The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Harrell, Chair
Senator Berman, Vice Chair

MEETING DATE: Monday, February 4, 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 182** Brandes (Compare S 372)	Smoking Marijuana for Medical Use; Redefining the term "medical use" to include the possession, use, or administration of marijuana in a form for smoking; deleting a provision prohibiting a medical marijuana treatment center from dispensing or selling specified products, etc. HP 02/04/2019 Fav/CS IT RC	Fav/CS Yeas 6 Nays 4
2	**SB 104** Book (Identical H 59)	Prescription Drug Donation Repository Program; Creating the "Prescription Drug Donation Repository Program Act"; creating the program within the Department of Health; authorizing the department to contract with a third-party vendor to administer the program; providing inspection, inventory, and storage requirements for centralized and local repositories; authorizing the department to establish a direct-support organization to provide assistance, funding, and promotional support for program activities; authorizing the Governor to waive program patient eligibility requirements during a declared state of emergency, etc. HP 02/04/2019 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
3	Post-Hurricane Michael Nursing Home Update: Bob Asztalos, Florida Health Care Association		Not Considered

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 182
INTRODUCER:	Health Policy Committee and Senator Brandes
SUBJECT:	Smoking Marijuana for Medical Use
DATE:	February 5, 2019
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 182 amends s. 381.986, F.S., to eliminate the prohibition against the smoking of marijuana from the definition of the "medical use" of marijuana. The bill also revises current-law prohibitions against the medical use of marijuana in certain locations to specify that the smoking of low-THC cannabis remains prohibited in public; on any form of public transportation; or in various other vehicles, regardless of current-law exceptions allowing the medical use of low-THC cannabis in those places.

For a patient not diagnosed with a terminal condition,[1] the bill requires that, prior to issuing a certification in which the qualified physician intends to certify smoking, the physician must determine that smoking is the only means of administering medical marijuana that is likely to benefit the qualified patient, and a second physician must concur with this determination. The second physician may not be registered with the Department of Health (DOH) as a certifying physician for any qualified patients. Additionally, the bill adds that the risks specifically associated with smoking marijuana be included in the required informed consent that each patient must sign prior to being certified to receive medical marijuana.

The bill's provisions take effect upon becoming law.

[1] Section 381.986(1)(o), F.S., defines "terminal condition" as a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

II. Present Situation:

Smoking Ban: Timeline of Events

On November 4, 2016, Amendment 2 was voted into law and established article X, section 29 of the State Constitution. This section of the constitution became effective on January 3, 2017, and created several exemptions from criminal and civil liability for:

- Qualifying patients medically using marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- Medical marijuana treatment centers (MMTCs), their agents, and employees for actions or conduct under the amendment and in compliance with rules promulgated by the DOH.

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.[2] The bill rewrote and expanded upon the Compassionate Medical Cannabis Act of 2014[3] and was designed to implement article X, section 29 of the State Constitution.

Included in the many provisions of SB 8-A, the bill defined the term "medical use" to exclude the "possession, use, or administration of marijuana in a form for smoking…or of marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping." This provision, which became colloquially known as the smoking ban, was challenged in the Circuit Court for the Second Judicial Circuit on July 6, 2017.

In its complaint, People United for Medical Marijuana, Inc., challenged the smoking ban on two counts:[4]

- That the smoking ban impermissibly altered the definition of "marijuana" established in article X, section 29(b)(4), of the State Constitution, by excluding the right to possess forms of marijuana for smoking; and
- That article X, section 29, of the State Constitution, implicitly authorized smoking marijuana in a private place by allowing the prohibition of smoking in public.

On May 25, 2018, Judge Karen Gievers issued an order agreeing with the plaintiffs on both counts and declaring the smoking ban unconstitutional. In her order, Judge Gievers found that "qualifying patients have the right to use the form of medical marijuana for treatment of their debilitating medical conditions as recommended by their certified physicians, including the use of smokable marijuana in private places."[5]

The DOH appealed the ruling to the First District Court of Appeal on May 29, 2018. The appeal is ongoing. However, on January 17, 2019, newly-elected Governor Ron DeSantis held a press conference in which he announced his intention to withdraw the appeal should the Legislature

[2] Chapter 2017-232, Laws of Fla.
[3] Chapter 2014-157, Laws of Fla.
[4] Complaint, case no. 2017-CA-1394, Florida Circuit Court for the Second Judicial Circuit, July 7, 2017.
[5] Order and Final Judgement, case no. 2017-CA-1394, Florida Circuit Court for the Second Judicial Circuit, May 5, 2018, p. 21.

not act to remove the smoking ban from Florida Statutes by mid-March 2019.[6] Additionally, both parties filed a motion to stay the appeal until March 15, 2019, that was granted on January 24, 2019.[7]

Effectiveness and Risks of Smoking Medical Marijuana

Although much of the scientific research is inconclusive, studies have shown that there are both benefits and risks to the smoking of marijuana as a means of delivery.

Some studies have shown that the administration of marijuana by inhalation, either by smoking or by vaping, increases the rate and consistency of the uptake of the active ingredients in marijuana, specifically THC.[8] In one randomized controlled trial, THC was detected in plasma immediately after the first inhalation of marijuana smoke, attesting to the efficient absorption of THC from the lungs.[9] This is likely because "THC is highly lipophilic, distributing rapidly to highly perfused tissues and later to fat."[10] The study also found that "a trial of 11 healthy subjects administered Δ^9-THC intravenously, by smoking, and by mouth demonstrated that plasma profiles of THC after smoking and intravenous injection were similar, whereas plasma levels after oral doses were low and irregular, indicating slow and erratic absorption."[11] Additionally, there is evidence that the use of a cannabis preparation, such as would be delivered to the body by smoking cannabis, with multiple cannabinoids and terpenes, versus a single molecule preparation (with pure THC or CBD[12]) may be more effective in treating seizure disorders[13] and potentially breast cancer.[14]

Although potentially more efficacious than other methods of delivery, smoking as a method of delivery for marijuana does not allow for accurate or consistent dosing measures.[15] Also, as with any smoked substance, smoking marijuana has inherent risks that have been identified. The National Institutes of Health (NIH) states that:

> Marijuana smoking is associated with large airway inflammation, increased airway resistance, and lung hyperinflation, and those who smoke marijuana

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[6] Governor's Announcement on Medical Marijuana (Jan. 17, 2019), *available at* https://thefloridachannel.org/videos/1-17-19-governors-announcement-on-medical-marijuana/ (last visited on Jan. 29, 2019).
[7] Motion to Stay, case no. 1D18-2206, Florida First District Court of Appeal, Jan. 24, 2019.
[8] THC, or tetrahydrocannabinol, is the main active ingredient in cannabis and is responsible for most of the psychological effects of cannabis.
[9] Bridgeman MB, Abazia DT. Medicinal Cannabis: History, Pharmacology, and Implications for the Acute Care Setting. P T. 2017;42(3):180-188.
[10] Id.
[11] Id.
[12] CBD, or cannabidiol, is another cannabinoid that is found in cannabis. In the form of the drug Epidiolex CBD has been approved by the Federal Food and Drug Administration to treat two childhood seizure disorders, Dravet syndrome and Lennox-Gastaut syndrome. (see https://www.epidiolex.com/seizure-reduction-and-risk-information, last visited on Jan. 31, 2019). CBD does not have the same psychoactivity as THC.
[13] Russo EB. The Case for the Entourage Effect and Conventional Breeding of Clinical Cannabis: No "Strain," No Gain. Front Plant Sci. 2019;9:1969. Published 2019 Jan 9. doi:10.3389/fpls.2018.01969.
[14] Blasco-Benito, et al., Appraising the "entourage effect": Antitumor action of a pure cannabinoid versus a botanical drug preparation in preclinical models of breast cancer. Biochemical Pharmacology, Volume 157, November 2018, Pages 285-293
[15] See Appellant's Initial Brief, case no. 2017-CA-1394, Florida Circuit Court for the Second Judicial Circuit, Aug. 3, 2017, p. 5.

> regularly report more symptoms of chronic bronchitis than those who do not smoke. One study found that people who frequently smoke marijuana had more outpatient medical visits for respiratory problems than those who do not smoke. Some case studies have suggested that, because of THC's immune-suppressing effects, smoking marijuana might increase susceptibility to lung infections, such as pneumonia, in people with immune deficiencies; however, a large AIDS cohort study did not confirm such an association. Smoking marijuana may also reduce the respiratory system's immune response, increasing the likelihood of the person acquiring respiratory infections, including pneumonia. Animal and human studies have not found that marijuana increases risk for emphysema.[16]

Additionally, the NIH indicates that smoking cannabis, much like smoking tobacco, can introduce levels of volatile chemicals and tar into the lungs that may raise concerns about risk for cancer and lung disease. However, the association between smoking cannabis and the development of lung cancer is not decisive.[17]

One other risk that may be associated with smoking cannabis is the unintentional introduction of cannabis and other harmful chemicals to other people present by second-hand smoke. The NIH states that:

> The known health risks of secondhand exposure to cigarette smoke—to the heart or lungs, for instance—raise questions about whether secondhand exposure to marijuana smoke poses similar health risks. At this point, very little research on this question has been conducted. A 2016 study in rats found that secondhand exposure to marijuana smoke affected a measure of blood vessel function as much as secondhand tobacco smoke, and the effects lasted longer. One minute of exposure to secondhand marijuana smoke impaired flow-mediated dilation (the extent to which arteries enlarge in response to increased blood flow) of the femoral artery that lasted for at least 90 minutes; impairment from 1 minute of secondhand tobacco exposure was recovered within 30 minutes. The effects of marijuana smoke were independent of THC concentration; i.e., when THC was removed, the impairment was still present. This research has not yet been conducted with human subjects, but the toxins and tar levels known to be present in marijuana smoke raise concerns about exposure among vulnerable populations, such as children and people with asthma.[18]

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[16] National Institutes of Health, Marijuana, What are Marijuana's Effects on Lung Health? (June 2018), *available at* https://www.drugabuse.gov/publications/research-reports/marijuana/what-are-marijuanas-effects-lung-health, (last visited on Jan. 29, 2019).

[17] Ayan J., Rasche K. (2016) Damaging Effects of Cannabis Use on the Lungs. In: Pokorski M. (eds) Advancements in Clinical Research. Advances in Experimental Medicine and Biology, vol 952. Springer, Cham.

[18] National Institutes of Health, Marijuana, What are Marijuana's Effects of Secondhand Exposure to Marijuana Smoke?, (June 2018), *available at* https://www.drugabuse.gov/publications/research-reports/marijuana/what-are-effects-secondhand-exposure-to-marijuana-smoke, (last visited on Jan 29, 2019).

Smoking Medical Marijuana in Other States

As with most aspects of the implementation of medical marijuana laws, the treatment of smoking medical marijuana varies from state to state. Several states, including New York, Ohio, Minnesota, and Pennsylvania, prohibit patients from smoking marijuana but allow vaporization. Other states allow smoking but include time, place, and manner prohibitions. For example:

- Connecticut prohibits minor patients from smoking, inhaling, or vaporizing medical marijuana;
- Arkansas, New Hampshire, Maryland, and Illinois specifically allow landlords to prohibit the smoking of medical marijuana on their premises;
- New Hampshire also prohibits the smoking and vaporizing of medical marijuana in a public place;
- Massachusetts and Washington state specify that nothing requires the accommodation of smoking marijuana in any public place; and
- Hawaii allows condominiums to prohibit smoking medical marijuana if they also prohibit smoking tobacco.[19]

III. Effect of Proposed Changes:

CS/SB 182 amends s. 381.986, F.S., to:

- Strike from the definition of "medical use" the prohibition against the possession, use, or administration of marijuana in a form for smoking and of marijuana flower.
- Specify that low-THC cannabis may not be smoked in the following locations:
  - In public;
  - On any form of public transportation; or
  - In a school bus, a vehicle, an aircraft, or a motorboat.
- Require that, for a patient not diagnosed with a terminal condition, prior to issuing a certification in which the qualified physician intends to certify smoking:
  - The physician must determine that smoking is the only means of administering medical marijuana that is likely to benefit the qualified patient;
  - A second physician, who is not registered with the DOH as a certifying physician for any qualified patients, must concur with this determination; and
  - Both determinations must be documented in the patient's medical record.
- Require that the risks specifically associated with smoking marijuana must be included in the informed consent that each patient must sign prior to being certified to receive medical marijuana.
- Remove the provision in current law that prohibits a medical marijuana treatment center from dispensing the following smoking-related items: pipes, bongs, and wrapping papers.

The bill's provisions take effect upon becoming law.

[19] State-by-State Medical Marijuana Laws Report, Marijuana Policy Project, *available at* https://www.mpp.org/issues/medical-marijuana/state-by-state-medical-marijuana-laws/state-by-state-medical-marijuana-laws-report/ (last visited on Jan. 30, 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 381.986 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on February 4, 2019:
The CS requires that, for a patient not diagnosed with a terminal condition, prior to issuing a certification in which the qualified physician intends to certify smoking, the certifying physician must determine that smoking is the only means of administering medical marijuana that is likely to benefit the qualified patient, and a second physician must concur with this determination. The second physician may not be registered with the DOH as a certifying physician for any qualified patients. Additionally, the bill adds that the risks specifically associated with smoking marijuana be included in the required informed consent that each patient must sign prior to being certified to receive medical marijuana.

B. Amendments:

None.

841422

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/05/2019	.	
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The Committee on Health Policy (Harrell) recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 50 and 51
insert:

(4) PHYSICIAN CERTIFICATION.—

(a) A qualified physician may issue a physician certification only if the qualified physician:

1. Conducted a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.

841422

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is

841422

made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

841422

f. The potential side effects of marijuana use.

g. The risks, benefits, and drug interactions of marijuana.

h. The risks specifically associated with smoking marijuana.

i.~~h.~~ That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

For a patient not diagnosed with a terminal condition, if the certifying physician intends to certify the patient's medical use of marijuana by way of smoking, the certifying physician must determine that smoking is the only means of administering medical marijuana that is likely to benefit the patient and a second physician must concur with that determination. The second physician must not be registered with the department as a certifying physician for any qualified patients. Such determination and concurrence must be documented in the patient's medical record.

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

And the directory clause is amended as follows:

Delete lines 13 - 14

and insert:

Section 1. Paragraph (j) of subsection (1), paragraph (a) of subsection (4), and paragraph (e) of subsection (8) of section 381.986, Florida Statutes, are

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

And the title is amended as follows:

841422

Between lines 6 and 7
insert:
requiring a patient's informed consent form to include the risks specifically associated with smoking marijuana; requiring a certifying physician to make a determination in concurrence with a second physician who meets specified requirements before certifying a patient not diagnosed with a terminal condition to smoke marijuana for medical use;

456218

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/05/2019	.	
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The Committee on Health Policy (Harrell) recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 50 and 51
insert:

(4) PHYSICIAN CERTIFICATION.—

(a) A qualified physician may issue a physician certification only if the qualified physician:

1. Conducted a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.

456218

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is

made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use.

g. The risks, benefits, and drug interactions of marijuana.

h. The risks specifically associated with smoking marijuana.

i.~~h.~~ That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

For a patient not diagnosed with a terminal condition, if the patient is younger than 18 years of age and the certifying physician intends to certify the patient's medical use of marijuana by way of smoking, the certifying physician must determine that smoking is the only means of administering medical marijuana that is likely to benefit the patient and a second physician must concur with that determination. The second physician must not be registered with the department as a certifying physician for any qualified patients. Such determination and concurrence must be documented in the patient's medical record.

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

And the directory clause is amended as follows:

Delete lines 13 - 14

and insert:

Section 1. Paragraph (j) of subsection (1), paragraph (a) of subsection (4), and paragraph (e) of subsection (8) of section 381.986, Florida Statutes, are

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

456218

And the title is amended as follows:

Between lines 6 and 7

insert:

requiring a patient's informed consent form to include the risks specifically associated with smoking marijuana; requiring a certifying physician to make a determination in concurrence with a second physician who meets specified requirements before certifying a patient younger than 18 years of age who is not diagnosed with a terminal condition to smoke marijuana for medical use;

815914

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/05/2019	.	
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 50 and 51
insert:

(4) PHYSICIAN CERTIFICATION.—

(a) A qualified physician may issue a physician certification only if the qualified physician:

1. Conducted a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.

2. Diagnosed the patient with at least one qualifying

medical condition.

3. Determined that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is made to the original physician certification to reflect such

change.

c. Deactivates the registration of the qualified patient and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use.

g. The risks, benefits, and drug interactions of marijuana.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

A qualified physician may not issue a physician certification for a patient younger than 18 years of age to receive marijuana in a form for smoking.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete lines 13 - 14

and insert:

Section 1. Paragraph (j) of subsection (1), paragraph (a) of subsection (4), and paragraph (e) of subsection (8) of section 381.986, Florida Statutes, are

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Between lines 6 and 7

insert:

prohibiting a qualified physician from issuing a physician certification for a patient younger than 18 years of age to receive marijuana in a form for smoking;

By Senator Brandes

24-01175C-19 2019182__

A bill to be entitled

An act relating to smoking marijuana for medical use; amending s. 381.986, F.S.; redefining the term "medical use" to include the possession, use, or administration of marijuana in a form for smoking; conforming a provision to changes made by the act; deleting a provision prohibiting a medical marijuana treatment center from dispensing or selling specified products; providing an effective date.

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

Section 1. Paragraph (j) of subsection (1) and paragraph (e) of subsection (8) of section 381.986, Florida Statutes, are amended to read:

381.986 Medical use of marijuana.—

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

(j) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does not include:

1. Possession, use, or administration of marijuana that was not purchased or acquired from a medical marijuana treatment center.

2. Possession, use, or administration of marijuana in ~~a form for smoking, in~~ the form of commercially produced food items other than edibles~~,~~ or of marijuana seeds ~~or flower, except for flower in a sealed, tamper-proof receptacle for vaping~~.

3. Use or administration of any form or amount of marijuana

in a manner that is inconsistent with the qualified physician's directions or physician certification.

4. Transfer of marijuana to a person other than the qualified patient for whom it was authorized or the qualified patient's caregiver on behalf of the qualified patient.

5. Use or administration of marijuana in the following locations:

a. On any form of public transportation, except for low-THC cannabis.

b. In any public place, except for low-THC cannabis.

c. In a qualified patient's place of employment, except when permitted by his or her employer.

d. In a state correctional institution, as defined in s. 944.02, or a correctional institution, as defined in s. 944.241.

e. On the grounds of a preschool, primary school, or secondary school, except as provided in s. 1006.062.

f. In a school bus, a vehicle, an aircraft, or a motorboat, except for low-THC cannabis.

<u>For the purposes of this subparagraph, the exceptions for low-THC cannabis do not include the smoking of low-THC cannabis.</u>

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(e) A licensed medical marijuana treatment center shall cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices, except that a medical marijuana treatment center licensed pursuant to subparagraph (a)1. may contract with a

single entity for the cultivation, processing, transporting, and dispensing of marijuana and marijuana delivery devices. A licensed medical marijuana treatment center must, at all times, maintain compliance with the criteria demonstrated and representations made in the initial application and the criteria established in this subsection. Upon request, the department may grant a medical marijuana treatment center a variance from the representations made in the initial application. Consideration of such a request shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting medical marijuana treatment center can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application. A variance may not be granted from the requirements in subparagraph 2. and subparagraphs (b)1. and 2.

1. A licensed medical marijuana treatment center may transfer ownership to an individual or entity who meets the requirements of this section. A publicly traded corporation or publicly traded company that meets the requirements of this section is not precluded from ownership of a medical marijuana treatment center. To accommodate a change in ownership:

a. The licensed medical marijuana treatment center shall notify the department in writing at least 60 days before the anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure

due to a change of ownership must submit an application that must be received by the department at least 60 days before the date of change of ownership.

c. Upon receipt of an application for a license, the department shall examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.

d. Requested information omitted from an application for licensure must be filed with the department within 21 days after the department's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.

Within 30 days after the receipt of a complete application, the department shall approve or deny the application.

2. A medical marijuana treatment center, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center, may not acquire direct or indirect ownership or control of any voting shares or other form of ownership of any other medical marijuana treatment center.

3. A medical marijuana treatment center may not enter into any form of profit-sharing arrangement with the property owner or lessor of any of its facilities where cultivation, processing, storing, or dispensing of marijuana and marijuana delivery devices occurs.

4. All employees of a medical marijuana treatment center must be 21 years of age or older and have passed a background

screening pursuant to subsection (9).

5. Each medical marijuana treatment center must adopt and enforce policies and procedures to ensure employees and volunteers receive training on the legal requirements to dispense marijuana to qualified patients.

6. When growing marijuana, a medical marijuana treatment center:

a. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

b. Must grow marijuana within an enclosed structure and in a room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state in accordance with chapter 581 and any rules adopted thereunder.

d. Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

7. Each medical marijuana treatment center must produce and make available for purchase at least one low-THC cannabis product.

8. A medical marijuana treatment center that produces edibles must hold a permit to operate as a food establishment pursuant to chapter 500, the Florida Food Safety Act, and must comply with all the requirements for food establishments pursuant to chapter 500 and any rules adopted thereunder.

Edibles may not contain more than 200 milligrams of tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles may have a potency variance of no greater than 15 percent. Edibles may not be attractive to children; be manufactured in the shape of humans, cartoons, or animals; be manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives. To discourage consumption of edibles by children, the department shall determine by rule any shapes, forms, and ingredients allowed and prohibited for edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date of the rule. The department shall also adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

9. Within 12 months after licensure, a medical marijuana treatment center must demonstrate to the department that all of its processing facilities have passed a Food Safety Good Manufacturing Practices, such as Global Food Safety Initiative or equivalent, inspection by a nationally accredited certifying body. A medical marijuana treatment center must immediately stop processing at any facility which fails to pass this inspection until it demonstrates to the department that such facility has met this requirement.

10. When processing marijuana, a medical marijuana treatment center must:

a. Process the marijuana within an enclosed structure and in a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

c. Comply with federal and state laws and regulations and department rules for solid and liquid wastes. The department shall determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing. The Department of Environmental Protection shall assist the department in developing such rules.

d. Test the processed marijuana using a medical marijuana testing laboratory before it is dispensed. Results must be verified and signed by two medical marijuana treatment center employees. Before dispensing, the medical marijuana treatment center must determine that the test results indicate that low-THC cannabis meets the definition of low-THC cannabis, the concentration of tetrahydrocannabinol meets the potency requirements of this section, the labeling of the concentration of tetrahydrocannabinol and cannabidiol is accurate, and all marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption. The department shall determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption. The Department of Agriculture and Consumer Services shall assist the department in developing the testing requirements for contaminants that are unsafe for human

consumption in edibles. The department shall also determine by rule the procedures for the treatment of marijuana that fails to meet the testing requirements of this section, s. 381.988, or department rule. The department may select a random sample from edibles available for purchase in a dispensing facility which shall be tested by the department to determine that the edible meets the potency requirements of this section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall edibles, including all edibles made from the same batch of marijuana, which fail to meet the potency requirements of this section, which are unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. The medical marijuana treatment center must retain records of all testing and samples of each homogenous batch of marijuana for at least 9 months. The medical marijuana treatment center must contract with a marijuana testing laboratory to perform audits on the medical marijuana treatment center's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for human consumption. A medical marijuana treatment center shall reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of such audits. A medical marijuana treatment center may use a laboratory that has not been certified by the department

under s. 381.988 until such time as at least one laboratory holds the required certification, but in no event later than July 1, 2018.

e. Package the marijuana in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

f. Package the marijuana in a receptacle that has a firmly affixed and legible label stating the following information:

(I) The marijuana or low-THC cannabis meets the requirements of sub-subparagraph d.

(II) The name of the medical marijuana treatment center from which the marijuana originates.

(III) The batch number and harvest number from which the marijuana originates and the date dispensed.

(IV) The name of the physician who issued the physician certification.

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children.

(VII) The recommended dose.

(VIII) A warning that it is illegal to transfer medical marijuana to another person.

(IX) A marijuana universal symbol developed by the department.

11. The medical marijuana treatment center shall include in each package a patient package insert with information on the specific product dispensed related to:

a. Clinical pharmacology.

b. Indications and use.

c. Dosage and administration.

d. Dosage forms and strengths.

e. Contraindications.

f. Warnings and precautions.

g. Adverse reactions.

12. Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 10. and 11., edible receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol. The receptacle must also include a list all of the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

13. When dispensing marijuana or a marijuana delivery device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC cannabis, medical cannabis and cannabis delivery devices issued pursuant to former s. 381.986, Florida Statutes 2016, which was entered into the medical marijuana use registry before July 1, 2017.

b. May not dispense more than a 70-day supply of marijuana to a qualified patient or caregiver.

c. Must have the medical marijuana treatment center's employee who dispenses the marijuana or a marijuana delivery device enter into the medical marijuana use registry his or her name or unique employee identifier.

d. Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled.

e. May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

f. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, ~~including pipes, bongs, or wrapping papers,~~ other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.

g. Must, upon dispensing the marijuana or marijuana delivery device, record in the registry the date, time, quantity, and form of marijuana dispensed; the type of marijuana delivery device dispensed; and the name and medical marijuana use registry identification number of the qualified patient or caregiver to whom the marijuana delivery device was dispensed.

h. Must ensure that patient records are not visible to anyone other than the qualified patient, his or her caregiver,

and authorized medical marijuana treatment center employees.

Section 2. This act shall take effect upon becoming a law.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 29, 2019

I respectfully request that **Senate Bill #182**, relating to **Smoking Marijuana for Medical Use**, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Jeff Brandes
Florida Senate, District 24

THE FLORIDA SENATE

APPEARANCE RECORD

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

2.4.19
Meeting Date

182
Bill Number (if applicable)

815914
Amendment Barcode (if applicable)

Topic Smoking Marijuana for Medical Purposes

Name Barney Bishop III

Job Title President & CEO

Address 2215 Thomasville Road
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850.510.9922

Email barney@barneybishop.com

Speaking: ☑ For ☑ Against ☐ Information

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

Representing Florida Smart Justice Alliance

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/19
Meeting Date

SB 182
Bill Number (if applicable)

★ 815914
Amendment Barcode (if applicable)

Bean amendment

Topic Smoking Medical Cannabis

Name Ron Watson

Job Title Lobbyist

Address 3738 Mudon Way
Street
Tallahassee FL 32309
City *State* *Zip*

Phone 850 567 1202

Email watson.strategies@comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AltMed 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

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2/4/2019
Meeting Date

SB 182
Bill Number (if applicable)

815914
Amendment Barcode (if applicable)

Topic SMOKING MEDICAL CANNABIS

Name GARY STEIN

Job Title EXEC DIRECTOR

Address 7035 BEN LINN LOOP
Street
WESLEY CHAPEL FL
City *State* *Zip*

Phone (503)305 8280

Email GSTEIN@CLARITYPAC.ORG

Speaking: ☐ For ☒ Against ☐ Information

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

Representing CLARITY PAC

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2.4.19
Meeting Date

182
Bill Number (if applicable)

841422
Amendment Barcode (if applicable)

Topic Smoking Marijuana for Medical Purposes

Name Barney Bishop III

Job Title President & CEO

Address 2218 Thomasville Road
Street

Phone 850.510.9922

Tallahassee FL 32308
City *State* *Zip*

Email barney@barneybishop.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Smart Justice Alliance

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/2019
Meeting Date

SB 182
Bill Number (if applicable)

~~844122~~ 456218
Amendment Barcode (if applicable)

Topic Smoking Medical Cannabis

Name Gary Stein

Job Title Exec. Director

Address 7035 Bent Link Loop
Street

Phone (513) 305-8280

Westley Chapel FL 33545
City *State* *Zip*

Email GStein@clarityPAC.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Clarity PAC

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

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2/4/19
Meeting Date

182
Bill Number (if applicable)

841422
Amendment Barcode (if applicable)

Topic Smoking

Name Jodi James

Job Title ED

Address 1375 Cypress Ave
Street

Melbourne FL 32935
City *State* *Zip*

Phone 321 890 7302

Email Jodi@flCAN.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Cannabis Action Network

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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2.4.19
Meeting Date

182
Bill Number (if applicable)

456218
Amendment Barcode (if applicable)

Topic Smoking Marijuana for Medical Purposes

Name Barney Bishop III

Job Title President & CEO

Address 2215 Thomasville Road
Street

Phone 850.510.9922

Tallahassee FL 32308
City *State* *Zip*

Email barney@barneybishop.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Smart Justice Alliance

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/19
Meeting Date

182
Bill Number (if applicable)

Topic Medical Marijuana Use

Amendment Barcode (if applicable)

Name Courtney Coppola

Job Title Intern Director

Address 4052 Bald Cypress Way
Street

Phone 850-510-7271

Tallahassee FL 32399
City *State* *Zip*

Email Courtney.Coppola@flhealth.gov

Speaking: ☐ For ☐ Against ☑ Information

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

Representing FDOH

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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2/4/19
Meeting Date

SB182
Bill Number (if applicable)

Topic Smoking Marijuana for Medical Use

Amendment Barcode (if applicable)

Name Josephine Cannella-Krehl

Job Title Licensed Clinical Social Worker

Address 500 W. Sawyer St.
Street

SGI Florida 32328
City *State* *Zip*

Phone (850) 653-6928

Email jokrehl@gmail.com

Speaking: ☐ For ☐ Against ☑ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/19
Meeting Date

SB 182
Bill Number (if applicable)

Topic Smokeable/Whole Flower Med Cannabis

Amendment Barcode (if applicable)

Name Jaime Renee Cruz

Job Title

Address 1711 NE 34th St
Street

Phone (239) 910-7685

Cape Coral FL 33909
City *State* *Zip*

Email info@420RxCCC.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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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/19
Meeting Date

SB 182
Bill Number (if applicable)

Topic Smoking Medical Cannabis

Amendment Barcode (if applicable)

Name Ron Watson

Job Title Lobbyist

Address 3738 Mudon Way
Street
Tallahassee FL 32309
City *State* *Zip*

Phone 850 567-1202

Email Watson.strategies@Comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AltMed Flordia

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2.4.19
Meeting Date

182
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Smoking Marijuana for Medical Purposes

Name Barney Bishop III

Job Title President & CEO

Address 2215 Thomasville Road
Street

Phone 850.510.9922

Tallahassee FL 32308
City *State* *Zip*

Email barney@barneybishop.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Smart Justice Alliance

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/19
Meeting Date

SB182
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Smoking Marijuana for Medical Use

Name Melissa Villar

Job Title Executive Director

Address PO Box 11254 Phone 850 354-8424
Street

TCH FL 32302 Email NORMLTallahassee@gmail.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☑ Information

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

Representing NORML Tallahassee

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

2-4-19
Meeting Date

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

SB 182
Bill Number (if applicable)

Topic SMOKING CANNABIS FOR MEDICAL USE

Amendment Barcode (if applicable)

Name PHILIP HISS

Job Title RETIRED

Address 718 GWEN ST.
Street

TALLAHASSEE FL 32303
City *State* *Zip*

Phone 850-251-3869

Email philiphiss@gmail.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/19
Meeting Date

SB 182
Bill Number (if applicable)

Topic MEDICAL MARIJUANA

Amendment Barcode (if applicable)

Name JEFFREY STARKEY

Job Title Regional CMO, MM

Address 1064 Colley Ave
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850 224 1660

Email

Speaking: ☒ For ☐ Against ☐ Information

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

Representing MEDICAL MARIJUANA BUSINESS ASSOCIATION OF FL

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/2019
Meeting Date

SB 182
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Smoking Medical Cannabis

Name Gary Stein

Job Title Exec. Dir.

Address 7035 Belt Line Loop
Street

Phone (513) 305-8280

Wesley Chapel FL 33545
City *State* *Zip*

Email GStein@clarityPNC.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Clarity PNC

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

Feb. 4, 2019
Meeting Date

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

SB 182
Bill Number (if applicable)

Topic Health Policy Cont. - Smoking Marijuana

Amendment Barcode (if applicable)

Name John M. Bench, PhD

Job Title

Address 17345 Emerald Chase Dr.
Street

Tampa FL 33647
City *State* *Zip*

Phone

Email

Speaking: ☒ For ☐ Against ☐ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2-4-19
Meeting Date

SB 182
Bill Number (if applicable)

Topic Smokable Cannabis

Amendment Barcode (if applicable)

Name Robert Roundtree

Job Title Patient Advocate

Address 3036 Foxhill Cir #203
Street

Phone 407-274-1779

Apopka FL 32703
City *State* *Zip*

Email Robert@floridamarijuana.net

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Myself a patient

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2 / 4 /2019
Meeting Date

Topic _____ Bill Number 182 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
Street

SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☐ For ☐ Against ☑ Information

Representing JUSTICE-2-JESUS

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 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/4/19
Meeting Date

SB 182
Bill Number (if applicable)

Topic Medical Cannabis

Amendment Barcode (if applicable)

Name Lisa McCorkle

Job Title disabled

Address 2303 La Rue Ct
Street

Tallahassee FL 32303
City *State* *Zip*

Phone 850 284 6832

Email Lisamm77@hotmail.com

Speaking: ☑ For ☐ Against ☑ Information

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

Representing self + other patients

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/19
Meeting Date

182
Bill Number (if applicable)

Topic Smoking

Amendment Barcode (if applicable)

Name Jodi James

Job Title Executive Director

Address 1375 Cypress Ave
Street

Melbourne, FL 32935
City *State* *Zip*

Phone 321 890 7302

Email jodi@flCAN.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Cannabis Action Network

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

The Florida Senate

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 104
INTRODUCER:	Health Policy Committee and Senator Book
SUBJECT:	Prescription Drug Donation Repository Program
DATE:	February 5, 2019
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 104 creates the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH) to facilitate the donation and distribution of prescription drugs and supplies to eligible patients in the state. The Program:

- Authorizes Florida residents with valid prescriptions who are either indigent, uninsured, or underinsured to receive donated prescription drugs and supplies under the Program.
- Specifies a list of entities that may donate prescription drugs or medical devices to the program and establishes requirements that must be met before donations may be accepted.
- Limits dispensing of prescription drugs under the Program to persons who are licensed, registered, or otherwise permitted by state law.
- Provides procedures for inventorying, storing, dispensing, recalling, and destroying prescription drugs under the Program.
- Provides recordkeeping and reporting requirements for participating facilities.
- Requires DOH to maintain and publish on its website registries of all participating facilities and available donated drugs and supplies.
- Authorizes the creation of a direct-support organization (DSO) to provide funding for the Program.
- Requires DOH to adopt rules necessary to implement the Program.

The bill amends s. 252.36(5), F.S., to allow the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

The bill is effective July 1, 2019.

II. Present Situation:

State Prescription Drug Donation and Reuse Programs

State prescription drug donation and reuse programs have been in effect since 1997.[1] Such drug donation and reuse programs permit unused prescription or non-prescription drugs to be donated and re-dispensed to patients within certain federal guidelines. Currently, 38 states have passed laws authorizing such programs; however, not all of these states have operationalized their programs.[2]

Pharmaceutical donation and reuse programs involve the voluntary collection and re-distribution of donated, unused prescription and non-prescription drugs from participating donors to eligible patients. States vary in the types of drugs and supplies that are accepted, the number and types of sites that are considered eligible locations where donors may deposit donations, participant eligibility requirements, and the dispensing fees for the donated drugs. Generally, the drugs are not controlled substances. Some programs, such as Florida's, are limited to only cancer treatment drugs. Twelve other states besides Florida – Colorado, Kentucky, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin – have prescription drug donation and reuse programs limited to cancer treatment drugs only.

Pharmacies, charitable clinics, and hospitals are locations where such donations are accepted. In Florida's Cancer Drug Donation Program,[3] only Class II hospital pharmacies that elect or volunteer to participate are eligible to accept donations of cancer drugs from designated individuals or entities.[4]

Individuals receiving donated drugs may be required to meet certain eligibility requirements beyond a cancer diagnosis to participate in the donation program such as proof of state residency (Minnesota), lack of access to other insurance coverage, or Medicaid ineligibility (Florida). Dispensing fees are set based on a maximum relative threshold above the Medicaid dispensing fee or capped at an absolute dollar amount that typically ranges from $10 to $15.

The statutory provisions of many pharmaceutical donation programs have several common requirements:

- No controlled substances are accepted as donations;
- No adulterated or misbranded medications are allowed;
- All donated pharmaceuticals must be checked by a pharmacist prior to being dispensed;
- Pharmaceuticals must not be expired and most pharmaceuticals must have at least six months or longer before expiration;

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[1] National Conference of State Legislatures, *State Prescription Drug Return, Reuse and Recycling Laws* (As of Oct. 1, 2018), http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx (last visited: Jan. 28, 2019).
[2] *Supra* note 1.
[3] Section 499.029, F.S.
[4] *See* s. 465.019, F.S. Class II institutional pharmacies are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to the patients of that institution, for use on the premises of that institution.

- All pharmaceuticals must be unopened and in original, sealed, tamper-evident packaging; and
- Liability protection is assured for both donors and recipients.[5]

Most states permit the donation of any non-controlled substance to a designated medical facility, clinic, or pharmacy that has elected to participate in the program. Currently, outside of Florida, 14 states allow any non-institutional donor to donate prescription drugs to a donation program under varying degrees of quality control.[6] Twenty states have operational repository programs – either cancer drug programs or broader collection programs – including states such as Iowa, which has served over 71,000 patients and re-distributed $17.7 million in donated prescriptions and supplies since 2007.[7] The Iowa program is limited to residents with incomes at or below 200 percent of the federal poverty level (FPL), or $51,500 for a family of four under the 2019 guidelines,[8] who are uninsured or underinsured, and are eligible to receive the donated medications and supplies.[9] The Iowa program accepts donations from any organization or individual in the country with the medication provided in its sealed or original, tamper-resistant packaging. Any pharmacy or medical facility with authorization to dispense under Iowa administrative rules may then re-dispense the donated medication or supplies.[10]

Wyoming has also had a long-running Medication Donation Program. The state's program filled over 150,000 prescriptions since its inception in 2007 and provided more than $2.4 million worth of donated prescriptions in 2016.[11] Recipients must be a Wyoming resident, have an income under 200 percent of the FPL, and be without prescription insurance or Medicaid coverage. Prescriptions are mailed to the recipient at no cost to the patient; however, neither controlled substances nor refrigerated prescriptions are covered in the program.[12]

Florida Cancer Drug Donation Program

The Florida Cancer Drug Donation Program (CDDP) was created in 2006[13] and is administratively housed within the Florida Department of Business and Professional Regulation (DBPR). The CDDP allows eligible donors to donate cancer drugs and related supplies to participating facilities that may dispense the donations to eligible cancer patients. The hospital pharmacies accept donations of cancer drugs and supplies from drug manufacturers and wholesalers; health care facilities, including nursing home facilities, hospices, or hospitals with a closed drug delivery system; or pharmacies, medical device manufacturers, or suppliers; and

[5] *Supra* note 1.
[6] *Supra* note 1.
[7] *Supra* note 1.
[8] U.S. Department of Health and Human Services, *U.S. Federal Poverty Guidelines Used to Determine Financial Eligibility for Certain Federal Programs (Effective January 1, 2019)*, https://aspe.hhs.gov/poverty-guidelines (last visited Jan. 28, 2019).
[9] Iowa Department of Public Health, *SafeNetRx Program,* https://idph.iowa.gov/ohds/rural-health-primary-care/repository, (last visited Jan. 28, 2019).
[10] *Id.*
[11] Wyoming Department of Health, *Wyoming Medication Donation Program,* https://health.wyo.gov/healthcarefin/medicationdonation/application-and-eligibilty/ (last visited: Jan. 28, 2019).
[12] *Id.*
[13] Chapter 2006-310, Laws of Fla. (creating s. 499.029, effective July 1, 2006). It was originally created within the Department of Health, but was part of a programmatic transfer by the 2010 Legislature to DBPR effective October 1, 2011.

patients or their representatives.[14] However, all donations to the CDDP must be maintained in a closed drug delivery system.[15]

Eligible participating facilities are limited to only those Florida hospital pharmacies with a Class II institutional pharmacy permit.[16] These pharmacies participate on a voluntary basis and must agree to accept, inspect, and dispense the donated drugs to the eligible patients in accordance with the statute. The DBPR is required to establish and maintain a participant facility registry for the CDDP. The law provides the content for the registry and a requirement for a website posting. Currently, the following 15 hospital pharmacies participate in the CDDP.

Cancer Drug Donation Program Participants[17]:	
Health Care Facility	**Location**
Moffitt Cancer Center	Tampa
Shands Hospital at the University of Florida	Gainesville
Sacred Heart Health	Pensacola
Halifax Medical Center	Daytona Beach
Jackson Memorial Hospital	Miami
Adventist Health System/Sunbelt Health Care	Celebration
Indian River Medical Center	Vero Beach
Tallahassee Memorial	Tallahassee
Baptist Medical Center	Jacksonville
Lower Keys Medical Center	Key West
Sun City Hospital, Inc.	Sun City Center
Mt. Sinai Medical Center	Miami Beach
Healthsouth Rehabilitation Hospital of Spring Hill	Brooksville
Baptist Hospital of Miami	Kendall
Palm Bay Hospital	Palm Beach

Florida's recipient eligibility requirements limit participation to Florida residents who:

- Have been diagnosed with cancer; and
- Are ineligible for the Medicaid program, or any other prescription drug program funded in whole or in part by the federal government, or do not have third party insurance unless the benefits have been exhausted or a certain cancer drug is not covered.[18]

Donated drugs may only be prescribed by a licensed practitioner and dispensed by a licensed pharmacist to an eligible patient.[19] Dispensed drugs and supplies under the CDDP are not eligible for reimbursement by third parties, either public or private. However, the facility may charge the recipient of the donated drug a handling fee of no more than 300 percent of

[14] Section 499.029(3)(c), F.S.
[15] Section 499.029(1)(b), F.S. A "closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.
[16] Section 499.029(2)(e), F.S.
[17] Florida Department of Business and Professional Regulation, *Cancer Drug Donation Program Participation Report*, http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/cancer-drug-donation-program/ (last visited Jan. 28, 2019).
[18] Rule 61N-1.026(1), F.A.C.
[19] Section 499.029(5), F.S.

the Medicaid dispensing fee or no more than $15, whichever is less, for each cancer drug that is dispensed.[20]

The Division of Drugs, Devices, and Cosmetics within DBPR does not maintain a list of available donated medications on its website; however, it does provide a list of other medical assistance programs that provide cancer medications based on different qualifications.[21] The DBPR also does not require the participating facilities to report the medications that are available for re-dispensing in the CDDP program or the number of donated drugs that have been administered.[22] A facility is required to maintain its own data for three years.[23]

The CDDP site will only accept drugs if:

- The donation is accompanied by a Program Donation and Destruction Record Form;
- The donation occurs at least six months before the drug's expiration date;
- The donated drug is in the original, unopened tamper-evident unit dose packaging;
- The drug must not be adulterated, misbranded, or mislabeled;
- The donated drug was maintained by a health care facility; and
- The drug is not a substance listed on Schedule II, III, IV, or V of s. 893.03, F.S.[24]

Under the act, a donor or a participant in the program who acts with reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies is immune from civil or criminal liability or professional disciplinary action for any kind of injury, death, or loss relating to such activities.[25]

Regulation of Pharmacy

The DBPR is the state agency charged with the regulation and licensure of businesses and professionals.[26] Under the provisions of chapter 499, F.S., the Division of Drugs, Devices, and Cosmetics safeguards the health, safety, and welfare of the state's citizens from injury due to the use of adulterated, contaminated, and misbranded drugs, drug ingredients and cosmetics. The Division oversees: the CDDP; issuance and regulation of licensure and permits for drug manufacturers, wholesalers, and distributers; controlled substance reporting requirements for certain wholesale distributors; issuance and regulation of other permits and licenses; and the Drug Wholesale Distributor Advisory Council.[27]

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[20] Section 409.029(7)(b), F.S. and Rule 61N-1.026(5), F.A.C.
[21] Florida Department of Business and Professional Regulation, *Medical Assistance Programs List* (last visited Jan. 30, 2019).
[22] Email correspondence from Colton Madill, Department of Business and Professional Regulation (Jan. 31, 2019) (on file with the Senate Committee on Health Policy).
[23] *Id.*
[24] *See* Rule 61N-1.026(6), F.A.C. and Florida Department of Business and Professional Regulation, *Florida Cancer Drug Donation Program Brochure*, *http://www.myfloridalicense.com/dbpr/ddc/documents/CDDP.Brochure.pdf* (last viewed: Jan. 28, 2019).
[25] Section 409.029(11), F.S.
[26] Section 20.165, F.S.
[27] Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, *http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/* (last visited Jan. 30, 2019).

The Florida Drug and Cosmetic Act (Act) is codified as ss. 499.001 - 499.081, F.S. The Act provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics. The Act provides definitions for what is considered a device, drug, and, specifically, a prescription drug.[28]

Chapter 465, F.S., governs the regulation of the practice of pharmacy by the Board of Pharmacy in the DOH. Section 465.019(2)(b), F.S., provides requirements for institutional pharmacies. "Class II institutional pharmacies" are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution for use on the premises of that institution.

Section 465.015(2)(c), F.S., makes it unlawful for a pharmacist to sell or dispense drugs without first being furnished a prescription. Section 465.016(1)(l), F.S., prohibits a pharmacist from placing into stock any part of any prescription compounded or dispensed which is returned by the patient. Additionally, the Board of Pharmacy has adopted an administrative rule that prohibits a pharmacist from placing into the stock of any pharmacy any part of any prescription compounded or dispensed, which is returned by a patient, except as specified in the Board of Pharmacy rules.[29]

There is an exception for a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to individuals who are admitted as inpatients[30] to a hospital. The unused medication may be returned to the pharmacy for re-dispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system – or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part – is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any. In the case of controlled substances, such drugs may only be returned as permitted under federal law.[31] A "closed drug delivery system" means a system in which control of the unit-dose medication is maintained by the facility rather than by the individual patient. A "unit dose system" means a system in which all the individually sealed unit doses are physically connected as a unit.[32]

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[28] A "prescription drug" under s. 499.003(40) is defined as a "prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described by, s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

[29] Rule 64B16-28.118(2), F.A.C.

[30] Generally, an inpatient is an individual who is admitted to the hospital by a licensed physician or dentist with the expectation that the recipient will stay in excess of 24 hours and occupy an inpatient bed. *See* Agency for Health Care Administration, *Florida Medicaid –Inpatient Hospital Services Coverage Policy (July 2016),* *http://ahca.myflorida.com/medicaid/review/specific_policy.shtml* (last visited: Feb. 1, 2019).

[31] Rule 64B16-28-118(2), F.A.C.

[32] Rule 64B16-28-118(1), F.A.C.

For nursing facility residents, s. 400.141(1)(d), F.S., requires a pharmacist licensed in Florida that is under contract with a nursing home to repackage a resident's bulk prescription medication which has been packaged by another pharmacist into a unit-dose system compatible with the system used by the nursing facility, if requested by the facility. In order to be eligible for the repackaging service, the resident or the resident's spouse's prescription medication benefits must be covered through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R. part 831, or a long-term care policy as defined under specified state law. A pharmacist who correctly repackages and relabels the medication, and the nursing home that correctly administers the repackaged medication, cannot be held liable in any civil or administrative action arising from the repackaging. The pharmacist may charge a reasonable fee for costs of the repackaging.

A nursing home typically has a Class I institutional permit. This permit authorizes the nursing home to have patient-specific medications that have already been dispensed to the resident. Prescription drugs may not be dispensed in a Class I pharmacy.[33]

Federal Law and Regulations

Controlled Substances Act

The federal Controlled Substances Act (CSA) was enacted by Congress in 1970 and codified as 21 U.S.C. §801, et seq. The CSA regulates the manufacture and distribution of controlled substances in the United States. The federal Drug Enforcement Agency (DEA) is responsible for the enforcement of the CSA.

The CSA categorizes drugs into five "schedules" based on their potential for abuse and safety or dependence liability.[34] The CSA provides for specific dispensing requirements for controlled substances, including written prescriptions, retention requirements, and refill restrictions, depending on the drug's schedule.[35] Prescriptions must also meet specific labeling and packaging requirements. For Schedule II, III, and IV drugs, the label must clearly contain a warning that it is a crime to transfer the drug to any person other than the patient.[36]

[33] Section 465.019(2)(a), F.S.
[34] U.S. Department of Justice, Diversion Control Division, *Controlled Substance Security Manual*, https://www.deadiversion.usdoj.gov/pubs/manuals/sec/app_law.htm (last visited Jan. 30, 2019). Drugs classified as Schedule I are those that are considered to have no medical use in the United States and have a high abuse potential and include drugs such as heroin, LSD, and marijuana. Schedule II substances have a high abuse potential with severe psychological or physical dependency, but have accepted medical use. Examples of Schedule II drugs include opium, morphine, codeine, and oxycodone. Schedule III drugs have an abuse potential and dependency liability less than Schedule II with an accepted medical use. Schedule III drugs may also contain limited quantities of certain narcotic and non-narcotic drugs. Schedule IV drugs have an abuse potential and dependency liability less than those drugs in Schedule III and have an accepted medical use and include drugs such as Valium, Xanax, and Darvon. The drugs in the fifth and final schedule, Schedule V, have an abuse potential less than those listed in Schedule IV, have an accepted medical use, and are often available without a prescription, including some for antitussive and antidiarrheal purposes.
[35] 21 U.S.C. §829 and 21 CFR §§1306.21 and 1306.22.
[36] 21 U.S.C. §825.

The CSA permits the delivery of controlled substances by an "ultimate user,"[37] who has lawfully obtained the drug, to a designated covered entity for disposal and destruction such as through a prescription drug take-back program.[38] An authorized covered entity is defined in federal law as:

- A specified law enforcement agency;
- A manufacturer, distributor, or reverse distributor of prescription medications;
- A retail pharmacy;
- A registered narcotic treatment program;
- A hospital or clinic with an onsite pharmacy;
- An eligible long-term care facility; or
- Any other entity authorized by the DEA to dispose of prescription medications.[39]

The last National Prescription Take Back Day sponsored by the DEA resulted in more than 914,236 pounds of expired, unused, and unwanted prescription drugs returned at 5,839 sites on October 27, 2018 of which 27,121 pounds were collected at 185 Florida sites.[40] The goal of the take-back program is to prevent the diversion of unwanted drugs to misuse and abuse and to avoid the potential safety hazard of drugs flushed into wastewater, sewage, or septic tank systems.[41]

Citizen-Support Organizations and Direct-Support Organizations

Citizen-support organizations (CSOs) and direct-support organization (DSOs) are statutorily created non-profit organizations[42] authorized to carry out specific tasks in support of public entities or public causes.[43] The function and purpose of a CSO or DSO are prescribed by an enacting statute and a written contract with the governmental agency the CSO or DSO supports.[44]

CSO and DSO Transparency and Reporting Requirements

In 2014, the Legislature created s. 20.058, F.S., establishing a comprehensive set of transparency and reporting requirements for CSOs and DSOs.[45] Specifically, the law requires each CSO and DSO to annually submit the following information to the appropriate agency by August 1:[46]

- The name, mailing address, telephone number, and website address of the organization;
- The statutory authority or executive order that created the organization;

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[37] An "ultimate user" is defined under 21 U.S.C. 802(27), as the person who has lawfully obtained, and who possesses, a controlled substance for his own use or the use of a member of his household or for an animal owned by him or by a member of his household.
[38] 21 U.S.C. 822a.
[39] *Id.*
[40] Drug Enforcement Administration, *16th National Take Back Day Collection Results (October 27, 2018) https://www.deadiversion.usdoj.gov/drug_disposal/takeback/* (last visited Jan. 29, 2019).
[41] *Id.*
[42] Chapter 617, F.S.
[43] *E.g.*, ss. 1009.983 and 413.0111, F.S.
[44] *See* ss. 14.29(9)(a), 16.616(1), and 258.015(1), F.S. *See also* Rules of the Florida Auditor General, Audits of Certain Nonprofit Organizations (effective June 30, 2018), *available at* https://flauditor.gov/pages/pdf_files/10_700.pdf (last visited: Jan. 29, 2019).
[45] Section 3, ch. 2014-96, L.O.F.
[46] Section 20.058(1), F.S.

- A brief description of the mission of, and results obtained by, the organization;
- A brief description of the organization's plans for the next three fiscal years;
- A copy of the organization's ethics code; and
- A copy of the organization's most recent Internal Revenue Service (IRS) Form 990.[47]

Each governmental agency receiving information from a CSO or DSO pursuant to law must make such information available to the public through the agency's website.[48] If the organization maintains a website, the agency's website must provide a link to the organization's website.[49] Any contract between an agency and a CSO or DSO must be contingent upon the CSO or DSO submitting and posting the required information to the agency as specified in law.[50] If a CSO or DSO fails to submit the required information to the agency for two consecutive years, the agency head must terminate any contract between the agency and the CSO or DSO.[51]

By August 15 of each year, the agency must report to the Governor, President of the Senate, Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability (OPPAGA) the information submitted by each CSO or DSO along with the agency's recommendation and supporting rationale to continue, terminate, or modify the agency's association with the CSO or DSO.[52]

Any law creating, or authorizing the creation of a CSO or DSO must state that the authorization for the organization repeals on October 1 of the 5th year after enactment, unless reviewed and reenacted by the Legislature. CSOs and DSOs in existence prior to July 1, 2014, must be reviewed by the Legislature by July 1, 2019.[53]

CSO and DSO Audit Requirements

Section 215.981, F.S., requires each CSO and DSO with annual expenditures in excess of $100,000 to provide for an annual financial audit of its accounts and records.[54] An independent certified public accountant in accordance with rules adopted by the Auditor General must conduct the audit. The audit report must be submitted within nine months after the end of the fiscal year to the Auditor General and to the governmental agency the CSO or DSO supports.[55] Additionally, the Auditor General may, pursuant to his or her own authority, or at the direction of the Legislative Auditing Committee, conduct audits or other engagements of a CSO's or DSO's accounts and records.[56]

[47] The IRS Form 990 is an annual information return required to be filed with the IRS by most organizations exempt from federal income tax under 26 U.S.C. 501. 26 C.F.R. 1.6033-2.
[48] Section 20.058(2), F.S.
[49] *Id.*
[50] Section 20.058(4), F.S.
[51] *Id.*
[52] *Id.* at (3).
[53] *Id.* at (5).
[54] The independent audit requirement does not apply to a CSO or DSO for a university, district board of trustees of a community college, or district school board. Additionally, the expenditure threshold for an independent audit is $300,000 for a CSO or DSO for the Department of Environmental Protection and the Department of Agriculture and Consumer Services.
[55] Section 215.981(1), F.S.
[56] Section 11.45(3), F.S.

CSO and DSO Ethics Code Requirement

Section 112.3251, F.S., requires a CSO or DSO to adopt a code of ethics. The code of ethics must contain the specified standards of conduct and disclosures provided in ss. 112.313 and 112.3143(2), F.S.[57] A CSO or DSO may adopt additional or more stringent standards of conduct and disclosure requirements and must post its code of ethics on its website.[58]

Governor's Executive Powers

During a declared state of emergency, the Governor has extensive authority to act as he or she deems necessary. Section 252.36(1), F.S., provides, in part, that "in the event of an emergency beyond local control, the Governor…may assume" or delegate "direct operational control over all or any part of the emergency management functions within this state…"

In addition, the Governor may "issue executive orders, proclamations, and rules" which "shall have the force and effect of law." Section 252.36(5), F.S., specifically authorizes the Governor to use all resources of the state government and of each political subdivision of the state, as reasonably necessary to cope with the emergency.

The Governor is also directed to "take such action and give such direction to state and local law enforcement officers," and state health officials as may be "reasonable and necessary" to secure compliance with the State Emergency Management Act and the Florida Hazardous Materials Emergency Response and Community Right-To-Know Act in ch. 252, F.S.

A declared State of Emergency is limited to 60 days, unless renewed by the Governor or terminated by the Legislature.

III. Effect of Proposed Changes:

Section 1 creates s. 465.1902, F.S., to establish the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH). The purpose of the program is to authorize and facilitate the donation and distribution of prescription drugs and supplies to eligible patients through a system of local and centralized repositories. The DOH may contract with a third party to implement and administer the Program.

The bill authorizes the following individuals or entities to donate prescription drugs and supplies:

- Nursing home facilities with closed drug delivery systems.
- Hospices that have maintained control of a patient's prescription drug.
- Hospitals with closed drug delivery systems.
- Pharmacies.
- Drug manufacturers or wholesale distributors.
- Medical device manufacturers or suppliers.
- Prescribing individuals who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

[57] Some of the standards of conduct and disclosures in ss. 112.313 and 112.3143(2), F.S., include misuse of public position, solicitation or acceptance of gifts, unauthorized compensation, and voting conflicts.
[58] Section 112.3251, F.S.

- Patients or a patient's legal representative or next of kin may donate to a local repository that qualifies as a free clinic or nonprofit health clinic if the following specific requirements are met:
  - An affidavit is signed by the donor on a form approved by the DOH which identifies the prescribing health care practitioner, and attests to the authenticity of the prescription drug or medical supply being donated;
  - The prescription drug or medical supply being donated is in its original tamper-evident packaging and does not have any signs of tampering, misbranding, deterioration, comprised integrity, or adulteration;
  - Any drug being donated has an expiration date that is more than 3 months after the date of donation; and
  - A licensed pharmacist inspects the prescription drug or medical supply and that it meets all of these requirements.

The bill requires that prescription drugs and supplies donated by a patient, a patient's legal representative, or a patient's next of kin are exempt from one, non-applicable safety provision that applies to other donations but are subject to all applicable safety and storage requirements within the bill.

The bill authorizes prescription drugs to be donated at the discretion of the centralized repository or a local repository if the drug:

- Is approved for medical use in the United States;
- Does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, F.S.;
- Is in its original sealed and tamper-evident packaging, and does not have any physical signs of tampering or adulteration;
- Requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia;
- Has been stored according to manufacturer or United States Pharmacopeia storage requirements;
- Packaging contains a lot number and expiration date of the drug, and will not expire within three months after the donation is made;
- Is not eligible for return to the Medicaid program for restocking; and
- Is not subject to a Federal Food and Drug Administration Risk Evaluation and Mitigation Strategy with Elements to Assure Safe Use.

The bill requires that prescription drugs or supplies must be donated at a repository and prohibits the use of a drop box and donation to a specific patient. Repositories must destroy any donated drug not eligible for dispensing and make a record of the destruction on a form developed by the DOH.

The bill requires a licensed pharmacist employed by, or under contract with, a repository to inspect all donated prescription drugs and supplies to determine whether they are eligible for donation under the Program, have been adulterated or misbranded, and are safe and suitable for dispensing. The pharmacist must sign an inspection record affirming the eligibility of the prescription drug or supply and attach the form to the inventory record. The pharmacist is not

required to re-inspect the prescription drug if the inspected drugs are redistributed to another repository under the Program.

The bill requires repositories to store all donated prescription drugs and supplies in a secure storage area, separate from non-donated inventory, and under the environmental conditions required by the manufacturer or the U.S. Pharmacopeia. Repositories must quarantine donated drugs and supplies from dispensing inventory until they have been inspected and approved for dispensing by the pharmacist.

The bill requires local repositories to maintain an inventory of all donated prescription drugs and supplies they receive and to notify the centralized repository within five days of receipt. The centralized repository maintains an inventory of all prescription drugs and supplies donated to the Program, including donations made at local repositories. The centralized repository may redistribute drugs and supplies to facilitate dispensing as needed throughout the state.

The bill makes participation in the Program voluntary and requires an eligible entity to notify the DOH of its intent to participate before accepting or dispensing any prescription drugs or supplies under the Program. The DOH shall establish in rule a form for such notification, to include, at a minimum:

- The name, street address, website, and telephone number of the local repository, and any state-issued license or registration number issued to the local repository, including the name of the issuing agency;
- The name and telephone number of the pharmacist employed by or under contract with the local repository responsible for the inspection of donated prescription drugs and supplies; and
- A statement signed and dated by the responsible pharmacist affirming that the local repository meets the eligibility requirements.

An eligible patient wishing to receive drugs or supplies under the Program may contact a local repository and submit an intake collection form. This form, to be created by the DOH in rule, shall include, at a minimum:

- The name, street address, and telephone number of the eligible patient;
- The specific basis for eligibility, which must be indigent, uninsured, or underinsured, as defined in the Program;[59] and
- A statement signed and dated by the eligible patient affirming that he or she meets the eligibility requirements of the Program.

The bill requires local repositories to collect an executed intake form from each eligible patient receiving drugs or supplies under the Program. Upon receiving a duly executed intake form, the local repository shall issue the eligible patient an identification card that is valid for up to one year. Local repositories must send a summary of the intake collection form data to the centralized repository within five days of receipt.

[59] The bill defines "indigent" as persons with an income below 200 percent of the federal poverty level, "uninsured" as persons who have no third-party insurance and are not eligible under Medicaid or any other federal program, and "underinsured" as persons who have third-party insurance or are eligible under Medicaid or other federal program, but have exhausted these benefits or do not have prescription drug coverage for the drug prescribed.

The bill permits licensed pharmacists and those health care practitioners already authorized by law to dispense prescription drugs and supplies in Florida to do so under the Program. Prior to dispensing a prescription drug or supply to an eligible patient, the dispenser must:

- Verify that the patient is eligible to receive donations under the Program, either through a Program identification card or a duly executed intake collection form; and
- Inspect the donated prescription drug or supply to confirm it is still eligible for dispensing under the Program.

The bill prohibits repositories from reselling drugs, submitting claims, or otherwise seeking reimbursement from any public or private third-party payer for donated drugs or supplies dispensed under the Program. However, the dispensing facility may charge a nominal handling fee, to be determined by the DOH in rule.

In the event of a prescription drug recall, the bill requires a local or centralized repository to:

- Have an established protocol to notify recipients of the drug;
- Destroy all of the recalled prescription drugs in the repository; and
- Complete a destruction information form for all donated prescription drugs that were destroyed.

The bill requires local repositories to maintain records of all prescription drugs and supplies accepted, donated, dispensed, distributed, or destroyed under the Program. Local repositories must submit these records quarterly to the centralized repository for data collection and the centralized repository must submit these records and the collected data in annual reports to the DOH.

The bill requires the DOH to maintain a registry on its website of all available drugs and supplies, including the name, strength, available quantity, and expiration date of each drug and supply, as well as the contact information for the repositories where it is available. The DOH is required to maintain a registry on its website of all participating local repositories, to include each repository's name, address, website, and telephone number.

The bill grants immunity from civil or criminal liability, and professional disciplinary actions, to a donor or participant relating to activities under the Program. Additionally, a pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the transfer of prescription drugs under the Program.

Before a donated drug may be dispensed, the bill requires the dispenser to provide written notification to the patient, or his or her legal representative, that:

- The drug was donated to the Program;
- The dispenser is not liable for any injury, death, or loss related to the dispensing of the drug; and
- The requirement of a nominal handling fee.

The bill authorizes the DOH to establish a direct-support organization (DSO) to provide assistance, funding, and promotional support for the activities authorized for the Program. The DSO is repealed on October 1, 2024, unless reviewed and saved from repeal by the Legislature.

The bill provides rulemaking authority to the DOH to administer the Program and establish the DSO.

Section 2 amends s. 252.36(5), F.S., to allow the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

Section 3 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

CS/SB 104 includes the issuance of an identification card to eligible patients who participate in the Program. These individuals are required to submit intake forms to either local or the central repository or a vendor that the DOH shall select to have their eligibility for the Program determined, and such eligibility is based on income and sensitive medical information. It is not clear if that information would then be stored by the DOH, the repositories, or any contracted vendor.

The bill also does not address how patient identification information from the medication donation process will be handled, or if any of the patient medical information that is not otherwise protected by other statutes such as Health Insurance Portability and Accountability Act of 1996 (HIPAA)[60] could be subject to a public records release request, since this bill does not have a companion public records exemption bill. If some of these records are subject to a public records release, it may impact participation in the Program.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

Program participation is voluntary. Participants may not be charged for the actual donated prescription or medical supply, but they may be charged a small handling fee

[60] The Health Insurance Accountability and Portability Act of 1996 or HIPAA, Public Law 104-191, was enacted to address concerns about both the effectiveness and the security of health care data. HIPAA required the federal Department of Health and Human Services to adopt rules relating to national standards for electronic health transactions, health care privacy and security, and health care clearinghouses. The privacy rule component of HIPAA sets standards for the use and disclosure of individuals' health care information, specifically what was protected, who was protected, how it was protected, and how it could be released and used. *See* Health Information Privacy, *HIPAA for Professionals,* https://www.hhs.gov/hipaa/for-professionals/index.html (last visited: Feb. 1, 2019).

which may be set by DOH rule. Current DBPR rules for the Cancer Drug Donation Program set the maximum handling fee at 300 percent of the Medicaid dispensing fee.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Hospitals and nursing homes volunteering to participate in the program may incur costs associated with collecting, storing, and re-dispensing donated prescription drugs. Those same hospitals and nursing homes may enjoy cost savings to the extent their patients might receive needed drugs or supplies on a more timely basis. Without such donations, some patients could return as sicker and costlier patients at a later date.

Participating hospitals and facilities are permitted to recoup some costs through a small handling fee. Current state regulations permit a handling fee of up to 300 percent of the Medicaid dispensing fee or $15, whichever is less, for each cancer drug or supply dispensed.[61]

C. Government Sector Impact:

The bill authorizes the creation of a direct-support organization (DSO) to provide assistance, funding, and promotional support for the Program's authorized activities. Sufficient funding and assistance provided by the DSO could relieve the DOH of negative fiscal impacts created by the bill.

Without sufficient DSO support, the DOH could experience a significant increase in workload, a need for additional facility space, and require updated technology resources to administer the Program. The DOH bill fiscal analysis details a need for over $400,000 for its first year of operations to implement the Program.

Department of Health – Agency Fiscal Analysis[62]	
Component	**Amount**
Space and Housing *Current market cost for lease space is $11,73 per square foot. Does not include Utilities which are estimated at $14,000 per year recurring* *Total annualized amount is $19,000.*	**$19,000**

[61] Rule 61N-1.026(5), F.A.C.

[62] Florida Dept. of Health, *Senate Bill 104 Fiscal Analysis* (Dec. 20, 2018) (on file with the Senate Committee on Health Policy per email received February 1, 2019, at 4:47 pm) pp.7-8.

Department of Health – Agency Fiscal Analysis[62]	
Component	**Amount**
Staffing *1 – Full Pharmacist* *1 – Administrator* *3 – Fulltime Pharmacy Techs* *1 – Fulltime Admin. Support*	**$282,603**
Enhancements to Pharmacy Systems *Enhancements to DOH Dispensing and PFS-Inventory systems. Average hourly costs for system enhancements by the provider ranges from $75-$95/hour.* *Estimated cost per system is approximately $35,000.* *A non-recurring cost.*	**$70,000**
Other Potential Costs *Shipping of product to eligible clients.* *Costs based on current shipping costs for prescriptions and related supplies.*	**$35,000**
TOTAL OVERALL FIRST YEAR COSTS:	**$406,603**

The bill also gives the DOH the option of contracting with a vendor to administer the Program. Several other states with drug donation programs have contracted with third party vendors.

VI. Technical Deficiencies:

The DOH notes that the use of terms within the bill may not be consistent with terms already in use in the pharmacy practice act and Chapter 456. Chapter 465 contains a definition of "prescriber" that differs from the term used in the bill. The DOH suggests that for consistency, the same definition be used. Secondly, the term "dispenser" is used in the bill versus "dispensing practitioner" in the current statutes.[63] For consistency, the DOH suggests that the term "dispensing practitioner" should be used.

On line 357, a technical correction to the phrase "centralized pharmacy" should be made as local repositories should send summaries of their intake forms to the "centralized repository."

VII. Related Issues:

The Cancer Drug Donation Program (CDDP) as previously described is not amended or incorporated into this proposed, broader drug donation program under the bill. The two programs would continue to run simultaneously and administered separately by the DOH and DBPR.

VIII. Statutes Affected:

This bill substantially amends section 252.36 of the Florida Statutes.

This bill creates section 465.1902 of the Florida Statutes.

[63] *Id at 8.*

IX. Additional Information:

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

Recommended CS by Health Policy on February 4, 2019.
The CS authorizes a patient, a patient's legal representative, or a patient's next of kin to donate unopened and unadulterated prescriptions or medical supplies to participating free clinics or nonprofit free clinics under the following conditions:

- The donor must sign an affidavit, on a form approved by the DOH, attesting to the authenticity of the items being donated, along with the identity of the prescriber.
- The items being donated must be inspected by a licensed pharmacist who examines them for any signs of tampering or adulteration.
- The donation itself and the items donated must meet all applicable safety and storage standards that are required in the bill for other donations.

B. Amendments:

None.

386006

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/04/2019	.	
	.	
	.	
	.	

The Committee on Health Policy (Book and Harrell) recommended the following:

Senate Amendment (with title amendment)

Delete lines 185 - 198

and insert:

(5) DONOR ELIGIBILITY.—

(a) The centralized repository or a local repository may accept a donation of a prescription drug or supply from:

1. Nursing home facilities with closed drug delivery systems.

2. Hospices that have maintained control of a patient's

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prescription drugs.

3. Hospitals with closed drug delivery systems.

4. Pharmacies.

5. Drug manufacturers or wholesale distributors.

6. Medical device manufacturers or suppliers.

7. Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(b) In addition to the donors specified in paragraph (a), a local repository that qualifies as a free clinic or nonprofit health clinic may accept a donation from a patient or a patient's legal representative or next of kin if the following requirements are met:

1. An affidavit, in a format approved by the department, signed by the donor must accompany the donation, identify the prescribing health care practitioner, and attest to the authenticity of the prescription drug or medical supply being donated;

2. The prescription drug or medical supply being donated is in its original tamper-evident packaging, in accordance with subparagraph (6)(b)1., and does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration;

3. Any drug being donated has an expiration date that is more than 3 months after the date of the donation; and

4. A licensed pharmacist inspects the prescription drug or medical supply and can attest to the authenticity of the donated prescription drug or medical supply and that it meets the requirements of this paragraph.

386006

Prescription drugs and supplies accepted under this paragraph are exempt from subparagraph (6)(b)3. but are subject to all other applicable requirements of subsections (6) and (7).

(c) Donations of prescription drugs or supplies may not be accepted by the centralized repository or a local repository from any donor not authorized under this subsection.

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

And the title is amended as follows:

Between lines 9 and 10

insert:

authorizing certain local repositories to accept a donation from specified persons under certain conditions; prohibiting a centralized repository or a local repository from accepting donations from unauthorized donors;

By Senator Book

32-00169-19 2019104__

A bill to be entitled

An act relating to the Prescription Drug Donation Repository Program; creating s. 465.1902, F.S.; providing a short title; defining terms; creating the Prescription Drug Donation Repository Program within the Department of Health; specifying the purpose of the program; authorizing the department to contract with a third-party vendor to administer the program; specifying entities that are eligible donors; providing criteria and procedures for eligible donations; prohibiting donations to specific patients; providing that certain prescription drugs eligible for return to stock must be credited to Medicaid and may not be donated under the program; prohibiting the donation of certain drugs pursuant to federal restrictions; clarifying that a repository is not required to accept donations of prescription drugs or supplies; providing inspection, inventory, and storage requirements for centralized and local repositories; requiring inspection of donated prescription drugs and supplies by a licensed pharmacist; requiring a local repository to notify the centralized repository within a specified timeframe after receiving a donation of prescription drugs or supplies; authorizing the centralized repository to redistribute prescription drugs or supplies; authorizing a local repository to transfer prescription drugs or supplies to another local repository with authorization from the centralized repository; requiring a local repository

to notify the department of its intent to participate in the program; providing notification requirements; providing a procedure for a local repository to withdraw from participation in the program; requiring the department to adopt rules regarding the disposition of prescription drugs and supplies of a withdrawing local repository; specifying conditions for dispensing donated prescription drugs and supplies to eligible patients; providing intake collection form requirements; requiring a local repository to issue an eligible patient who completes an intake collection form a program identification card; prohibiting the sale of donated prescription drugs and supplies under the program; authorizing a repository to charge the patient a nominal handling fee for the preparation and dispensing of prescription drugs or supplies under the program; requiring repositories to establish a protocol for notifying recipients of a prescription drug recall; providing for destruction of donated prescription drugs under certain circumstances; providing recordkeeping requirements; requiring the centralized repository to submit an annual report to the department; requiring the department or contractor to establish, maintain, and publish a registry of participating local repositories and available donated prescription drugs and supplies; requiring the department to publish certain information and forms on its website; providing immunity from civil and criminal liability and from professional disciplinary

action for participants under certain circumstances; providing immunity to pharmaceutical manufacturers, under certain circumstances, from any claim or injury arising from the donation of any prescription drug or supply under the program; requiring dispensers to provide certain notice to patients; authorizing the department to establish a direct-support organization to provide assistance, funding, and promotional support for program activities; providing organizational requirements for a direct-support organization; specifying direct-support organization purposes and objectives; prohibiting the direct-support organization from lobbying; specifying that the direct-support organization is not a lobbying firm; prohibiting the direct-support organization from possessing prescription drugs on behalf of the program; providing limitations on expenditures of such direct-support organizations; specifying that the direct-support organization must operate under contract with the department; specifying required contract terms; providing for the direct-support organization board of directors; specifying the board's membership requirements; specifying requirements and requiring the department to adopt rules relating to a direct-support organization's use of department property; specifying requirements for the deposit and use of funds by the direct-support organization; providing for annual audits of a direct-support organization; providing for future legislative

review and repeal of provisions relating to the direct-support organization; requiring the department to adopt rules; amending s. 252.36, F.S.; authorizing the Governor to waive program patient eligibility requirements during a declared state of emergency; providing an effective date.

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

Section 1. Section 465.1902, Florida Statutes, is created to read:

465.1902 Prescription Drug Donation Repository Program.—

(1) SHORT TITLE.—This section may be cited as the "Prescription Drug Donation Repository Program Act."

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

(a) "Centralized repository" means a distributor permitted under chapter 499 who is approved by the department or the contractor to accept, inspect, inventory, and distribute donated drugs and supplies under this section.

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility, rather than by the individual patient.

(c) "Contractor" means the third-party vendor approved by the department to implement and administer the program as authorized in subsection (4).

(d) "Controlled substance" means any substance listed under Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(e) "Direct-support organization" means the entity created under subsection (15).

(f) "Dispenser" means a health care practitioner who, within the scope of his or her practice act, is authorized to dispense medicinal drugs and who does so under this act.

(g) "Donor" means an entity specified in subsection (5).

(h) "Eligible patient" means a Florida resident who is indigent, uninsured, or underinsured and who has a valid prescription for a prescription drug or supply that may be dispensed under the program.

(i) "Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.

(j) "Health care practitioner" or "practitioner" means a practitioner licensed under this chapter, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

(k) "Indigent" means an individual whose family income for the 12 months preceding the determination of income is below 200 percent of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.

(l) "Local repository" means a health care practitioner's office, a pharmacy, a hospital with a closed drug delivery system, a nursing home facility with a closed drug delivery system, or a free clinic or nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in the state.

(m) "Nonprofit health clinic" means a nonprofit legal entity that provides medical care to patients who are indigent, uninsured, or underinsured. The term includes, but is not

limited to, a federally qualified health center as defined in 42 U.S.C. s. 1396d(l)(2)(B) and a rural health clinic as defined in 42 U.S.C. s. 1396d(l)(1).

(n) "Nursing home facility" has the same meaning as in s. 400.021.

(o) "Prescriber" means a health care practitioner who, within the scope of his or her practice act, is authorized to prescribe medicinal drugs.

(p) "Prescription drug" has the same meaning as the term "medicinal drugs" or "drugs," as those terms are defined in s. 465.003(8), but does not include controlled substances or cancer drugs donated under s. 499.029.

(q) "Program" means the Prescription Drug Donation Repository Program created by this section.

(r) "Supplies" means any supply used in the administration of a prescription drug.

(s) "Tamper-evident packaging" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred.

(t) "Underinsured" means a person who has third-party insurance or is eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription drug program funded in whole or in part by the Federal Government, but who has exhausted these benefits or does not have prescription drug coverage for the drug prescribed.

(u) "Uninsured" means a person who has no third-party insurance and is not eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription

drug program funded in whole or in part by the Federal Government.

(3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM; CREATION; PURPOSE.—The Prescription Drug Donation Repository Program is created within the department for the purpose of authorizing and facilitating the donation of prescription drugs and supplies to eligible patients.

(4) PROGRAM IMPLEMENTATION; ADMINISTRATION.—The department may contract with a third-party vendor to administer the program.

(5) DONOR ELIGIBILITY.—The centralized repository or a local repository may accept a donation of a prescription drug or supply only from:

(a) Nursing home facilities with closed drug delivery systems.

(b) Hospices that have maintained control of a patient's prescription drugs.

(c) Hospitals with closed drug delivery systems.

(d) Pharmacies.

(e) Drug manufacturers or wholesale distributors.

(f) Medical device manufacturers or suppliers.

(g) Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(6) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR DONATION; DONATION REQUIREMENTS; PROHIBITED DONATIONS.—

(a) Only prescription drugs and supplies that have been approved for medical use in the United States and that meet the criteria for donation established by this section may be

accepted for donation under the program. Donations must be made on the premises of the centralized repository or a local repository to a person designated by the repository. A drop box may not be used to accept donations.

(b) The centralized repository or a local repository may accept a prescription drug only if:

1. The drug is in its original sealed and tamper-evident packaging. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened.

2. The drug requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia.

3. The drug has been stored according to manufacturer or United States Pharmacopeia storage requirements.

4. The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.

5. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.

6. The packaging indicates the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall.

7. The drug has an expiration date that is more than 3 months after the date that the drug was donated.

(c) The centralized repository or a local repository may accept supplies only if they are in their original, unopened, sealed packaging and have not been tampered with or misbranded.

(d) Prescription drugs or supplies may not be donated to a

specific patient.

(e) Prescription drugs billed to and paid for by Medicaid in long-term care facilities which are eligible for return to stock under federal Medicaid regulations must be credited to Medicaid and may not be donated under the program.

(f) Prescription drugs with an approved Federal Food and Drug Administration Risk Evaluation and Mitigation Strategy that includes Elements to Assure Safe Use are not eligible for donation under the program.

(g) This section does not require the centralized repository or a local repository to accept a donation of prescription drugs or supplies.

(7) INSPECTION AND STORAGE.—

(a) A licensed pharmacist employed by or under contract with the centralized repository or a local repository shall inspect donated prescription drugs and supplies to determine whether they meet the requirements of subsections (5) and (6).

(b) The inspecting pharmacist must sign an inspection record on a form prescribed by the department by rule which verifies that the prescription drugs and supplies meet the criteria of subsections (5) and (6) and must attach the record to the inventory required by paragraph (d). A local repository that receives drugs and supplies from the centralized repository is not required to reinspect them.

(c) The centralized repository and local repositories shall store donated prescription drugs and supplies in a secure storage area under the environmental conditions specified by the manufacturer or the United States Pharmacopeia for the respective prescription drugs or supplies. Donated prescription

drugs and supplies may not be stored with other inventory. A local repository shall quarantine donated prescription drugs or supplies until they are inspected and approved for dispensing under this section.

(d) The centralized repository and local repositories shall maintain an inventory of all donated prescription drugs or supplies. Such inventory at local repositories shall be recorded on a form prescribed by the department by rule.

(e) A local repository shall notify the centralized repository within 5 days after receipt of any donation of prescription drugs or supplies to the program. The notification must be on a form prescribed by the department by rule.

(f) The centralized repository may redistribute prescription drugs and supplies by transferring them to or from the centralized repository and a local repository, as needed. A local repository that receives donated prescription drugs or supplies may, with authorization from the centralized repository, distribute the prescription drugs or supplies to another local repository.

(8) PROGRAM PARTICIPATION.—

(a) A practitioner, pharmacy, facility, or clinic must notify the department of its intent to participate in the program as a local repository before accepting or dispensing any prescription drugs or supplies pursuant to this section. The notification must be made on a form prescribed by the department by rule and must, at a minimum, include:

1. The name, street address, website, and telephone number of the intended local repository and any license or registration number issued by the state to the intended local repository,

including the name of the issuing agency.

2. The name and telephone number of the pharmacist employed by or under contract with the intended local repository who is responsible for the inspection of donated prescription drugs and supplies.

3. A signed and dated statement by the responsible pharmacist affirming that the intended local repository meets the eligibility requirements of this section.

(b) A local repository may withdraw from participation in the program at any time by providing written notice to the department or contractor, as appropriate, on a form prescribed by the department by rule. The department shall adopt rules addressing the disposition of prescription drugs and supplies in the possession of the withdrawing local repository.

(9) DISPENSING REQUIREMENTS; PROHIBITIONS.—

(a) Each eligible patient without a program identification card must submit an intake collection form to a local repository before receiving prescription drugs or supplies under the program. The department shall prescribe a form by rule, which must include at least all of the following:

1. The name, street address, and telephone number of the eligible patient.

2. The basis for eligibility, which must specify that the patient is indigent, uninsured, or underinsured.

3. A statement signed and dated by the eligible patient affirming that he or she meets the eligibility requirements of this section.

(b) Upon receipt of a completed and signed intake collection form, the local repository shall issue him or her a

program identification card, which is valid for 1 year after its date of issuance. The card must be in a form prescribed by the department by rule.

(c) The local repository shall send a summary of each intake collection form to the centralized pharmacy within 5 days after receiving it.

(d) A dispenser may dispense donated prescription drugs or supplies only to an eligible patient who has a program identification card or who has submitted a completed intake collection form.

(e) A dispenser shall inspect the donated prescription drugs or supplies before dispensing them.

(f) A dispenser may provide dispensing and consulting services to an eligible patient.

(g) Donated prescription drugs and supplies may not be sold or resold under the program.

(h) A dispenser of donated prescription drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription drugs or supplies dispensed under this program. However, a repository may charge the patient a nominal handling fee, established by department rule, for the preparation and dispensing of prescription drugs or supplies under the program.

(10) RECALLED PRESCRIPTION DRUGS AND SUPPLIES.—

(a) The centralized repository and each local repository shall establish and follow a protocol for notifying recipients in the event of a prescription drug recall.

(b) Local repositories shall destroy all recalled or expired prescription drugs and all prescription drugs that are

not suitable for dispensing in the repository. Local repositories must complete a destruction information form for all such drugs, in accordance with department rule.

(11) RECORDKEEPING.—

(a) Local repositories shall maintain records of prescription drugs and supplies that are accepted, donated, dispensed, distributed, or destroyed under the program.

(b) All required records must be maintained in accordance with any applicable practice act. Local repositories shall submit these records quarterly to the centralized repository for data collection, and the centralized repository shall submit these records and the collected data in annual reports to the department.

(12) REGISTRIES; PUBLICATION OF FORMS.—

(a) The department or contractor shall establish and maintain registries of all local repositories and of prescription drugs and supplies available under the program. The registry of local repositories must include each repository's name, address, website, and telephone number. The registry of available prescription drugs and supplies must include the name, strength, available quantity, and expiration date of the prescription drug or supplies and the name and contact information of each repository where such drug or supplies are available. The department shall publish the registries on its website.

(b) The department shall publish all forms required by this section on its website.

(13) IMMUNITY FROM LIABILITY, DISCIPLINARY ACTION.—

(a) Any donor of prescription drugs or supplies and any

participant in the program who exercises reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies under the program is immune from civil or criminal liability and from professional disciplinary action by the state for any injury, death, or loss to person or property relating to such activities.

(b) A pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the donation of any prescription drug or supply under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the donated prescription drug, including its expiration date.

(14) NOTICE TO PATIENTS.—Before dispensing a donated prescription drug under the program, the dispenser must provide written notification to the eligible patient or his or her legal representative, receipt of which must be acknowledged in writing, of all of the following information:

(a) The prescription drug was donated to the program.

(b) The donors and participants in the program are immune from civil or criminal liability or disciplinary action.

(c) The eligible patient is not required to pay for the prescription drug, but may be required to pay a nominal handling fee, which may not exceed the amount established by department rule.

(15) DIRECT-SUPPORT ORGANIZATION.—The department may establish a direct-support organization to provide assistance, funding, and promotional support for the activities authorized under the act.

(a) *Entity organization.*—The direct-support organization

must operate in accordance with s. 20.058 and is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds and request and receive grants, gifts, and bequests of moneys; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the program.

(b) *Purposes and objectives.*—The purposes and objectives of the direct-support organization must be consistent with the goals of the department, in the best interest of the state, and in accordance with the adopted goals and the mission of the department.

(c) *Prohibition against lobbying.*—The direct-support organization is not considered a lobbying firm, as that term is defined in s. 11.045(1). All expenditures of the direct-support organization must be directly related to program administration within the requirements of this section. Funds of the direct-support organization may not be used for the purpose of lobbying, as that term is defined in s. 11.045(1).

(d) *Possession of prescription drugs.*—The direct-support organization may not possess any prescription drugs on behalf of the program.

(e) *Contract.*—The direct-support organization shall operate under a written contract with the department.

1. The contract must require the direct-support

organization to submit to the department, annually by August 1, the following information, which must be posted on the websites of the direct-support organization and the department:

a. The articles of incorporation and bylaws of the direct-support organization, as approved by the department.

b. A proposed annual budget for the approval of the department.

c. The code of ethics of the direct-support organization.

d. The statutory authority or executive order that created the direct-support organization.

e. A brief description of the direct-support organization's mission and any results obtained by the direct-support organization.

f. A brief description of the direct-support organization's annual plan for each of the next 3 fiscal years.

g. A copy of the direct-support organization's most recent federal Internal Revenue Service Return Organization Exempt from Income Tax form (Form 990).

h. Certification by the department that the direct-support organization is complying with the terms of the contract and operating in a manner consistent with the goals and purposes of the department and the best interest of the program and the state. Such certification must be made annually and reported in the official minutes of a meeting of the board of directors of the direct-support organization.

2. The contract must, at a minimum, provide for:

a. The reversion without penalty to the department, or to the state if the department ceases to exist, of all moneys and property held in trust by the direct-support organization for

the benefit of the program if the direct-support organization ceases to exist or if the contract is terminated.

b. A disclosure of material provisions of the contract and the distinction between the department and the direct-support organization to appear on all promotional and fundraising publications.

c. A list of prescription drugs solicited by the direct-support organization for distribution to the centralized repository or a local repository.

(f) *Board of directors.*—The State Surgeon General shall appoint the board of directors, which must consist of at least 5 members, but not more than 15 members, who serve at his or her pleasure. The board must elect a chair from among its members. Board members must serve without compensation but may be entitled to reimbursement of travel and per diem expenses in accordance with s. 112.061, if funds are available for this purpose.

(g) *Use of property.*—The department may allow, without charge, appropriate use of fixed property, facilities, and personnel services of the department by the direct-support organization for purposes related to the program. For purposes of this paragraph, the term "personnel services" includes full-time or part-time personnel, as well as payroll processing services.

1. The department may prescribe any condition with which the direct-support organization must comply in order to use fixed property or facilities of the department.

2. The department may not allow the use of any fixed property or facilities of the department by the direct-support

organization if the organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, sex, age, or national origin.

3. The department shall adopt rules prescribing the procedures by which the direct-support organization is governed and any conditions with which a direct-support organization must comply to use property or facilities of the department.

(h) *Deposit of funds.*—Any moneys of the direct-support organization may be held in a separate depository account in the name of the organization and subject to the provisions of the organization's contract with the department.

(i) *Use of funds.*—Funds designated for the direct-support organization must be used for the enhancement of program projects and in a manner consistent with that purpose. Any administrative costs of running and promoting the purposes of the organization or program must be paid by private funds.

(j) *Audit.*—The direct-support organization shall provide for an annual financial audit in accordance with s. 215.981.

(k) *Repeal.*—This subsection is repealed on October 1, 2024, unless reviewed and saved from repeal by the Legislature.

(16) RULEMAKING.—The department shall adopt rules necessary to administer this section. When applicable, the rules may provide for the use of electronic forms, recordkeeping, and meeting by teleconference.

Section 2. Paragraph (o) is added to subsection (5) of section 252.36, Florida Statutes, to read:

252.36 Emergency management powers of the Governor.—

(5) In addition to any other powers conferred upon the

Governor by law, she or he may:

(o) Waive the patient eligibility requirements of s. 465.1902.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

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

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR LAUREN BOOK
32nd District

December 17, 2018

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

Chair Harrell:

I respectfully request that **SB 104—Prescription Drug Donation Repository Program** be placed on the agenda for the next Committee on Health Policy meeting.

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

Thank you,

Lauren Book

Senator Lauren Book
Senate District 32

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

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

Senate's Website: *www.flsenate.gov*

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

2 / 4 /2019
Meeting Date

Topic _____ Bill Number 204 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
Street

SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☐ For ☐ Against ☑ Information

Representing JUSTICE-2-JESUS

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 (10/20/11)

Florida Health Care Association

Post-Hurricane Michael Nursing Home Update
Florida Senate Committee on Health Policy

February 4, 2019

Bob Asztalos

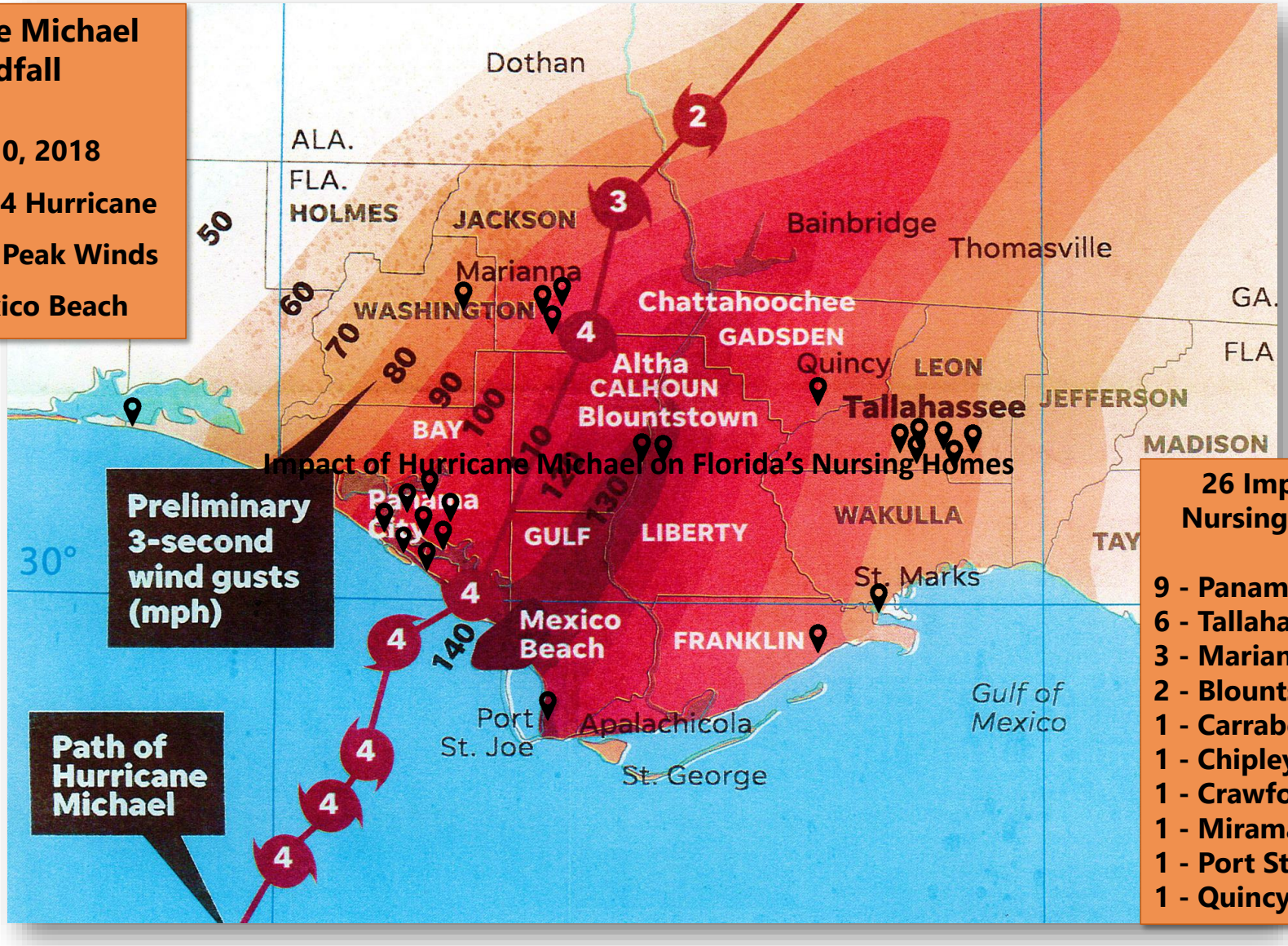
Chief Lobbyist/Emergency Response Coordinator

Florida Health Care Association

www.fhca.org

Hurricane Michael Landfall

- October 10, 2018
- Category 4 Hurricane
- 155 MPH Peak Winds
- Near Mexico Beach



Impact of Hurricane Michael on Florida's Nursing Homes

26 Impacted Nursing Homes

- 9 - Panama City
- 6 - Tallahassee
- 3 - Marianna
- 2 - Blountstown
- 1 - Carrabelle
- 1 - Chipley
- 1 - Crawfordville
- 1 - Miramar Beach
- 1 - Port St. Joe
- 1 - Quincy

Florida Health Care Association

Hurricane Michael Impact on Florida Nursing Homes

• Total nursing homes in impact zone	26
• Total residents (approx.)	3,200
• Total nursing homes evacuated	9
• Total residents evacuated (approx.)	900
• Total nursing homes evacuated long term	7
• Total number of beds	712
• Total nursing homes on generator power	18
• Total residents on generator power (approx.)	2,500

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Damaged Nursing Homes

7 Evacuated Nursing Homes

- 1 currently reopening; 3 projected late 2019
- 2 projected 2020
- 1 uncertain
- Residents relocated to north and central Florida

Structural Damages $58 Million (approx.)

- 7 evacuated $46 million
- 15 damaged $12 million

Panhandle LTC Infrastructure Faces Long, Slow Rebuild

(Similar issues to general community)

- Lack of contractors
- Insurance issues
- Loss of current staff, lack of potential staff and housing

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Florida Health Care Association

Outcomes

"We are not going to have another Hollywood Hills"

- **All residents safely evacuated and cared for in temperature-controlled environments - no deaths or injury as a result of the hurricane.**
- **Generators allowed nursing homes to care for their residents as well as community by serving as defacto shelters**
  - **Families of staff, residents and people from community**
  - **Marianna center took in insulin dependent individuals from community**
  - **Blountstown Administrator housed homebound individual**
- **Internal nursing home plans worked**
  - **Extra support from community, emergency planners, regulators etc.**
  - **Community Health and Rehabilitation Center**

Outcomes

Outreach by AHCA and DOH with professional associations unique among states

- **Florida Hospital Association and FHCA working in State Emergency Operations Center**
- **Coordination with other health care associations**
  (LeadingAge, Florida Assisted Living Association, Florida Senior Living Association)

Power restoration was much improved

- **Better communication between providers and power companies**
- **Emphasis placed on restoring nursing home power at local and state EOC levels**

Florida Health Care Association

Lessons Learned/Continued Challenges

Power Restoration

- Still need to develop working relationship with other power companies

Evacuations

- Inherent conflict between Emergency Management and Providers on when to evacuate
- Receiving facilities became strained caring for evacuees
- Transfer Trauma to residents/some residents moved up to four locations

Florida Health Care Association

Implementation of Generator Rule on Nursing Homes

- **After Hurricane Irma, AHCA/DOEA issued rules requiring Nursing Homes and Assisted Living Facilities to acquire a generator and 96 hours of fuel to cool an area for residents.**
- **Nursing homes and ALFs were to comply by June 2018 or have temporary cooling plan in place and seek a waiver until January 1, 2019.**
- **Nursing homes can petition for a rule variance as long as the nursing home continues to have a temporary plan and demonstrates progress toward an implementation date.**

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Current Status of Generator Rule on Nursing Homes

687 Licensed Nursing Homes

- 186 have approved permanent generator and fuel storage
- 469 have a pending or approved variance
- 32 have expired extensions

Florida Health Care Association

Reasons for Granting Temporary Variances to the Generator Rule

- Sample of 50 of the 469 variances on file
- All provided a plan to meet the temperature requirements using portable or temporary generators while completing process
- 28% are awaiting generators, which are custom built, or other equipment
- 18% experienced delays in delivery, installation or electrical wiring upgrades
- 28% are under review by AHCA's Office of Plans and Construction
- 14% are under review by local permitting
- 12% are under review by AHCA's Office of Plans and Construction and local permitting

Florida Health Care Association

Expected Implementation Timeline

27% currently have permanent generator and fuel storage

Variances were approved by AHCA for a maximum of 6 months until June 1, 2019. Based on sample:

- **20% projected by March 31**
- **10% projected by April 30**
- **Remainder requests through May 31**

Florida Health Care Association

Questions?

Bob Asztalos
Florida Health Care Association
basztalos@fhca.org | (850) 224-3907

www.fhca.org

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: /SBSenate Health Policy Committee **Judge:**

Started: 2/4/2019 1:34:00 PM
Ends: 2/4/2019 3:27:58 PM Length: 01:53:59

1:33:59 PM Meeting called or order
1:34:54 PM Quorum
1:36:01 PM Senator Bean - Introduction
1:37:02 PM Tab 1 - SB 182 by Senator Brandes, Smoking Marijuana for Medical Use
1:37:17 PM Senator Baxley - Question
1:37:41 PM Senator Brandes
1:38:16 PM Senator Baxley
1:38:52 PM Senator Brandes
1:39:07 PM Senator Baxley
1:39:14 PM Senator Brandes
1:39:39 PM Senator Baxley
1:40:06 PM Senator Brandes
1:41:01 PM Senator Mayfield
1:42:20 PM Senator Brandes
1:42:44 PM Senator Mayfield
1:42:53 PM Senator Brandes
1:43:48 PM Senator Mayfield
1:44:03 PM Senator Brandes
1:44:44 PM Senator Mayfield
1:44:59 PM Senator Brandes
1:45:49 PM Senator Rouson
1:46:54 PM Senator Rouson
1:47:18 PM Senator Brandes
1:48:25 PM Senator Hooper
1:49:11 PM Senator Brandes
1:49:17 PM Senator Hooper
1:49:23 PM Senator Brandes
1:50:36 PM Chair
1:50:55 PM Courtney Coppola, Interim Director, FDOH, Medical Marijuana Use
1:51:00 PM Chair
1:51:49 PM Courtney Coppola
1:52:08 PM Chair
1:52:17 PM Daniel Looke, Staff Attorney, to address question
1:53:44 PM Questions? None
1:53:58 PM Late Filed Amendment 815914- by Senator Bean. No objections to late file amendment
1:54:18 PM Senator Bean moves to withdraw late filed amendment 815914
1:58:14 PM Chair - 815914 is withdrawn
1:59:14 PM Gavel to Senator Berman
1:59:24 PM Amendment 841422 by Senator Harrell
2:10:06 PM Chair - Questions?
2:11:09 PM Senator Bean
2:11:56 PM Senator Harrell
2:12:37 PM Senator Brandes
2:13:09 PM Daniel Looke, Staff Attorney to explain
2:13:44 PM Senator Rouson
2:14:08 PM Senator Brandes
2:14:23 PM Senator Rouson
2:14:35 PM Senator Brandes
2:14:56 PM Senator Book
2:15:25 PM Senator Harrell
2:16:08 PM Senator Book
2:16:43 PM Senator Harrell

2:17:34 PM Senator Book
2:17:40 PM Senator Harrell
2:18:31 PM Senator Book
2:19:22 PM Senator Cruz
2:20:29 PM Senator Harrell
2:21:54 PM Senator Mayfield
2:22:13 PM Senator Harrell
2:22:26 PM Appearance Cards
2:22:48 PM Barney Bishop - President & CEO, Florida Smart Justice Alliance speaking for amendment
2:28:14 PM Gary Stein, Executive Director, Clarity PAC
2:32:58 PM Chair
2:34:12 PM Jodi James, Executive Director, Florida Cannabis Action Network, speaking against Amendment
2:38:03 PM Chair - Any debate?
2:38:19 PM Senator Diaz
2:39:23 PM Senator Brandes
2:41:46 PM Senator Harrell to close
2:44:06 PM Chair
2:45:10 PM Voice vote - Amendment 841422 is adopted
2:45:21 PM Raise of hands - Roll call - Amendment favorable
2:46:10 PM Amendment 456218 - by Senator Harrell
2:46:33 PM Senator Harrell withdraws amendment
2:46:40 PM Senator Harrell is in chair
2:47:10 PM Questions on bill as amended? None
2:47:30 PM Appearance Cards SB 182
2:47:46 PM Jaime Renee Cruz, Smokeable /whole flower Medical Cannabis
2:49:44 PM Ron Watson, AHMed Fla. waives in support
2:50:00 PM Barney Bishop waives in opposition
2:50:21 PM Melissa Miller, Executive Director, NORML of Tallahassee
2:52:40 PM Phillip Hiss, Retired, NORML
2:55:53 PM Jeffrey Sharkee, Medical Marijuana, Business Association of Florida, waive in support
2:56:10 PM Gary Stein, Clarity Pack, support bill in original form. Has questions on amended bill.
2:57:23 PM John Brunch, Ph.D, Health Policy, speaking for bill
3:00:10 PM Robert Roundtree, patient, speaking against bill as amended
3:02:23 PM Brian Pitts, Justice -2- Jesus
3:04:26 PM Lisa McCorkle, patient waives in support of bill before amended
3:05:29 PM Jodi James, Executive Director, Florida Cannabis Action Network, opposing bill as amended
3:05:36 PM Josephine Cannella- Krehl, Licensed Clinical Social Worker
3:08:27 PM Debate?
3:08:29 PM Senator Berman
3:09:11 PM Senator Diaz
3:11:15 PM Senator Book
3:13:47 PM Senator Baxley
3:15:23 PM Senator Cruz
3:17:33 PM Senator Rouson
3:19:11 PM Senator Mayfield
3:21:49 PM Chair
3:22:05 PM Senator Brandes to close
3:23:30 PM Roll Call - CS/SB 182, tied vote
3:24:32 PM Chair - Motion to reconsider - favorable
3:25:13 PM Roll Call - CS/SB 182 - Favorable
3:26:10 PM Tab 2 - SB 104 by Senator Book, Prescription Drug Donation Repository Program
3:26:35 PM Amendment 386006 by Harrell - passes
3:26:43 PM Bill as amended no questions
3:26:51 PM No debate
3:26:56 PM Close on bill
3:27:01 PM Roll Call - SB 104 - favorable
3:27:15 PM
3:27:30 PM Senator Berman moves to adjourn
3:27:57 PM Meeting adjourned