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 7066
INTRODUCER:	Health Policy Committee and Regulated Industries Committee
SUBJECT:	Low-THC Cannabis
DATE:	March 31, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
	Kraemer/Oxamendi	Imhof		**RI Submitted as Committee Bill**
1.	Looke	Stovall	HP	**Fav/CS**
2.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 7066 significantly revises the provisions of s. 381.986, F.S., related to the compassionate use of low-THC cannabis.

The bill amends provisions related to the use of low-THC cannabis by:

- Increasing the number of conditions for which a physician may order the use of low-THC cannabis. The new list of conditions includes human immunodeficiency virus, acquired immune deficiency syndrome, epilepsy, amyotrophic lateral sclerosis, multiple sclerosis, Crohn's disease, Parkinson's disease, paraplegia, quadriplegia, and terminal illness;
- Permitting the use of low-THC cannabis to treat the listed conditions, symptoms of those conditions, and symptoms created by treatments for those conditions;
- Requiring a physician to register a patient's legal representative with the compassionate use registry in order for that person to be authorized to assist the patient with his or her use of low-THC cannabis;
- Requiring a dispensing organization (DO) to verify the identity of the person being dispensed low-THC cannabis before dispensing; and
- Restricting the locations where low-THC cannabis may be used.

The bill amends provisions related to the cultivation, processing, and dispensing of low-THC cannabis by:

- Increasing the number of DOs that the Department of Health (DOH) is required to license from 5 to 20;

- Requiring the DOH to choose which applicants to license by lottery if more than 20 qualified applicants apply and specifying a timeline for the licensure of DOs;
- Specifying an application fee of $50,000, a licensure fee of $125,000, and a licensure renewal fee of $125,000;
- Reducing the performance and compliance bond from $5 million to $1 million;
- Significantly revising and expanding the criteria required for an applicant to qualify for licensure;
- Preempting regulation of DO cultivation and processing facilities to the state and allowing municipalities and counties to choose by ordinance the number and location of any DO retail facilities authorized in that municipality or the unincorporated area of that county, respectively;
- Requiring DO vehicles to be permitted by the DOH;
- Authorizing the DOH to inspect DO premises and facilities. The DOH is required to perform an inspection of all DO facilities before such facilities become operational and at licensure renewal;
- Allowing the DOH to fine a DO up to $10,000 or to revoke, suspend, or deny a DO's license for listed violations including failure to maintain the qualifications for licensure and endangering the health, safety, and welfare of a qualified patient; and
- Requiring DOs to have all low-THC cannabis and low-THC cannabis product tested by an independent testing laboratory before dispensing it. The DO must determine that the tests results show that the low-THC cannabis or product meets the applicable definition, is free from contaminants, and is safe for human consumption. Licensed laboratories and their employees are exempt from provisions in ch. 893, F.S., for the possession of cannabis for the purpose of testing such cannabis.

The bill also amends provisions related to the study of the safety and efficacy of low-THC cannabis by the University of Florida (UF) by requiring the UF College of Pharmacy (UFCP) to create a research program that includes a fully integrated electronic information system. The bill allows UF researchers to access the compassionate use registry, the prescription drug monitoring program database (PDMP), and Medicaid records[1] for qualified patients in order to conduct research required by the bill. The bill also requires physicians to submit requested medical records for qualifying patients to the UFCP.

The bill exempts the rules of the DOH under this act from the rule ratification requirements of s. 120.541(3), F.S.

The bill is effective upon becoming law.

[1] To the extent allowed by Federal law.

II. Present Situation:

Compassionate Medical Cannabis Act of 2014

Patient Treatment with Low-THC Cannabis

The Compassionate Medical Cannabis Act of 2014[2] (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[3] for the medical use[4] by 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 training[5] and has examined and is treating such a patient may order low-THC cannabis for that patient to treat a disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for that patient. In order to meet the requirements of the act 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;[6]
- 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 UF College of Pharmacy 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 of the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.

---

[2] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.

[3] The act defined "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. *See* s. 381.986(1)(b), F.S. Eleven states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol): Alabama, Florida, Iowa, Kentucky, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Utah, and Wisconsin. Twenty-three states, the District of Columbia, and Guam have laws that permit the use of marijuana for medicinal purposes. See infra note 28. *See* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (Tables 1 and 2), (last visited on March 27, 2015).

[4] Pursuant to s. 381.986(1)(c), F.S., "medical use" means 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), F.S., defines "smoking" as burning or igniting a substance and inhaling the smoke; smoking does not include the use of a vaporizer.

[5] 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

[6] 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.

A physician who orders low-THC cannabis for a patient without a reasonable belief that the patient is suffering from a required condition and any person who fraudulently represents that he or she has a required condition to a physician for the purpose of being ordered low-THC cannabis commits a misdemeanor of the first degree. The DOH is required to monitor physician registration and ordering of low-THC cannabis in order to take disciplinary action as needed.

The act creates exceptions to existing law to allow qualified patients[7] 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 DOs, 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.[8]

Dispensing Organizations

The act requires the DOH to approve five DOs with one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida and southwest Florida.[9] 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 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.[10]

Upon approval, a DO must post a $5 million performance bond. The DOH is authorized to charge an initial application few and a licensure renewal fee, but is not authorized to charge an initial licensure fee.[11] An approved DO must also maintain all approval criteria at all times.

[7] *See* s. 381.986(1)(d), F.S., which provides that a "qualified patient" is 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.
[8] *See* s. 381.986(7)(c), F.S.
[9] *See* s. 381.986(5)(b), F.S.
[10] Id.
[11] Id.

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. The registry must allow DOs to record the dispensation 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. The DOH has indicated that the registry is built and ready to move to the operational phase.[12]

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

The act requires the DOH to establish the Office of Compassionate Use under the direction of the deputy state health officer to administer the act. 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.[13]
- Making any necessary application to the United States Food and Drug Administration 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.[14]

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;
- 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; and
- Appropriating $1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.

Challenges to Proposed DOH Rules

Beginning on July 7, 2014, the DOH held several rule workshops intended 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. 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 the Administrative Law Judge on November 14, 2014.[15] Afterward, the DOH held a

[12] Conversation with Jennifer Tschetter, Chief of Staff (DOH) (March 20, 2015).
[13] *See* s. 381.925, F.S.
[14] *See* s. 385.212, F.S.
[15] *See* https://www.doah.state.fl.us/ROS/2014/14004296.pdf (last accessed March 27, 2015).

negotiated rulemaking workshop in February of 2015, which resulted in a new proposed rule being published on February 6, 2015. The new proposed rule has also been challenged and a hearing is scheduled for April 14, 2015.[16] The challenge on the February 6, 2015, rule includes, among other things, a challenge of the DOH's statement of estimated regulatory costs (SERC) and the DOH's conclusion that the rule will not require legislative ratification.

Section 120.541, F.S., requires legislative ratification of rules that are likely to have an adverse impact on economic growth, private sector job creation or employment, or private sector investment in excess of $1 million in the aggregate within 5 years after the implementation of the rule. The DOH has estimated a 5-year regulatory cost totaling $750,000 on the five DOs. The Joint Administrative Procedures Committee has raised several questions regarding the DOH's estimate, including additional impacts for nurseries that are approved for more than one region, and the cost of the biennial renewal. If a rule exceeds the threshold amount, the rule may not take effect until it is ratified by the Legislature.

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,"[17] and places it, along with other sources of THC, on the list of Schedule I controlled substances.[18] The definition of cannabis was amended by the act to exclude "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. As a Schedule I controlled substance, possession and trafficking in cannabis carry criminal penalties that vary from a first degree misdemeanor[19] up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a $200,000 fine.[20] Paraphernalia[21] 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.[22]

[16] E-mail from Marjorie Holladay, Chief Attorney, Joint Administrative Procedures Committee, to Patrick Imhof, Staff Director, Senate Committee on Regulated Industries (March 19, 2015) (on file with the Senate Committee on Regulated Industries).
[17] Section 893.02(3), F.S.
[18] Section 893.03(1)(c)7. and 37., F.S.
[19] 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.
[20] 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.
[21] This term is defined in s. 893.145, F.S.
[22] Section 893.147, F.S.

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*[23] 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.

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[24] have some form of law that permits the use of marijuana for medicinal purposes. These laws vary widely in detail but most are similar in that they touch on several recurring themes. Most state laws include the following in some form:

- A list of medical conditions for which a practitioner can recommend the use of medical marijuana to a patient.
  - Nearly every state that permits the use of marijuana for medicinal purposes has a list of applicable medical conditions, though the particular conditions vary from state to state. Most states also include a way to expand the list either by allowing a state agency or board to add medical conditions to the list or by including a "catch-all" phrase.[25] Most states require that the patient receive certification from at least one, but often two, physicians designating that the patient has a qualifying condition before the patient may be issued an identification card needed for the acquisition of medical marijuana.
- Provisions for the patient to designate one or more caregivers who can possess the medical marijuana and assist the patient in preparing and using the medical marijuana.
  - The number of caregivers allowed and the qualifications to become a caregiver vary from state to state. Most states allow one or two caregivers and require that they be at least

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

[24] 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. The New York legislation became effective July 5, 2014. Eleven states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol). Alabama, Florida, Iowa, Kentucky, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Utah, and Wisconsin. *See* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited on March 27, 2015).

[25] An example is California's law that includes "any other chronic or persistent medical symptom that either: Substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans with Disabilities Act of 1990, or if not alleviated, may cause serious harm to the patient's safety or physical or mental health."

21 years of age and, typically, cannot be the patient's physician. Caregivers are generally allowed to purchase or grow marijuana for the patient, be in possession of the allowed quantity of marijuana, and aid the patient in using the marijuana, but are strictly prohibited from using the marijuana themselves.

- A required identification card for the patient, caregiver, or both that is typically issued by a state agency.
- A registry of people who have been issued an identification card.
- A method for registered patients and caregivers to obtain medical marijuana.
  - There are two general methods by which patients can obtain medical marijuana. They must either self-cultivate the marijuana in their homes or the state allows specified marijuana points-of-sale or dispensaries. The regulations governing such dispensaries vary widely.
- General restrictions on where medical marijuana may be used.
  - Typically, medical marijuana may not be used in public places, such as parks and on buses, or in areas where there are more stringent restrictions placed on the use of drugs, such as in or around schools or in prisons.

Most states with low-THC cannabis laws similar to s. 381.986, F.S., specify that the use of such low-THC cannabis is reserved for patients with epileptic or seizure disorders. Of the 11 states with such laws, only Florida allows the treatment of cancer with low-THC cannabis. Additionally, the definition of low-THC cannabis differs from state to state. Iowa has the highest THC level allowed in such states at 3 percent and most other states have the level of THC restricted to below 1 percent. CBD levels are generally required to be high with most states requiring at least 10 percent CBD.[26]

State Medical Marijuana Laws and Their Interaction with the Federal Government

The Federal Controlled Substances Act lists Marijuana as a Schedule 1 drug with no accepted medical uses. Under federal law possession, manufacturing, and distribution of marijuana is a crime.[27] Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under the guidelines established in that state, such laws do not protect individuals from prosecution under federal law if the federal government decides to enforce those laws.

In August 2013, the United States Justice Department (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century."[28] This document details the federal government's current stance on low-level drug crimes and contains the following passage:

> … the Attorney General is announcing a change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations,

[26] Supra note 24, table 2.
[27] The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. *See* http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm#cntlsbd. (last visited on March 27, 2015).
[28] *See* http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on March 27, 2015).

> gangs, or cartels, will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather than excessive prison terms more appropriate for violent criminals or drug kingpins.

In addition, the USDOJ published, on August 29, 2013, a memorandum with the subject "Guidance Regarding Marijuana Enforcement." This memorandum makes clear that the USDOJ considers small-scale marijuana use to be a state matter which states may choose to punish or not, and, while larger operations would fall into the purview of the USDOJ, those operations that adhere to state laws legalizing marijuana in conjunction with robust regulatory systems would be far less likely to come under federal scrutiny.[29] These announcements generally indicate the USDOJ's current unwillingness to prosecute such cases and its inclination to leave such prosecutions largely up to state authorities.

Tetrahydrocannabinol

THC is the major psychoactive constituent of marijuana. The potency of marijuana, in terms of psychoactivity, is dependent on THC concentration and is usually expressed as a percent of THC per dry weight of material.

The average THC concentration in marijuana is 1 percent to 5 percent; the form of marijuana known as *sinsemilla* is derived from the unpollinated female cannabis plant and is preferred for its high THC content (up to 17 percent THC). Recreational doses are highly variable and users often concentrate their own dose. A single intake of smoke from a pipe or joint is called a hit (approximately 1/20th of a gram). The lower the potency or THC content the more hits are needed to achieve the desired effects.[30]

Marinol is a currently-approved drug[31] that consists of a man-made form of THC known as dornabinol.[32] Marinol is used to treat anorexia associated with weight loss in patients with AIDS and nausea and vomiting associated with cancer chemotherapy in patients who have failed to adequately respond to conventional antiemetic treatments. Marinol has a variety of side-effects including a cannabinoid dose-related "high."[33]

Cannabidiol

CBD is another cannabinoid that is found in marijuana and, although THC has psychoactive effects, CBD and other cannabinoids are not known to cause intoxication.[34] Some evidence

---

[29] *See* USDOJ memo on "Guidance Regarding Marijuana Enforcement," (August 29, 2013) *available at* http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited on March 27, 2015).
[30] Drugs and Human Performance Fact Sheet for Cannabis / Marijuana, National Highway Traffic Safety Administration (April 2014) *available at* http://www.nhtsa.gov/people/injury/research/job185drugs/cannabis.htm (last visited on March 27, 2015).
[31] The drug is approved by the US Food and Drug Administration.
[32] *See* http://www.marinol.com/about-marinol.cfm (last visited on March 27, 2015).
[33] For Marinol prescribing information, *see* http://www.rxabbvie.com/pdf/marinol_PI.pdf (last visited on March 27, 2015).
[34] This information is from GW Pharmaceuticals, *see* http://www.gwpharm.com/FAQ.aspx (last visited on March 27, 2015).

shows that CBD is effective in treating seizure disorders,[35,36] although much of this evidence is anecdotal. Currently, the drug Epidiolex, which is a liquid form of highly purified CBD extract, was approved by the FDA in November 2013, as an orphan drug[37] that may be used to treat Dravet syndrome.[38,39]

Dravet Syndrome

Also known as Severe Myoclonic Epilepsy of Infancy (SMEI), Dravet syndrome is a rare form of intractable epilepsy that begins in infancy.[40] Initial seizures are most often prolonged events and, in the second year of life, other seizure types begin to emerge. Individuals with Dravet syndrome face a higher incidence of SUDEP (sudden unexplained death in epilepsy) and typically have associated conditions that also need to be properly treated and managed. These conditions include:

- Behavioral and developmental delays;
- Movement and balance issues;
- Orthopedic conditions;
- Delayed language and speech issues;
- Growth and nutrition issues;
- Sleeping difficulties;
- Chronic infections;
- Sensory integration disorders; and
- Disruptions of the autonomic nervous system (which regulates bodily functions such as temperature regulation and sweating).

Individuals with Dravet syndrome do not outgrow the condition. Current treatment options are extremely limited and constant care and supervision are typically required.

III. Effect of Proposed Changes:

CS/SB 7066 significantly revises the provisions of s. 381.986, F.S., related to the compassionate use of low-THC cannabis.

---

[35] *See* Saundra Young, *Marijuana Stops Child's Severe Seizures*, CNN (August 7, 2013) *available at* http://www.cnn.com/2013/08/07/health/charlotte-child-medical-marijuana/ (last visited on March 27, 2015).
[36] *See* also the presentation to the Florida House Criminal Justice Subcommittee on the Charlotte's Web strain of marijuana on January 9, 2014.
[37] An orphan drug is defined as a drug that is intended for the safe and effective treatment, diagnosis, or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. *See* http://www.fda.gov/forindustry/DevelopingProductsforrareDiseasesConditions/default.htm. (last visited on March 27, 2015).
[38] *See* http://www.gwpharm.com/LGS%20Orphan%20Designation.aspx (last visited on March 27, 2015).
[39] National Institute of Neurological Disorders and Stroke, *Dravet Syndrome Information Page*. *See* http://www.ninds.nih.gov/disorders/dravet_syndrome/dravet_syndrome.htm (last visited on March 27, 2015).
[40] Dravet Syndrome Foundation, *What is Dravet Syndrone?* http://www.dravetfoundation.org/dravet-syndrome/what-is-dravet-syndrome (last visited on March 27, 2015).

Patient Use of Low-THC Cannabis

The bill revises the conditions for which low-THC cannabis may be ordered for a qualified patient's medical use. A physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms no longer qualifies as an eligible condition. Along with cancer, the following additional conditions qualify for the ordering of low-THC cannabis to qualified patients:[41]

- Human immunodeficiency virus;
- Acquired immune deficiency syndrome;
- Epilepsy;
- Amyotrophic lateral sclerosis;
- Multiple sclerosis;
- Crohn's disease;
- Parkinson's disease;
- Paraplegia;
- Quadriplegia; or
- Terminal illness.

The bill also revises the definition of "medical use" of low-THC cannabis to exclude the use of or administration of low-THC cananbis:

- On any form of public transportation;
- In any public place;
- In a registered qualified patient's place of work, if restricted by his or her employer;
- In a correctional facility;
- On the grounds of any preschool, primary school, or secondary school; or
- On a school bus.

The bill provides that low-THC cannabis may be ordered to treat a listed disease, disorder, or condition; to alleviate symptoms of such disease, disorder, or condition; or to alleviate symptoms caused by a treatment for such disease, disorder, or condition.

Requirements for Physicians

The bill requires that the physician register the patient and the patient's legal representative, if requested by the patient, with the compassionate use registry established by the DOH. If the patient is a minor, the physician must register a legal representative with the registry.

The bill also requires physicians to submit all requested medical records to the UFCP for research on the safety and efficacy of low-THC cannabis on patients, in addition to the patient treatment plan currently required.

A physician who improperly orders low-THC cannabis is subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k), F.S., addressing grounds for discipline. The

[41] Anyone who fraudulently represents to a physician that he or she has at least one of the above conditions for the purpose of being ordered low-THC cannabis commits a first degree misdemeanor, which is punishable as provided in s. 775.082, F.S., or s. 775.083, F.S.; a sentence of a term of imprisonment up to 1 year may be imposed, along with a fine not to exceed $1,000.

bill also conforms the criminal penalties to the change in listed conditions required to qualify for low-THC cannabis for physicians and patients who fraudulent order or attempt to receive low-THC cannabis.

Duties and Powers of the Department

The bill increases the number of DO licenses from 5 to 20 and requires, if more than 20 applicants meet the licensure criteria, that the DOH must determine the licensees by lottery.

The bill amends s. 381.986(5)(b), F.S., to provide the following time frame for the issuance of DO licenses:

- Seven days after the effective date of the act the DOH must begin to accept applications for licensure and to review the applications to determine compliance with the license criteria;
- Within 10 days of receiving an application, the DOH must notify the applicant of any errors in the application;
- Applications for licensure must be filed with the DOH no later than 30 days after the effective date of this act; and
- All applications must be complete no later than 60 days after the effective date of this act.

The DOH must also use the same timeframes for the issuance of any additional licenses. The bill exempts the issuance of DO licenses by the DOH from s. 120.60, F.S., which provides the procedure for the issuance of licenses by the DOH and requires that a license application that is not approved or denied within 90 days of receipt of the completed license application is deemed approved.

Beginning March 15, 2016, and every six months thereafter, if all 20 licenses are not issued during the initial licensing period, the bill requires the DOH to issue additional licenses to qualified applicants up to the 20-organization maximum. If more applicants meet the licensure criteria than remaining available licenses, the DOH must determine the licensees by lottery.

The bill deletes the requirement that the DOH must approve five DOs with one in northwest Florida, one in northeast Florida, one in central Florida, one in southeast Florida, and one in southwest Florida. It also deletes the license criteria in current law.

Section 381.986(5)(c), F.S., specifies the identifying information that must be included in the initial licensure or renewal application.

Section 381.986(5)(d), F.S., provides the following fees:

- Initial application fee of $50,000.
- Initial license fee of $125,000.
- Biennial renewal fee of $125,000.

Section 381.986(5)(e), F.S., requires the DOH to inspect each DO's properties, cultivation facilities, processing facilities, and retail facilities before they begin operations. The DOH must conduct inspections at least once every 2 years after licensure, but may conduct additional announced or unannounced inspections, including follow-up inspections, at reasonable hours in order to ensure that such property and facilities maintain compliance with all applicable

requirements. The DO must make all facility premises, equipment, documents, low-THC cannabis, and low-THC cannabis products available to the DOH upon inspection. The DOH may test any low-THC cannabis or low-THC cannabis product in order to ensure that it is safe for human consumption and meets the testing requirements in s. 381.986(7), F.S.

Section 381.986(5)(f), F.S., provides the grounds for revoking, suspending, denying, or refusing to renew a license, and for imposing an administrative penalty not to exceed $10,000, including a violation of any provision in s. 381.986, F.S., failure to maintain the qualifications for a license, and endangering the health, safety, and welfare of a qualified patient.

Section 381.986(5)(g), F.S., requires the DOH to create a permitting process for all vehicles used by DOs to transport low-THC cannabis and low-THC products.

Dispensing Organization Applications

The bill amends ss. 381.986(6)(a)-(b), F.S., to detail the criteria for the issuance or renewal of a DO license. It requires the DOH to review all applications for completeness and to inspect the applicant's property and facilities to verify the authenticity of the information provided in, or in connection with, the application. It provides that an applicant authorizes the DOH to inspect his or her property and facilities for licensure by applying for the license.

The applicant must also have a $1 million performance and compliance bond, or other means of security deemed equivalent by the DOH, such as an irrevocable letter of credit or a deposit in a trust account or financial institution. The bond must be payable to the DOH, and posted once the applicant is approved as a DO. The purpose of the bond is to secure payment of any administrative penalties imposed by the DOH and any fees and costs incurred by the DOH regarding the DO license, such as the DO failing to pay 30 days after the fine or costs become final.

The DOs must also employ a medical director who is a physician licensed under ch. 458, F.S., or ch. 459, F.S., to supervise the activities of the DO.

An approved DO is required to maintain compliance with the license criteria at all times.

Dispensing Low-THC Cannabis and Products

Section 381.986(6)(c), F.S., requires DOs to verify the identity of the qualified patient or the legal representative before dispensing low-THC cannabis or low-THC product by requiring the person to produce a government issued identification.

Section 381.986(6)(d), F.S., permits DOs to have cultivation facilities, processing facilities, and retail facilities.

The bill preempts to the state all matters regarding the location of cultivation facilities and processing facilities. It requires that cultivation facilities and processing facilities must be closed to the public, and low-THC cannabis may not be dispensed on the premises of such facilities.

The bill requires that a municipality or county determine by ordinance the criteria for the number, location, and other permitting requirements for all retail facilities located within that municipality or the unincorporated area of that county, respectively. A retail facility may only be established after a municipality or county has adopted such an ordinance. The bill states that retail facilities must have all utilities and resources necessary to store and dispense low-THC cannabis and low-THC cannabis products and that retail facilities must be secured and have theft-prevention systems including an alarm system, cameras, and 24-hour security personnel.

Section 381.986(6)(e), F.S., requires that a DO provide the DOH with the following information within 15 days of such information becoming available:

- The location of any new or proposed facilities;
- Updated contact information for all DO facilities;
- Registration information for any vehicles used for the transportation of low-THC cannabis and low-THC cannabis product; and
- A plan for the recall of any or all low-THC cannabis or low-THC cannabis product.

Section 381.986(6)(f), F.S., requires that all vehicles used to transport all low-THC cannabis or low-THC cannabis products must have a permit issued by the DOH. The cost of the permit is $5. The permit must be in the vehicle whenever low-THC cannabis or low-THC cannabis products is being transported. The vehicle must be driven by the person identified in the permit. By acceptance of a DO license and the use of the vehicles, the licensee agrees that the vehicle shall always be subject to be inspected and searched without a search warrant, for the purpose of ascertaining that the licensee is complying with all provisions of the act. The inspection may be made during business hours or other times the vehicle is being used to transport low-THC cannabis or low-THC cannabis products.

Testing and Labeling of Low-THC Cannabis

The bill creates s. 381.986(7), F.S., to require that all low-THC cannabis and low-THC cannabis products must be tested by an independent testing laboratory before the DO may dispense it. The independent testing laboratory shall provide the lab results to the DO, and the DO must determine that the lab results indicate that the low-THC cannabis or low-THC cannabis products meet the definition of low-THC cannabis or low-THC cannabis product, is safe for human consumption, and is free from harmful contaminants before it can be given to a patient.

The bill requires that all low-THC cannabis and low-THC cannabis products must be labeled before dispensing, and specifies the information that must be included on the label, including the batch and harvest numbers.

Safety and Efficacy Research for Low-THC Cannabis

The bill creates s. 381.986(8), F.S., to require the UFCP to establish and maintain a safety and efficacy research program for the use of low-THC cannabis or low-THC cannabis products to treat qualifying conditions and symptoms. The bill requires that the DOH provide the UFCP with access to information from the compassionate use registry and the PDMP database, established in s. 893.055, F.S., as needed to conduct research. The Agency for Healthcare Administration

must also provide access to registered patient Medicaid records, to the extent allowed under federal law, as needed to conduct research.

Exemptions to Other Laws

The bill amends s. 381.986(9), F.S., to exempt the following persons from the prohibition against the possession of the controlled substance cannabis in ss. 893.13, 893.135, and 893.147, F.S., or any other provision of law:

- The patient's qualified representative who is registered with the DOH on the compassionate use registry as a condition to having legal possession of low-THC cannabis;
- The owners, managers, and employees of contractors of a DO who have direct contact with low-THC cannabis or low-THC cannabis products; and
- A licensed laboratory and its employees who receive and possess low-THC cannabis for the sole purpose of testing to ensure compliance.

The bill clarifies that nothing in s. 381.986, F.S., exempts any person form the prohibition against driving under the influence in s. 326. 193, F.S.

Legislative Ratification

The bill creates s. 381.986(10), F.S., to exempt rules of the DOH under this section from the ratification requirements of s. 120.541(3), F.S.

Public Records Exceptions

The bill revises the public records exemption relating to the compassionate use registry in s. 381.987, F.S., to permit UF employees to have access to the compassionate use registry for the purpose of maintaining the registry and periodic reporting or disclosure of information that has been redacted to exclude personal identifying information. It also permits persons engaged in research at the UF pursuant to s. 381.986(8), F.S., to have access to the registry.

The bill amends the public records exemption for the PDMP in ss. 893.055 and 893.0551, F.S., to permit persons engaged in research at the UF pursuant to s. 381.986(8), F.S., to have access to information in the prescription drug monitoring program's database which relates to qualified patients as defined in s. 381.986(1), F.S., for the purpose of conducting research.

Effective Date

The bill is effective upon becoming 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:

Persons who apply for a DO license will incur costs in the preparation of the application. A DO must pay the fees required for applying for and obtaining a license.
Section 381.986(5)(d), F.S., provides the following fees:

- Initial application fee of $50,000;
- Initial license fee of $125,000; and
- Biennial renewal fee of $125,000.

Section 381.986(6)(f), F.S., requires that all vehicles used to transport all low-THC cannabis or low-THC cannabis products must have a permit issued by the DOH, and the permit cost is $5.

B. Private Sector Impact:

CS/SB 7066 requires that all persons who have a direct or indirect interest in the DO and the applicant's managers, employees, and contractors who directly interact with low-THC cannabis or low-THC cannabis products must be fingerprinted and successfully pass a level 2 background screening pursuant to s. 435.04, F.S. The amount of the fee for fingerprinting varies by vendor. For example, the Department of Business and Professional Regulation assesses a total fee of $54.50, which includes a $40.50 payment to the Florida Department of Law Enforcement and the Federal Bureau of Investigation to process the fingerprints, and an additional $14.00 processing charge to have the fingerprints scanned and submitted electronically.

DOs may incur regulatory costs once licensed including costs for any violations for which they may be fined and costs for testing low-THC cannabis and low-THC cannabis product. A DO is also required to post a $1 million bond which will cover the costs of fines incurred from cited violations.

C. Government Sector Impact:

The DOH must accept and review applications for approval of licensure as a DO. Depending on the number of qualified applicants, a lottery may be needed to determine the selection of the qualified applicants for the 20 available licenses to be issued to DOs. The DOH may also incur costs for rulemaking and for the requirement to inspect DO facilities at least once every 2 years.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.986, 381.987, 893.055, and 893.0551.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 31, 2015:
The CS incorporates a number of amendments which:

- Allow municipalities to determine by ordinance the number and location of retail facilities within the municipality's boundaries and allow counties to determine the number and location of retail facilities within unincorporated areas of the county;
- Clarify that the DOH must use the same timeframes for future DO licensing cycles and lotteries as will be used for the first licensure cycle;
- Clarify that retail facilities must have all utilities and resources necessary to store and dispense low-THC cannabis and low-THC cannabis products and that retail facilities must be secured and have certain theft-prevention systems;
- Clarify that all law enforcement officials may stop and inspect permitted dispensing organization vehicles;
- Clarify that patients using low-THC cannabis must adhere to laws regarding driving under the influence; and
- Make several technical amendments including:
  - Correcting a drafting error so that a dispensing organization is run by a nurseryman and has been operated as a nursery for 30 years; and
  - Correcting a reference to low-THC cannabis.

B. Amendments:

None.