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 Regulated Industries

BILL:	SPB 7066
INTRODUCER:	For consideration by the Regulated Industries Committee
SUBJECT:	Low-THC Cannabis
DATE:	March 23, 2015
REVISED:	3/23/15

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kraemer/Oxamendi	Imhof		**Pre-meeting**

I. Summary:

SPB 7066 revises the requirement for the licensing of dispensing organizations to permit the cultivation, processing, and dispensing of low-THC cannabis and low-THC cannabis products. The bill revises the conditions for which low-THC cannabis or low-THC cannabis products may be ordered for a qualified patient's medical use to include: human immunodeficiency virus, acquired immune deficiency syndrome, epilepsy, amyotrophic lateral sclerosis, multiple sclerosis, Crohn's disease, Parkinson's disease, paraplegia, quadriplegia, and terminal illness. The bill also permits the use of low-THC cannabis and low-THC cannabis products to alleviate symptoms caused by a treatment of these diseases, disorders, or conditions.

In addition to registration of the physician ordering the low-THC cannabis and of the qualified patient, the bill requires that the physician register the patient's legal representative upon the request of the patient, on the Compassionate Use Registry maintained by the Florida Department of Health (DOH). If the patient is a minor, the physician is required to register a legal representative on the compassionate use registry.

The bill provides the following time frame for the issuance of dispensing organization 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 bill limits the number of dispensing organization licenses to 20 licenses. If more than 20 applicants meet the licensure criteria, licensure is determined by lottery.

Beginning March 15, 2016, 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 there are more qualified applicants than available licenses to be issued, licensure is required by lottery.

The bill specifies additional licensing criteria for dispensing organization, including having experience cultivating and introducing multiple varieties of plants in this state, including plants that are not native to Florida, propagating plants; and genetic modification or breeding of plants. The bill also requires that dispensing organizations have the capability to serve at least 15,000 patients with an assumed daily use of 1,000 mg per patient per day of low-THC cannabis or low-THC cannabis products. The bill also provides specific criteria for financial disclosures, security and safety systems, and diversion and tracking prevention procedures.

The bill provides an initial application fee of $50,000, an initial license fee of $125,000, and a biennial renewal fee of $125,000.

The bill requires the inspection of each dispensing organization's properties, cultivation facilities, processing facilities, and retail facilities before they begin operations, inspections at least once every 2 years after licensure, and authorizes additional announced or unannounced inspections, including follow-up inspections, at reasonable hours in order to ensure compliance with all applicable requirements.

The bill 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.

The bill requires that all vehicles used by dispensing organizations to transport low-THC cannabis and low-THC products have a permit. It also provides that acceptance of the license and the permit are consent to search the vehicle by the department and law enforcement.

The bill also requires that dispensing organizations verify the identity of the qualified patient or the legal representative before dispensing low-THC cannabis or low-THC products by requiring the person to produce a government issued identification.

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 county determine by ordinance the criteria for the number, location, and other permitting requirements for all retail facilities located within that county. A retail facility may only be established after a county has adopted such an ordinance.

The bill requires that all low-THC cannabis and low-THC cannabis products must be tested by an independent testing laboratory before being dispensed.

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

The bill revises the public records exemption relating to the compassionate use registry in s. 381.987, F.S., to permit employees of the University of Florida 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, and for research.

The bill is effective upon becoming law.

II. Present Situation:

Compassionate Medical Cannabis Act of 2014

Pursuant to the Compassionate Medical Cannabis Act of 2014,[1] (the act), "low-THC cannabis," may be dispensed by an authorized and licensed dispensing organization. The physical manifestation of low-THC cannabis" is 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.[2]

The act provides that a physician licensed under ch. 458, F.S., or ch. 459, F.S.,[3] who has examined and is treating a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may order for the patient's medical use[4] low-THC cannabis to treat such disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for that patient and all of the following conditions apply:[5]

- 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; if a patient is younger than 18 years of age, a second

[1] *See* ch. 2014-157, L.O.F.
[2] *See* s. 381.986(1)(b), F.S.,
[3] 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.
[4] Pursuant to 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] *See* s. 381.986(2), F.S.

physician must concur with this determination, and such determination must be documented in the patient's medical record;

- The physician registers as the orderer of low-THC cannabis for the patient on the compassionate use registry maintained by DOH and updates the registry to reflect the contents of the order; the patient's registration must be deactivated by the physician when treatment is discontinued;
- 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 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.
- Pursuant to s. 381.986(3), F.S., a physician commits a misdemeanor of the first degree,[6] if the physician orders low-THC cannabis for a patient without a reasonable belief that the patient is suffering from:
    - Cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be treated with low-THC cannabis; or
    - Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis.

Any person who fraudulently represents that he or she has cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms to a physician for the purpose of being ordered low-THC cannabis by such physician commits a misdemeanor of the first degree.[7]

A dispensing organization is required to employ 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.[8]

The act authorizes one dispensing organization in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida and southwest Florida, for a total of five statewide.[9] The criteria for approval as a dispensing organization include possessing 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, have been operating as a

[6] A misdemeanor of the first degree 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 one year may be imposed, along with a fine not to exceed $1,000.
[7] *See* note 6 supra.
[8] *See* s. 381.986(4) and (5), F.S.
[9] *See* s. 381.986(5)(b), F.S.

registered nursery in this state for at least 30 continuous years, and provide certified financials.[10] Upon approval, a dispensing organization must post a $5 million performance bond.[11]

The act requires the Department of Health (DOH) to accomplish the following by January 1, 2015:

- Create a secure, electronic, and online registry for the registration of physicians and patients and for the verification of patient orders by dispensing organizations, which is accessible to law enforcement. The registry must allow dispensing organizations to record the dispensation of low-THC cannabis, and must prevent an active registration of a patient by multiple physicians.
- Authorize at least one, but no more than four, dispensing organizations to ensure reasonable statewide accessibility and availability of low-THC cannabis as necessary.
- Develop an application form and impose initial and biennial renewal fees sufficient to cover the costs of administering its responsibilities.
- Require any applicant seeking licensure as a dispensing organization to demonstrate the:
  - Technical and technological ability to cultivate and produce low-THC cannabis;
  - Ability to secure the premises, resources, and personnel necessary to operate;
  - Ability to maintain accountability of all cannabis-related products and to prevent diversion of those substances;
  - Existence of infrastructure reasonably located to dispense low-THC cannabis statewide or regionally, as determined by the DOH;
  - Financial ability to maintain operations throughout the two-year licensure cycle;
  - Passage by all owners, managers, and employees of level 2 background screening; and
  - Necessary compliance with additional criteria determined by the DOH as necessary to safely function as a dispensary.
- Monitor physician registration and ordering of low-THC cannabis in order to take disciplinary action as needed.
- Implement a process for issuing identification cards to patients registered in the compassionate use registry which expire one year after the date issued; new identification cards may be issued to a patient who continues to be registered and is being treated with low-THC cannabis.
- Monitor and inspect the activities of each licensed dispensing organization for compliance with the requirements of this section of law; and
- Adopt rules necessary to implement the act.

As required by the act, the DOH established an 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.[12]

[10] *See* s. 381.986(5)(b)1., F.S.
[11] *See* s. 381.986(5)(b)5., F.S.
[12] *See* s. 381.925, F.S.

- 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
- Enter into agreements necessary to facilitate enhanced access to compassionate use for Florida patients.[13]

A dispensing organization must comply with all listed criteria for approval at all times and must verify before dispensing any low-THC cannabis that a patient has an active registration, and that the patient's order matches the one recorded on the registry and has not yet been filled.[14] When a dispensing organization dispenses low-THC cannabis, the date, time, quantity, and form of the cannabis dispensed must be recorded.[15]

The act creates exceptions to existing law to allow qualified patients[16] 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, 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. Dispensing organizations and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.[17]

The act addresses refractory and intractable epilepsy treatment and research, and provides funding for research of cannabidiol and its effect on intractable childhood epilepsy.[18]
The administrative rules proposed by DOH were challenged, and a hearing was held before the Division of Administrative Hearings; a Final Order was issued,[19] finding that various rules were invalid exercises of delegated legislative authority. Subsequently, negotiated rulemaking was undertaken in February 2015; a rule challenge has been filed but is not scheduled to be heard until April 14, 2015.[20]

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 dispensing organization. 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.

---

[13] *See* s. 385.212, F.S.
[14] *See* s. 381.986(6), F.S.
[15] *Id.*
[16] *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 dispensing organization.
[17] *See* s. 381.986(7)(c), F.S.
[18] *See* s. 385.211, F.S., and s. 1004.441, F.S.
[19] *See* https://www.doah.state.fl.us/ROS/2014/14004296.pdf (last accessed March 22, 2015).
[20] Email from Marjorie Holladay, Chief Attorney of the Joint Administrative Procedures Committee, to Patrick Imhof (March 19, 2015) (on file with the Senate Committee on Regulated Industries).

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,"[21] and places it, along with other sources of THC, on the list of Schedule I controlled substances.[22] 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[23] up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a $200,000 fine.[24] Paraphernalia[25] 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.[26]

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*[27] 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.

[21] Section 893.02(c), F.S.
[22] Section 893.03(c)7. and 37., F.S.
[23] 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.
[24] 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.
[25] This term is defined in s. 893.145, F.S.
[26] Section 893.147, F.S.
[27] 582 So.2d 676 (Fla. 1st DCA 1991), *review denied*, 589 So.2d 292 (Fla. 1991)

Medical Marijuana Laws in Other States

Currently, 23 states, the District of Columbia, and Guam [28] 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.[29] 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 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.

[28] 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 on July 5, 2014. *See* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited on March 22, 2015).

[29] 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."

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.[30] 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."[31] 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, 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.[32] 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

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

[30] 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 22, 2015).
[31] *See* http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on March 22, 2015).
[32] *See* USDOJ memo on "Guidance Regarding Marijuana Enforcement," August 29, 2013, available at http://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf (last visited on March 22, 2015).

(approximately 1/20th of a gram). The lower the potency or THC content the more hits are needed to achieve the desired effects.[33]

Marinol is a currently-approved drug[34] that consists of a man-made form of THC known as dornabinol.[35] 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."[36]

Cannabidiol

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.[37] Some evidence shows that CBD is effective in treating seizure disorders,[38,39] 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[40] that may be used to treat Dravet syndrome.[41,42]

Dravet Syndrome

Also known as Severe Myoclonic Epilepsy of Infancy (SMEI), Dravet syndrome is a rare form of intractable epilepsy that begins in infancy.[43] 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;

---

[33] Drugs and Human Performance Fact Sheet for Cannabis / Marijuana, National Highway Traffic Safety Administration, available at http://www.nhtsa.gov/people/injury/research/job185drugs/cannabis.htm (last visited on March 22, 2015).
[34] The drug is approved by the US Food and Drug Administration.
[35] *See* http://www.marinol.com/about-marinol.cfm (last visited on March 22, 2015).
[36] For Marinol prescribing information, *see* http://www.rxabbvie.com/pdf/marinol_PI.pdf (last visited on March 22, 2015).
[37] This information is from GW Pharmaceuticals, *see* http://www.gwpharm.com/FAQ.aspx (last visited on March 22, 2015).
[38] *See* http://www.cnn.com/2013/08/07/health/charlotte-child-medical-marijuana/ (last visited on March 22, 2015).
[39] *See* also the presentation to the Florida House Criminal Justice Subcommittee on the Charlotte's Web strain of marijuana on January 9, 2014.
[40] 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 22, 2015).
[41] *See* http://www.gwpharm.com/LGS%20Orphan%20Designation.aspx (last visited on March 22, 2015).
[42] Dravet syndrome is a rare form of childhood epilepsy. *See* http://www.ninds.nih.gov/disorders/dravet_syndrome/dravet_syndrome.htm (last visited on March 22, 2015).
[43] Dravet Syndrome Foundation, http://www.dravetfoundation.org/dravet-syndrome/what-is-dravet-syndrome (last visited on March 22, 2015).

- 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:

Cultivation, Processing, and Dispensing Low-THC Cannabis

SPB 7066 provides for the cultivation, processing, and dispensing of low-THC cannabis, and licensure of dispensing organizations, including:

- The identification of a harvest as a specifically identified and numbered quantity of low-THC cannabis cultivated using the same herbicides, pesticides, and fungicides, and harvested at the same time from a single facility; and
- The identification of a low-THC cannabis product as any product derived from low-THC cannabis, including the resin extracted from any part of such plant or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin which is dispensed from a dispensing organization; such products include, but are not limited to, oils, tinctures, creams, encapsulations, and food products, which must maintain concentrations, weight for weight, of 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol.

Medical use of low-THC cannabis does not include the use of or administration of medical-grade marijuana:

- 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 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:[44]

- Human immunodeficiency virus;
- Acquired immune deficiency syndrome;

[44] 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 one year may be imposed, along with a fine not to exceed $1,000.

- Epilepsy;
- Amyotrophic lateral sclerosis;
- Multiple sclerosis;
- Crohn's disease;
- Parkinson's disease;
- Paraplegia;
- Quadriplegia; or
- Terminal illness.

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

Requirements for Physicians

In addition to registration of the physician as the orderer of low-THC cannabis, the bill requires that the physician register the patient and the patient's legal representative if requested by the patient. If the patient is a minor, the physician must register a legal representative on the compassionate use registry.

Physicians must submit any other requested medical records to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis on patients, in addition to the patient treatment plan currently required.

A patient's voluntary informed consent (or the consent of the patient's legal representative) must address the effectiveness of treatment with low-THC cannabis of not only the patient's condition, but all the patients conditional or symptoms.

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 bill provides that a physician commits a misdemeanor of the first degree,[45] if the physician orders low-THC cannabis for a patient without a reasonable belief that the patient is suffering from at least one of the following conditions:

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

[45] A misdemeanor of the first degree 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 one year may be imposed, along with a fine not to exceed $1,000.

- Terminal illness.

Duties and Powers of the Department

The bill amends s. 381.986(5)(b), F.S., to provide the following time frame for the issuance of dispensing organization 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 bill limits the number of dispensing organization licenses to 20 licenses. If more than 20 applicants meet the licensure criteria, the DOH must determine the licensees by lottery.

Beginning March 15, 2016, 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 than 20 applicants meet the licensure criteria, the DOH must determine the licensees by lottery.

The bill exempts the issuance of dispensing organization 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.

The bill deletes the requirement that the DOH must approve five dispensing organization licenses, and the issuance of the licenses to 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 dispensing organization'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 dispensing organization 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 dispensing organizations to transport low-THC cannabis and low-THC products.

Dispensing Organization

The bill amends ss. 381.986(6)(a)-(b), F.S., to detail the criteria for the issuance or renewal of a dispensing organization 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 bill specifies the proof that the applicant must submit to the DOH to receive or renew a dispensing organization license, including:

- The applicant, or a separate entity that is owned solely by the same persons or entities in the same ratio as the applicant, possesses a valid certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants;
- The applicant's land is operated by a nurseryman as defined in s. 581.011, F.S.;
- The land has been operated as a registered nursery in this state for at least 30 continuous years;
- The applicant has experience cultivating and introducing multiple varieties of plants in this state, including plants that are not native to Florida, propagating plants; and genetic modification or breeding of plants;
- The applicant has at least one person on staff or under contract who has the specified experience, including analytical laboratory quality control measures, chain of custody procedures, and inventory control;
- All persons with a direct or indirect interest in the applicant as well as the applicant's owners, managers, employees, and any contractors who directly interact with low-THC cannabis or low-THC cannabis product have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04, F.S.;
- The applicant owns, or has at least a 2-year long-term lease of, all properties, facilities, and equipment necessary for the cultivation and processing of low-THC cannabis.
- The applicant has the capability to serve at least 15,000 patients with an assumed daily use of 1,000 mg per patient per day of low-THC cannabis or low-THC cannabis product;
- The applicant's facility is secured and has theft-prevention systems including an alarm system, cameras, and 24-hour security personnel;
- The applicant's has diversion and tracking prevention procedures;

- The applicant has financial documentation with the specified information, including the applicant's assets, credit, and projected revenues.

The applicant must also have a $1 million performance and compliance bond, or other equivalent 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 dispensing organization. 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 dispensing organization license, such as the dispensing organization failing to pay 30 days after the fine or costs become final.

The dispensing organizations 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 dispensing organization.

An approved dispensing organization 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 dispensing organizations 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 dispensing organizations 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 county determine by ordinance the criteria for the number, location, and other permitting requirements for all retail facilities located within that county. A retail facility may only be established after a county has adopted such an ordinance.

Section 381.986(6)(e), F.S., requires that a dispensing organization 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 dispensing organization 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 dispensing organization 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 dispensing organization may dispense it. The independent testing laboratory shall provide the lab results to the dispensing organization, and the dispensing organization 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 University of Florida College of Pharmacy 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 University of Florida College of Pharmacy with access to information from the compassionate use registry and the prescription drug monitoring database, established in s. 893.055, F.S., as needed to conduct research. The Agency for Health Care 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)(a), 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 dispensing organization 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.

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 employees of the University of Florida 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 University of Florida pursuant to s. 381.986(8), F.S., to have access to the registry.

The bill amends the public records exemption for the prescription drug monitoring program in ss. 893.055 and 893.0551, F.S., to permit persons engaged in research at the University of Florida 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 dispensing organization license will incur costs in the preparation of the application. A dispensing organization 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:

The bill requires that all persons who have a direct or indirect interest in the dispensing organization 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.[46]

C. Government Sector Impact:

The Department of Health must accept and review applications for approval of licensure as a dispensing organization. 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 dispensing organizations. The DOH may also incur costs for rulemaking.

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

None.

B. Amendments:

None.

[46] *See* Department of Business and Professional Regulation, *How much does electronic fingerprinting cost?*, (last visited March 22, 2015).