rub.
- Breathing problems that can range from slow to shallow breathing in a patient who cannot be awakened
- Fingernails or lips turning blue or purple.
- Extremely small "pinpoint" pupils
- Slow heartbeat and/or low blood pressure

1. Substance Abuse and Mental Health Services Administration. (2015). Opioid overdose. Retrieved from http://www.samhsa.gov/medication-assisted-treatment/treatment/opioid-overdose
2. U.S. National Library of Medicine. (2016). Naloxone injection. MedlinePlus. Retrieved from http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601070.html
3. Substance Abuse and Mental Health Services Administration. (2015). SAMHSA opioid overdose prevention toolkit. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from http://store.samhsa.gov/shin/content/SMA15-4742/SMA15-4742.pdf
4. Campo-Flores, A., & Lopez, J. (2014). States expand access to overdose-reversal drug. The Wall Street Journal. Retrieved from http://www.wsj.com/articles/states-expand-access-to-overdose-reversal-drug-1409347374
5. Dennis, B. (2014). As opioid deaths surge, a push to get antidote into hands of abusers' friends and family. The Washington Post. Retrieved from http://www.washingtonpost.com/national/health-science/2014/09/20/8ce4356-a827-11e4-a5b8-4f1b9497a3cf_story.html
6. U.S. Food and Drug Administration. (2017). Information about naloxone. Retrieved from http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm472637.htm
7. Burris, S. (n.d.). The law in my state. Project on Harm Reduction in the Health Care System. Retrieved from http://www.temple.edu/lawschool/phrhcs/Naloxone/Naloxonepolicy.htm
8. Chicago's Choice. (2012). State laws regulating naloxone and Good Sam 911. Retrieved from http://chicagosquads.com/t/concerns/naloxone-state-laws.html

SMA 17 5053 13

SAMHSA CDC

List of local organizations that carry naloxone kits to be distributed to every patient and family member that presents with an overdose:

- Centerstone Access Center (free, no R_x needed): 2020 26th Ave East, Bradenton, Florida
- CVS Pharmacies without a prescription:
  - 6204 14th Street West, Bayshore Gardens Parkway, Bradenton, FL 34207
  - 6150 14th Street West, Bradenton, FL 34207 (inside Target)
  - 7195 State Road 70, Bradenton, FL 34203
  - 4302 Cortez Road West, Bradenton, FL 34210
  - 5310 48th Street East, Bradenton, FL 34203
  - 3813 Manatee Avenue West, Bradenton, FL 34205
  - 1520 Lakewood Ranch Boulevard, Bradenton, FL 34210

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: Senate Health Policy Committee **Judge:**

Started: 3/11/2019 1:32:24 PM
Ends: 3/11/2019 3:29:11 PM Length: 01:56:48

1:32:23 PM Meeting called to order
1:32:30 PM Chair Harrell
1:32:38 PM Roll call - Quorum present
1:32:52 PM Comments from Chair
1:33:27 PM Tab 2 - SB 732 by Senator Flores - Office Surgery
1:33:58 PM Strike all amendment 859422
1:34:06 PM Senator Flores to explain the bill and the amendment
1:38:10 PM Questions on the strike all
1:38:15 PM Senator Rouson
1:38:31 PM Senator Flores
1:39:06 PM Senator Cruz
1:39:23 PM Senator Flores
1:42:19 PM Senator Bean
1:42:26 PM Senator Flores
1:43:41 PM Senator Hooper
1:45:19 PM Senator Flores
1:45:38 PM Chair
1:46:07 PM Senator Hooper
1:46:12 PM Chair
1:46:58 PM Senator Mayfield
1:47:08 PM Senator Flores
1:47:38 PM Senator Mayfield
1:48:15 PM Senator Flores
1:48:34 PM Chair
1:48:42 PM Appearance Cards?
1:49:18 PM Chris Nuland, Florida Society of Plastic Surgeons, speaking for the amendment
1:51:17 PM Chris Lyon, Florida Association of Nurse Anesthetist, speaking against amendment
1:54:40 PM Senator Mayfield
1:55:54 PM Chair
1:56:12 PM Chris Lyon
1:56:20 PM Senator Rouson
1:56:34 PM Chris Lyon
1:56:45 PM Senator Rouson
1:56:49 PM Chris Lyon
1:57:39 PM Senator Harrell
1:58:04 PM Senator Berman
1:58:44 PM Chris Lyon
1:58:53 PM Chair
1:59:16 PM Nancy Thomas, Assistant General Counsel, Florida Medical Association, waives in support
1:59:19 PM Stephen Winn, Executive Director, Florida Osteopathic Medical Association, waives in support
1:59:30 PM Debate?
1:59:32 PM Senator Bean
2:00:00 PM Chair
2:00:03 PM Senator Flores waives close on Strike All
2:00:26 PM Amendment 859422 is adopted
2:00:32 PM Back on bill as amended
2:00:47 PM Stephen Winn, Florida Osteopathic Medical Association, waives in support
2:00:51 PM Chris Nuland, Florida Society of Plastic Surgeons, waives in support
2:00:59 PM Brence Sell, M.D., Florida Society of Anesthesiologist, waives in support
2:01:13 PM Michael Salzman, Plastic Surgeon, speaking for the bill
2:05:26 PM Questions?
2:06:01 PM Senator Bean

2:06:15 PM Michael Salzman
2:07:02 PM Chair
2:07:17 PM Debate: on bill as amended?
2:07:26 PM Senator Cruz
2:08:02 PM Senator Rouson
2:10:06 PM Senator Mayfield
2:11:12 PM Chair
2:11:28 PM Senator Flores to close
2:15:31 PM Chair
2:15:33 PM Roll Call - SB 732 - Favorable
2:15:45 PM Favorable
2:16:05 PM Senator Berman in the Chair
2:16:17 PM Chair
2:16:18 PM Tab 5 - Presentation - Alternative to Opioids Tool Kit, presented by Manatee Memorial Hospital
2:17:07 PM Kevin DiLallo, CEO of Manatee Memorial Hospital
2:24:50 PM Dr. Candace Smith, PhD, RN: Chief Nursing Officer of Manatee Memorial Hospital
2:31:39 PM Chair Berman
2:31:44 PM Questions?
2:31:47 PM Senator Book
2:32:07 PM Dr. Smith
2:32:28 PM Senator Rouson
2:33:03 PM Dr. Smith
2:36:13 PM Chair Berman
2:36:19 PM Dr. Smith
2:37:29 PM Kevin DiLallo
2:38:01 PM Senator Cruz
2:39:19 PM Kevin
2:39:26 PM Chair Berman
2:40:18 PM Senator Rouson
2:41:07 PM Chair Berman
2:41:08 PM Tab 3 - SB 1124 by Senator Harrell -Dispensing Medicinal Drugs
2:42:34 PM Questions?
2:42:37 PM Senator Rouson
2:42:47 PM Senator Harrell
2:43:33 PM Senator Book
2:43:46 PM Senator Harrell
2:44:25 PM Appearance Card
2:44:35 PM Dorene Barker, Association State Director, AARP FL, waives in support
2:44:40 PM Debate?
2:44:45 PM Senator Harrell to close
2:44:57 PM Roll Call - SB 1124 - Favorable
2:45:16 PM Tab 4 - SB 1126 by Senator Harrell - Pediatric Cardiac Technical Advisory Panel
2:47:43 PM Chair Berman
2:48:43 PM Questions?
2:48:50 PM Senator Rouson
2:49:13 PM Senator Harrell
2:49:51 PM Senator Rouson
2:49:54 PM Senator Harrell
2:51:55 PM Chair Berman
2:52:01 PM Appearance Cards?
2:52:07 PM Dr. William B. Blanchard, M.D., Pediatric Cardiologist, Pediatric Cardiac technical Advisory Panel- former At-Large Member, speaking for information, waives in support
2:54:27 PM Chair Berman
2:54:41 PM Marnie George, Sr. Advisory Buchanan Ingersoll and Rooney, Fla. Chapter AM College of Cardiology, waives in support
2:54:48 PM Debate?
2:54:51 PM Senator Hooper
2:55:42 PM Senator Rouson
2:56:55 PM Debate? None
2:57:55 PM Senator Harrell to close
2:58:22 PM Roll Call - SB 1126 - Favorable
2:59:07 PM Senator Harrell back in Chair

2:59:22 PM Chair - informal recess
2:59:55 PM Recording Paused
3:15:08 PM Recording Resumed
3:15:26 PM Tab 1 - SB 1088 by Senator Albritton - Nursing Home Facility Staffing
3:16:26 PM Senator Hooper for a motion
3:16:33 PM Motion for time certain on SB 1088 to be set for a vote at 3:28 pm
3:16:43 PM Chair, any objections to the motion? None. Motion is adopted
3:18:39 PM Questions?
3:18:41 PM Senator Rouson
3:19:03 PM Senator Albritton
3:19:22 PM Senator Rouson
3:19:28 PM Senator Albritton
3:20:32 PM Chair
3:21:13 PM Amendment 614608 by Senator Albritton
3:22:07 PM Chair
3:22:41 PM Questions? None
3:22:45 PM Objection to amendment? None
3:22:53 PM Appearance Cards. None
3:23:01 PM Amendment is adopted
3:23:06 PM Back in bill as amended
3:23:23 PM Michael Milliken, State Ombudsman, State Long Term Care Ombudsman Program, waives in opposition
3:23:37 PM Tracy Greene, VP of Operations, Southern Health Care Management, waives in support
3:23:46 PM Peggy R. Norris, SCC - Signature Care Consultant, Signature Healthcare, waives in support
3:24:01 PM Mauri Mizrah, waives in support
3:24:13 PM Senator Bean
3:24:29 PM Marty Geotz, CEO, River Garden Hebrew Home, speaking against the bill
3:26:00 PM Chair
3:26:02 PM Steve Waltrel, Attorney, Victims of Nursing Home Abuse and Neglect, waive in opposition
3:26:22 PM Lisa, Lyons, Executive Director, Westminster Communities of Florida, Leadinginage Florida, waives in opposition
3:26:29 PM Tyna C. Jackson, Partner, PinPoint Results, SEJU-1199, waives in strong opposition
3:26:41 PM Connie Cheap, Leading Age Florida, waives in opposition
3:26:49 PM Bruce Jones, CEO, waives in opposition
3:26:58 PM Kip Corriveau, Director of Missions, Bon Serouis, St. Petersburg Health System, waives in opposition
3:27:07 PM Steve Bohmer, CEO/President, LeadingAgeFlorida, waives in opposition
3:27:14 PM Jack McRay, AARP, waives in opposition
3:27:38 PM Senator Berman
3:27:56 PM Senator Albritton to close
3:28:21 PM Roll call - SB 1088 - favorable
3:28:40 PM Does any Senator wish to be recorded as voting on bills before the committee today?
3:28:46 PM Senator Bean voting affirmative on SB 1124 and 1126
3:28:59 PM Is there other business before the committee? Seeing None
3:29:06 PM Senator Hooper moves to adjourn. Is there objection? Seeing none, show the motion adopted. We are adjourned.