

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 Rules

BILL: CS/SB 460

INTRODUCER: Rules Committee; and Senator Bradley and others

SUBJECT: Medical Use of Cannabis

DATE: March 1, 2016

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	Favorable
2.	<u>Clodfelter</u>	<u>Sadberry</u>	<u>ACJ</u>	Recommend: Favorable
3.	<u>Pace</u>	<u>Hrdlicka</u>	<u>FP</u>	Favorable
4.	<u>Stovall</u>	<u>Phelps</u>	<u>RC</u>	Fav/CS

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 460 expands the regulatory structure relating to dispensing low-THC cannabis and authorizes approved dispensing organizations to cultivate and dispense medical cannabis to eligible patients as defined under the Right to Try Act. The bill defines medical cannabis to include all parts of the cannabis plant that is dispensed only from a dispensing organization for medical use by an eligible patient and includes medical cannabis within the definition of an investigational drug, biological product, or device under the Right to Try Act.

Under the Right to Try Act, an eligible patient is defined as a person who has a terminal condition that is not considered by the treating physician to be reversible, and without life-sustaining procedures the condition will result in death within one year if the condition runs its normal course.

The bill preserves the authorization for the five approved dispensing organizations to continue operations in compliance with law. The bill also provides for the applicant that received the highest aggregate score in the evaluation process and other challengers that have received a final determination from the Division of Administrative Hearing, the Department of Health, or a court of competent jurisdiction that it was entitled to be a dispensing organization to operate as a dispensing organization. The bill provides that a new dispensing organization may operate within the same region with an approved dispensing organization, as applicable.

The bill may result in increased sales tax revenue from new sales of medical cannabis, if it is not determined to be exempt from sales tax. However, it is likely that the fiscal impact would be insignificant due to eligibility restrictions in the Right to Try Act.

The act takes effect upon becoming a law.

II. Present Situation:

Treatment of Marijuana in Florida

Florida law defines cannabis as “all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin,”¹ and places it, along with other sources of THC, on the list of Schedule I controlled substances.² The definition excludes “low-THC cannabis” as defined in s. 381.986, F.S., if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed in conformance with that section.

Schedule I controlled substances are substances that have a high potential for abuse and no currently accepted medical use in the United States.³ As a Schedule I controlled substance, possession and trafficking of cannabis carry criminal penalties that vary from a first degree misdemeanor⁴ up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a \$200,000 fine.⁵ Paraphernalia⁶ that is sold, manufactured, used, or possessed with the intent to be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance, is also prohibited and carries criminal penalties ranging from a first degree misdemeanor to a third degree felony.⁷

Medical Marijuana in Florida: the Compassionate Medical Cannabis Act of 2014

Patient Treatment with Low-THC Cannabis

The Compassionate Medical Cannabis Act of 2014⁸ (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)⁹ for medical use¹⁰ by

¹ Section 893.02(3), F.S.

² Section 893.03(1)(c)7. and 37., F.S.

³ Section 893.03(1), F.S.

⁴ This penalty is applicable to possession or delivery of less than 20 grams of cannabis. *See* s. 893.13(3) and (6)(b), F.S.

⁵ Trafficking in more than 25 pounds, or 300 plants, of cannabis is a first degree felony with a mandatory minimum sentence that varies from 3 to 15 years in state prison depending on the quantity of the cannabis possessed, sold, etc. *See* s. 893.135(1)(a), F.S.

⁶ Section 893.145, F.S.

⁷ Section 893.147, F.S.

⁸ Chapter 2014-157, L.O.F., and s. 381.986, F.S.

⁹ Section 381.986(b), F.S., defines “low-THC cannabis,” as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

¹⁰ Section 381.986(1)(c), F.S., defines “medical use” as administration of the ordered amount of low-THC cannabis; and the term does not include the possession, use, or administration by smoking, or the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient’s legal representative. Section 381.986(1)(e),

patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. The act provides that a Florida licensed allopathic or osteopathic physician who has completed the required training¹¹ and has examined and is treating such a patient may order low-THC cannabis for that patient to treat such disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for that patient. In order for a physician to order low-THC cannabis for a patient, all of the following conditions must apply:

- The patient is a permanent resident of Florida;
- The physician determines that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient;¹²
- The physician registers as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the DOH and updates the registry to reflect the contents of the order;
- The physician maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis;
- The physician submits the patient treatment plan quarterly to the University of Florida College of Pharmacy (UFCP) for research on the safety and efficacy of low-THC cannabis on patients; and
- The physician obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community about the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.¹³

The act creates exceptions to existing law to allow qualified patients¹⁴ and their legal representatives to purchase, acquire, and possess low-THC cannabis (up to the amount ordered) for that patient's medical use; and to allow dispensing organizations (DO) and their owners, managers, and employees to acquire, possess, cultivate, and dispose of excess product in reasonable quantities to produce low-THC cannabis and to possess, process, and dispense low-THC cannabis. DOs and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.¹⁵

F.S., defines "smoking" as burning or igniting a substance and inhaling the smoke; smoking does not include the use of a vaporizer.

¹¹ Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing.

¹² If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record.

¹³ Section 381.986(2), F.S.

¹⁴ Section 381.986(1)(d), F.S., defines a "qualified patient" as a Florida resident who has been added by a physician licensed under ch. 458, F.S., or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a DO.

¹⁵ Section 381.986(7), F.S.

Dispensing Organizations under the Act

On November 23, 2015, the Department of Health (DOH) approved a DO in each of the following five regions as required by the act: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.¹⁶ In order to be approved as a DO, an applicant must possess a certificate of registration issued by the Department of Agriculture and Consumer Services (DACS) for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in this state for at least 30 continuous years. Applicants are also required to demonstrate:

- The technical and technological ability to cultivate and produce low-THC cannabis;
- The ability to secure the premises, resources, and personnel necessary to operate as a DO;
- The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances;
- An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department;
- The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department;
- That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04, F.S; and
- The employment of a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis.¹⁷

An approved DO must post a \$5 million performance bond within 10 business days of approval. The DOH is authorized to charge an initial application fee and a licensure renewal fee, but is not authorized to charge an initial licensure fee.¹⁸ An approved DO must maintain all approval criteria at all times.¹⁹

Beginning on July 7, 2014, the DOH held several rule workshops²⁰ to write and adopt rules implementing the provisions of s. 381.986, F.S., and the DOH put forward a proposed rule on September 9, 2014.²¹ This proposed rule was challenged by multiple organizations involved in the rulemaking workshops and was found to be an invalid exercise of delegated legislative authority by an administrative law judge on November 14, 2014.²² Afterward, the DOH held a negotiated rulemaking workshop in February of 2015, which resulted in a new proposed rule

¹⁶ Section 381.986(5)(b), F.S. A map of the dispensing regions and approved dispensing organizations is available on the DOH website at: <http://www.floridahealth.gov/media/ocu/compassionate-dispensing-org-map.pdf> (last visited Jan. 14, 2016).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Section 381.986(6), F.S.

²⁰ An audio recording of the rule development workshops is available on the DOH website at: <http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/rulemaking/index.html> (last visited Jan. 14, 2016).

²¹ Proposed Rule ch. 64-4, F.A.C., ID 14941024, (Aug. 14, 2014) and changed, ID 15040352, (Sept. 9, 2014).

²² *Tornello Landscape Corp. v. DOH*, Case No. 14-4547RP; *Fl. Medical Cannabis Assoc. v. DOH*, Case No. 14-4517RP; *Plants of Ruskin, Inc. v. DOH*, Case No. 14-4299RP; *Costa Farms, LLC v. DOH*, Case No. 14-4296RP (Fla. DOAH 2014). A copy of each Final Order is available on the Division of Administrative Hearings website.

being published on February 6, 2015.²³ The new proposed rule was also challenged on, among other things, the DOH's statement of estimated regulatory costs and the DOH's conclusion that the rule will not require legislative ratification. Hearings were held on April 23 and 24, 2015, and a final order was issued on May 27, 2015, which found the rule to be valid.²⁴ The rules took effect June 17, 2015, and the DOH held an application period for DO approval which ended on July 8, 2015. The five approved DOs were selected from 28 applications that were submitted.²⁵

Several unsuccessful applicants challenged the DOH's selection of the five DOs to the Division of Administrative Hearings (DOAH). Two challenges have been dismissed and these DOAH cases are closed. As of February 6, 2016, the southeast has no outstanding challenges. Four applicants are challenging the selection in the southwest region, three applicants are challenging the selection in the central region, two petitioners are challenging the selection in the northeast region, and one challenger remains in the northwest region.²⁶

The Compassionate Use Registry

The act requires the DOH to create a secure, electronic, and online registry for the registration of physicians and patients and for the verification of patient orders by DOs, which is accessible to law enforcement.²⁷ The registry must allow DOs to record the dispensing of low-THC cannabis, and must prevent an active registration of a patient by multiple physicians. Physicians must register qualified patients with the registry and DOs are required to verify that the patient has an active registration in the registry, that the order presented matches the order contents as recorded in the registry, and that the order has not already been filled before dispensing any low-THC cannabis. DOs are also required to record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.²⁸ The DOH has indicated that the registry is built and ready to move to the operational phase.²⁹

The Office of Compassionate Use and Research on Low-THC Cannabis

The DOH was required to establish the Office of Compassionate Use under the direction of the deputy state health officer to administer the act.³⁰ The Office of Compassionate Use is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies by:

- Creating a network of state universities and medical centers recognized for demonstrating excellence in patient-centered coordinated care for persons undergoing cancer treatment and therapy in this state;³¹

²³ Proposed Rule ch. 64-4, ID 15645147, (Feb. 2, 2015).

²⁴ Baywood Nurseries Co., Inc. v. DOH, Case No. 15-1694RP (Fla. DOAH 2015).

²⁵ Information about the applications and the approved DOs is available on the DOH, Office of Compassionate Use, Resources website, available at: <http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/index.html> (last visited Jan. 18, 2016).

²⁶ Email from the Department of Health, dated February 5, 2016, on file with the Senate Health Policy Committee.

²⁷ Section 381.986(5)(a), F.S.

²⁸ Section 381.986(6), F.S.

²⁹ Conversation of Health Policy Committee staff with Jennifer Tschetter, Chief of Staff (DOH) (March 20, 2015).

³⁰ Section 385.212, F.S.

³¹ See s. 381.925, F.S.

- Making any necessary application to the United States Food and Drug Administration (FDA) or a pharmaceutical manufacturer to facilitate enhanced access to compassionate use for Florida patients; and
- Entering into agreements necessary to facilitate enhanced access to compassionate use for Florida patients.³²

The act includes several provisions related to research on low-THC cannabis and cannabidiol including:

- Requiring physicians to submit quarterly patient treatment plans to the UFCP for research on the safety and efficacy of low-THC cannabis;³³
- Authorizing state universities to perform research on cannabidiol and low-THC cannabis and exempting them from the provisions in ch. 893, F.S., for the purposes of such research;³⁴ and
- Appropriating \$1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.³⁵

Medical Marijuana in Florida: The Necessity Defense

Despite the fact that the use, possession, and sale of marijuana are prohibited by state law, Florida courts have found that circumstances can necessitate medical use of marijuana and circumvent the application of criminal penalties. The necessity defense was successfully applied in a marijuana possession case in *Jenks v. State* where the First District Court of Appeal found that “section 893.03 does not preclude the defense of medical necessity” for the use of marijuana if the defendant:

- Did not intentionally bring about the circumstance which precipitated the unlawful act;
- Could not accomplish the same objective using a less offensive alternative available; and
- The evil sought to be avoided was more heinous than the unlawful act.³⁶

In the cited case, the defendants, a married couple, were suffering from uncontrollable nausea due to AIDS treatment and had testimony from their physician that he could find no effective alternative treatment. Under these facts, the court found that the defendants met the criteria to qualify for the necessity defense and ordered an acquittal of the charges of cultivating cannabis and possession of drug paraphernalia.

Medical Marijuana Laws in Other States

Currently, 23 states, the District of Columbia, and Guam have some form of law that permits the use of marijuana for medicinal purposes.³⁷ These laws vary widely in detail but most are similar

³² Section 385.212, F.S.

³³ Section 381.986(2)(e), F.S.

³⁴ Section 385.211, F.S.

³⁵ Chapter 2014-157, L.O.F.

³⁶ *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *review denied*, 589 So.2d 292 (Fla. 1991).

³⁷ These states include: Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and New York was the most recent state to pass medical marijuana legislation in June 2014. Seventeen states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol). Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana,

in that they touch on several recurring themes. For example, most state laws require an identification card and registry for patients and caregivers to use medical marijuana; require the patient to receive certification from up to two physicians that the patient has a qualifying condition before the patient may use medical marijuana; allow a patient to designate a caregiver who can possess the medical marijuana and assist the patient in using the medical marijuana; and provide general restrictions on how medical marijuana can be obtained (self-cultivated or from a dispensary) and where it can be used.³⁸

Of the 17 states with low-THC cannabis laws similar to s. 381.986, F.S., most specify that the use of such low-THC cannabis is reserved for patients with epileptic or seizure disorders. Florida allows the treatment of cancer and Georgia allows the treatment of end stage cancer and other specified conditions. Additionally, the definition of low-THC cannabis differs from state to state. The THC level allowed range from as high as below 5 percent to less than 0.3 percent; most states restrict the level of THC to below 1 percent. CBD levels are generally required to be high, with most states requiring at least 10 percent.³⁹

Interaction with the Federal Government

The Federal Controlled Substances Act lists marijuana as a Schedule 1 drug and provides no exceptions for medical uses.⁴⁰ Possession, manufacture, and distribution of marijuana is a crime under federal law.⁴¹ Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under state law, state medical marijuana laws do not protect individuals from prosecution under federal law.

In 2013, the United States Department of Justice (USDOJ) issued statements indicating that the federal government would not pursue cases for low-level drug crimes, leaving such prosecutions largely up to state authorities. The U.S. Attorney General issued a statement that the USDOJ was changing policy such that individuals “who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels, will no longer be charged with offenses that impose draconian mandatory minimum sentences... [and] would instead receive sentences better suited to their individual conduct...”⁴² Further, the USDOJ issued a memorandum clarifying that the department considers small-scale marijuana use to be a state matter which states may choose to punish and certain operations adhering to state laws legalizing marijuana in conjunction with robust state regulatory systems would be far less likely to come under federal scrutiny.⁴³ In addition, a rider in recent appropriations acts and continuing

Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. National Conference of State Legislatures, *State Medical Marijuana Laws*, (Jan. 8, 2016), available at: <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx> (last visited Jan. 13, 2016).

³⁸ Analysis by Senate Health Policy committee staff of *supra* note 36.

³⁹ *Supra* note 36.

⁴⁰ 21 U.S.C. s. 812

⁴¹ The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. *See* 21 U.S.C ss. 841-865.

⁴² USDOJ, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century*, (Aug. 2013), p. 3, available at: <http://www.justice.gov/ag/smart-on-crime.pdf> (last visited on Jan. 13, 2016).

⁴³ USDOJ Memorandum for all U.S. Attorneys, “*Guidance Regarding Marijuana Enforcement*,” (August 29, 2013), available at: <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> (last visited Jan. 13, 2016).

resolutions has prohibited the USDOJ from using appropriated funds to prevent specified states (including Florida) from implementing the states own medical marijuana laws.⁴⁴

The Florida Right to Try Act

Section 499.0295, F.S., creates the Right to Try Act which allows drug manufacturers to make investigational drugs, biological products, or devices⁴⁵ (experimental treatment) available to an eligible patient (with or without compensation). The Right to Try Act defines an “eligible patient” as a person who meets all of the following requirements:

- Has a terminal condition⁴⁶ attested to by that patient’s physician and confirmed by a second independent specialist physician;
- Has considered all other treatment options for that condition currently approved by the FDA;
- Has given written informed consent for the use of an experimental treatment, which must include:
 - An explanation of the currently approved products and treatment for the patient’s condition;
 - An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient’s life;
 - Identification of the specific experimental treatment the patient is seeking to use;
 - A realistic description of the most likely outcomes of using the experimental treatment;
 - A statement that the patient’s health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the experimental treatment unless required to do so by law or contract;
 - A statement that the patient’s eligibility for hospice care may be withdrawn if the patient begins such treatment and that hospice care may be reinstated once the treatment ends if the patient meets hospice eligibility requirements; and
 - A statement that the patient understands that he or she is liable for all expenses consequent to the use of the experimental treatment and that the liability extends to the patient’s estate unless otherwise stated in the contract;⁴⁷
- Has documentation from his or her treating physician that the patient meets the above requirements.⁴⁸

⁴⁴ See s. 542, Pub. L. No. 114-113 (Consolidated Appropriations Act, 2016). A recent court order by the U.S. District Court for the Northern District of California recently held that a similar provision in the previous appropriations act (s. 538, Pub. L. No. 113-235) does not prohibit the USDOJ from enforcing violations of *federal* marijuana laws by individuals or businesses who are complying with state medical marijuana laws. *U.S. v. Marin Alliance for Medical Marijuana and Shaw*, Order re: Motion to Dissolve Permanent Injunction, No. C 98-00086 CB, (Oct. 19, 2015), available at <http://www.scribd.com/doc/286089509/US-vs-Marin-Alliance-for-Medical-Marijuana#scribd> (last visited Jan. 13, 2016).

⁴⁵ Section 499.0295(2)(b), F.S. defines “investigational drug, biological product, or device” as a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the FDA and remains under investigation in a clinical trial approved by the FDA.

⁴⁶ Section 499.0295(2)(c), 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 even with the administration of available treatment options currently approved by FDA, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

⁴⁷ Section 499.0295(2)(d), F.S.

⁴⁸ Section 499.0295(2)(a), F.S.

The Right to Try Act prescribes how the eligible patient's use of the experimental treatment may impact certain third parties including that:

- A health plan, third party administrator, or governmental agency may, but is not required to, provide coverage for the costs of such treatment;⁴⁹
- A hospital or health care facility is not required to provide new or additional services unless such services are approved by that hospital or health care facility;⁵⁰
- The patient's heirs are not liable for any outstanding debt related to the patient's use of such treatment if the patient dies while undergoing such treatment;⁵¹
- A licensing board and a state entity responsible for Medicare certification may not revoke, fail to renew, suspend, or take other action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to treatment under the Right to Try Act;⁵² and
- The Right to Try Act does not create a private cause of action:
 - Against the manufacturer of the experimental treatment;
 - Against a person or entity involved in the care of an eligible patient who is using the experimental treatment; or
 - For any harm to the patient that is the result of the use of the experimental treatment if the manufacturer or other person or entity complies in good faith with the terms of Right to Try Act and exercises reasonable care.⁵³

III. Effect of Proposed Changes:

The bill amends s. 381.986, F.S., relating to the compassionate use of low-THC cannabis and s. 499.0295, F.S., the Right to Try Act, to allow the ordering by physicians and dispensing by DOs of medical cannabis for eligible patients. The bill strengthens the regulatory structure for the cultivation and dispensing of low-THC cannabis and includes cultivation and dispensing of medical cannabis in that regulatory structure.

Section 1 amends s. 381.986, F.S., relating to compassionate use of low-THC cannabis or medical cannabis.

Definitions

The bill defines the following new terms:

- "Cannabis delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis or medical cannabis into the human body.
- "Independent testing laboratory" means a laboratory, including the managers, employees, or contractors of the laboratory, which has no direct or indirect interest in a DO.
- "Legal representative" means the qualified patient's:
 - Parent,

⁴⁹ Section 499.0295(4), F.S.

⁵⁰ Section 499.029(5), F.S.

⁵¹ Section 499.0295(6), F.S.

⁵² Section 499.0295(7), F.S.

⁵³ Section 499.0295(8), F.S.

- Legal guardian acting pursuant to a court’s authorization as required under s. 744.3215(4), F.S.,
- Health care surrogate acting pursuant to the qualified patient’s written consent or a court’s authorization as required under s. 765.113, F.S., or
- An individual who is authorized under a power of attorney to make health care decisions on behalf of the qualified patient.
- “Medical cannabis” means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a DO for medical use by an eligible patient as defined in the Right to Try Act.

Existing definitions are modified as follows:

- “Dispensing organization” is amended to also provide for the approval by the DOH to transport low-THC cannabis and to cultivate, process, transport, and dispense medical cannabis pursuant to this law.
- “Medical use” now includes medical cannabis and has been modified to exclude the use or administration of low-THC cannabis or medical cannabis:
 - On any form of public transportation,
 - In any public place,
 - In a qualified patient’s place of employment, if restricted by his or her employer,
 - In a correctional institution,
 - On the grounds of a preschool, primary school, or secondary school, or
 - On a school bus or in a vehicle, aircraft, or motorboat.⁵⁴
- “Qualified patient” is expanded to include a resident of this state who has been added to the compassionate use registry by a physician licensed under the medical practice act or the osteopathic medical practice act to receive medical cannabis from a dispensing organization.

Physician Ordering and Penalties

A physician who holds an unrestricted license under the Florida Medical Practice Act or the Florida Osteopathic Medical Practice Act is authorized to order:

- Low-THC cannabis, if no other satisfactory alternative treatment options exist, to treat a qualified patient
 - Suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent medical spasms or
 - To alleviate symptoms of such disease, disorder, or condition.
- Medical cannabis to treat an eligible patient.
- A cannabis delivery device for the medical use of low-THC cannabis or medical cannabis.

In addition to the Florida licensure requirement, the physician must:

- Have treated the patient for at least three months immediately preceding the patient’s registration in the compassionate use registry.

⁵⁴ A patient who uses medical cannabis and a patient’s legal representative who administers medical cannabis in or on an excluded place commits a first degree misdemeanor.

- Have successfully completed the 8-hour course and examination relating to the clinical indications for the appropriate use of low-THC cannabis and medical cannabis, appropriate cannabis delivery devices, contraindications for such use, and relevant state and federal laws governing the ordering, dispensing, and possessing of these substances and devices. Successful completion of the course and examination are required for each biennial license renewal.
- Have determined that the risks of treating the patient with low-THC cannabis or medical cannabis are reasonable in light of the potential benefit to the patient. If the patient is younger than 18 years of age, a second physician must concur with this determination.
- Have obtained a voluntary written informed consent from the patient or the patient's legal representative.⁵⁵
- Have registered as the orderer of low-THC cannabis or medical cannabis for the patient on the compassionate use registry.
- Record the amount of low-THC cannabis or medical cannabis ordered for the patient for up to a 45-day supply and the cannabis delivery device needed for the medical use of the ordered low-THC cannabis or medical cannabis. Updates to this order must be recorded in the registry within seven days after any change.
- Maintain a patient treatment plan, which must be submitted quarterly to the University of Florida, College of Pharmacy for research purposes.

The bill no longer requires the patient to be a *permanent* resident of this state prior to the physician ordering low-THC medical cannabis.

The ordering physician may not be a medical director or employed by a DO. A physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device and receives compensation from a DO is subject to licensure disciplinary action.

The bill adds that a physician commits a first degree misdemeanor if he or she orders medical cannabis for a patient without a reasonable belief that the patient has a terminal condition as defined under the Right to Try Act, similar to the existing provision relating to ordering low-THC cannabis.

Unlawful Action by Patients

A person who fraudulently represents that he or she has a terminal condition to a physician for the purpose of being ordered medical cannabis or a cannabis delivery device commits a first degree misdemeanor.

An eligible patient who uses medical cannabis, or a patient's legal representative who administers medical cannabis in or on a place excluded within the definition of medical use commits a first degree misdemeanor.

The bill provides that this law does not exempt a person from being prosecuted for a criminal offense related to impairment or intoxication resulting from the medical use of low-THC

⁵⁵ The contents of the information in the informed consent differ for the ordering of low-THC cannabis or medical cannabis.

cannabis or medical cannabis or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

Department of Health Responsibilities

The bill expands the compassionate use registry that is maintained by the DOH to include the registration of the patient's legal representative and to record the ordering of medical cannabis and a cannabis delivery device.

Upon the registration of 250,000 active qualified patients in the compassionate use registry, the DOH is authorized to approve additional DOs, at least one of which is an applicant that is a recognized class member of *Pigford v. Glickman* or *In Re Black Farmers Litigation*⁵⁶ and a member of the Black Farmers and Agriculturalists Association. The new DOs must meet the requirements set out for approval of the initial five DOs, except for the requirements that an applicant must possess a valid certificate of registration issued by the DACS which is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operated as a registered nursery in this state for at least 30 continuous years.

The bill requires the DOH to monitor physician registration and ordering of medical cannabis or a cannabis delivery device for ordering practices that could facilitate the unlawful diversion or misuse of medical cannabis or a cannabis delivery device and take disciplinary action as indicated. This provision currently applies to monitoring physician activities with respect to low-THC cannabis.

The DOH is authorized to conduct announced or unannounced inspections of DOs and is required to inspect upon receiving a complaint. The DOH is also required to inspect a DO at least every two years to evaluate the DO's records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices. The DOH may enter into interagency agreements with the DACS, the Department of Business and professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration to conduct inspections or perform other responsibilities assigned to the DOH in this bill.

The bill requires the DOH to list all approved DOs, qualified ordering physicians, and medical directors on its website.

The bill authorizes the DOH to issue and renew registration cards, for a fee, to patients and their legal representations, as well as a process for revoking the registration and requiring the card to be returned. The bill provides content and other specifications for the registration card, including but not limited to, a color photograph of the holder and that the card be resistant to counterfeiting or tampering.

The bill authorizes the DOH to impose fines in an amount not to exceed \$10,000 on a DO and suspend, revoke, or refuse to renew a DO's approval for specified violations.

⁵⁶ *Pigford v. Glickman*, 182 F.R.D. 82 (D.D.C. 1999) or *In Re Black Farmers Litig.*, 856 F. Supp 2d 1(D.D.C. 2011).

The DOH is authorized to adopt rules necessary to implement this bill.

Dispensing Organization Requirements and Authorizations

The bill authorizes:

- The five approved DOs to also cultivate and dispense medical cannabis pursuant to this bill. This authority will also extend to any additional DOs that are authorized.
- A reduction in the amount of the performance bond that a DO must maintain from \$5 million to \$2 million when the DO begins serving at least 1,000 qualified patients.
- A DO to engage in wholesale purchases and sales of low-THC cannabis or medical cannabis from and to other DOs.
- A DO to use pesticides that the DOH has determined can be safely applied to plants intended for human consumption and prohibits the use of pesticides designated as restricted-use pesticides.⁵⁷

The bill strengthens the regulation of DOs with respect to growing, processing packaging, labeling, dispensing, and transporting low-THC cannabis or medical cannabis as well as the general security of the facility. More specifically, the bill requires a DO to:

- Grow and process low-THC cannabis or medical cannabis within an enclosed structure and in a room separate from any other plant.
- Inspect seeds and growing plants for certain harmful plant pests, notify the DACS within ten days after a determination that a plant is infested or infected, and implement phytosanitary policies and procedures, if applicable.
- Perform fumigation or treatment of plants, or remove and destroy infested or infected plants.⁵⁸
- Test processed low-THC cannabis and medical cannabis before dispensing:
 - For low-THC cannabis, that it meets the definition of low-THC cannabis,
 - For both medical cannabis and low-THC cannabis, that it is safe for human consumption and free from contaminants that are unsafe for human consumption, and
 - Verify test results and provide for two DO employees to sign the results.
- Retain records of all testing and two processed samples from each homogenous batch of cannabis and low-THC cannabis for at least nine months.
- Contract with an independent testing laboratory to perform audits on the DO's standard operating procedures, testing records, and samples; and provide the results to the DOH.
- Package low-THC or medical cannabis in compliance with the United States Poison Prevention Packaging Act and in a receptacle that has a firmly affixed and legible label with specified information.

⁵⁷ Section 487.042, F.S., authorizes the DACS to designate by rule a pesticide, or a pesticide applied under certain conditions or for a certain purpose, as a "restricted-use pesticide" if the pesticide, when applied in accordance with its directions for use, warnings, and cautions, for uses for which it is registered or for one or more such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment or injury to the applicator or other persons

⁵⁸ The fumigation, treatment, removal or destruction is to be done in accordance with ch. 581, F.S., relating to plant industry under regulatory authority of the DACS.

- Require the employee who dispenses the low-THC cannabis, medical cannabis, or a cannabis delivery device to enter his or her name or unique employee identifier into the compassionate use registry when dispensing.
- Verify the patient or patient's legal representative has an active registration in the registry and holds a valid and active registration card.
- Verify in the registry that a physician has ordered the low-THC cannabis, medical cannabis, or a specific type of a cannabis delivery device for the patient and the order has not already been filled.
- Record in the registry the date, time, quantity, and form of low-THC or medical cannabis and the type of cannabis delivery device dispensed.
- Restrict the sale of other substances, such as alcohol or illicit drug-related products, other than physician-ordered cannabis delivery devices.
- Maintain a fully operational security alarm system with specified features or a video surveillance system with specified features.
- Ensure the DO's outdoor premises have sufficient lighting from dusk until dawn.
- Maintain a department-approved tracking system that accounts for key events including when seeds are planted, when plants are harvested and destroyed, and when low-THC cannabis or medical cannabis is transported, sold, stolen, diverted, or lost.
- Restrict dispensing from its premises between the hours of 9:00 p.m. and 7:00 a.m.; however other activities and delivery to a qualified patient may occur 24 hours each day.
- Maintain low-THC cannabis or medical cannabis in a secured, locked room or vault.
- Require at least two employees or two contracted security personnel to be on the premises at all times.
- Require employees and visitors to wear identification badges or passes.
- Implement an alcohol and drug-free workplace policy.
- Report to local law enforcement any theft, diversion, or loss of low-THC cannabis or medical cannabis within 24 hours of discovery.
- Ensure the safe transport of low-THC cannabis or medical cannabis by maintaining a transportation manifest, using only vehicles in good working order, securing low-THC cannabis or medical cannabis in a separate compartment or container within the vehicle, requiring at least two persons in the vehicle when transporting and at least one person while the low-THC cannabis or medical cannabis is being delivered, and providing specific safety and security training to the employees.

The bill also requires the medical director of each DO to hold an active, unrestricted license as a physician under the Florida Medical Practice Act or the Florida Osteopathic Medical Act.

Preemption

The bill preempts to the state all matters regarding the regulation of the cultivation and processing of low-THC cannabis or medical cannabis.

Local government may determine by ordinance the number and location of, and other permitting requirements that do not conflict with state law or department rule for, dispensing facilities of dispensing organizations. A municipality may govern dispensing facilities located within its

boundaries and a county may govern dispensing facilities located within the unincorporated areas of that county.

Protections from Other Law

The bill provides protection from ss. 893.013, 893.135, 893.147, F.S.,⁵⁹ under the Florida Comprehensive Drug Abuse Prevention and Control Act, or any other law, subject to the requirements of this bill to:

- A qualified patient and his or her legal representative to purchase and possess for the patient's medical use up to the amount of low-THC cannabis or medical cannabis ordered for the patient, but not more than a 45-day supply, and a cannabis delivery device ordered for the patient.
- An approved DO and its owners, managers, and employees to manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities of low-THC cannabis, medical cannabis, or a cannabis delivery device.
- An approved independent testing laboratory to possess, test, transport, and lawfully dispose of low-THC cannabis or medical cannabis as provided by DOH rule.

An approved DO and its owners, manager, and employees are exempt from licensure or regulation under the Florida Pharmacy Act or the Florida Drug, Devices, and Cosmetic Act for activities related to low-THC cannabis, medical cannabis, or a cannabis delivery device.

The bill provides that an approved DO that continues to meet the requirements for approval is presumed to be registered with the DOH and to meet the rules adopted by the DOH or its successor agency for the purpose of dispensing low-THC cannabis or medical cannabis under Florida law. Furthermore, the authority provided to a DO under the Right to Try Act does not impair the approval of a DO.

Section 2 amends s. 499.0295, F.S., relating to experimental treatments for terminal conditions to include within the definition of “investigational drug, biological product, or device” medical cannabis that is manufactured and sold by a DO. A DO is defined under this section of law by referring to the DOH-approved DO under s. 381.986, F.S.

The bill authorizes, upon a physician's order pursuant to s. 381.986, a DO to provide medical cannabis or a cannabis delivery device to an eligible patient.

Section 3 creates an undesignated section of law to address the uncertainty surrounding the challenges to the DOH selection process. The bill ensures that the five approved DOs may continue operating as a DO in compliance with law. The bill requires the DOH to approve as a dispensing organization an applicant that received the highest aggregate score through the department's evaluation process, notwithstanding any prior determination by the DOH that the applicant failed to meet the requirements of s. 381.986, F.S., and for this DO to comply with the bond requirement and other applicable rule requirements.

⁵⁹ Specifically, the bill exempts patients from s. 893.13, F.S., related to unauthorized selling, purchasing, manufacturing, and possessing of controlled substances; s. 893.135, F.S., related to trafficking in controlled substances; and s. 893.147, F.S., related to the use, manufacture, possession, and sale of drug paraphernalia.

The bill also provides that if the DOAH, the DOH, or a court of competent jurisdiction makes a final determination that an applicant was entitled to be a DO, that both this DO and currently approved DOs may both operate in the same region.

The bill preserves the ability of the DOH to enforce the rules relating to the compassionate use of low-THC cannabis.

The bill also clarifies that these provisions in this section of the bill do not apply to the three new DOs that will be approved when the compassionate use registry reaches 250,000 active qualified patients.

Section 4. The bill takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The state may see increased sales tax revenue from new sales of medical cannabis that would be generated under the provisions of the bill, if determined taxable. However, it is likely that the fiscal impact would be insignificant due to eligibility restrictions in the Right to Try Act.

B. Private Sector Impact:

The bill may have a positive fiscal impact on approved DOs that may see new sales generated by an increased number of patients to whom they may sell medical cannabis as well as on any newly authorized DOs.

C. Government Sector Impact:

See Tax/Fee Issues.

VI. Technical Deficiencies:

Line 804 requires the DOH to grant approval as a DO to an applicant that meets certain requirements but was not previously approved by the DOH within 10 days before the effective date of this act. Until the act goes into effect, the DOH is not authorized to grant this approval since existing law has no similar provision.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.986 and 499.0295.

The bill creates an undesignated section of law.

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 Rules on February 29, 2016:

- Creates definitions for cannabis delivery device, independent testing laboratory, legal representative, medical cannabis, and modifies the definition of medical use;
- Adds medical cannabis for the treatment of eligible patients to the regulatory structure for low-THC cannabis;
- Enhances the regulatory structure for and oversight of dispensing organizations and physician ordering;
- Authorizes, when 250,000 active qualified patient registrations are in the compassionate use registry, the approval of three additional dispensing organizations, at least one of which must be a class member of specified litigation and meet other conditions;
- Provides for state preemption of matters pertaining to cultivation and processing, and local determination on the number and location of dispensing facilities;
- Preserves the status and ongoing operations of the approved dispensing organizations; and
- Provides authorization for certain challengers to the evaluation and selection process to operate as dispensing organizations.

B. Amendments:

None.