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 Criminal Justice

BILL: CS/SB 1030

INTRODUCER: Health Policy Committee and Senators Bradley, Bean, Brandes, and others

SUBJECT: Low-THC Marijuana and Cannabis

DATE: March 21, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Erickson	Cannon	CJ	**Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1030 creates s. 456.60, F.S., in order to allow the compassionate use of low-THC marijuana. The bill allows certain patients whose Florida licensed physician registers them with the Department of Health (DOH) to use low-THC marijuana under limited circumstances. The bill defines low-THC marijuana as containing no more than .5 percent of tetrahydrocannabinol (THC) and at least 15 percent of cannabidiol (CBD).

Physicians may only register patients with severe and chronic seizures or muscle spasms who they have treated for 6 or more months and they must adhere to a number of requirements including keeping a plan of treatment for that patient and monitoring the patient's use of the low-THC marijuana. Patients who are ordered low-THC marijuana by their physician are added to a registry that is created and maintained by the DOH. Such patients may only purchase or acquire low-THC marijuana in the amount ordered by their physician and only from a dispensing organization that is approved by the DOH.

The bill establishes a number of criteria that an organization must meet and continuously adhere to in order to be approved by the DOH as a dispensing organization. The DOH is required to approve at least one, but no more than four, such organizations.

The bill also exempts patients and their legal representatives from the legal restrictions on purchasing, acquiring, possession, and medical use of low-THC marijuana in other parts of the Florida Statutes. Approved dispensing organizations, including its owners, managers, and

employees are exempted from such legal restrictions for the cultivation, production, possession, and sale of low-THC marijuana and for possessing and disposing of any byproducts of such cultivation and production.

II. Present Situation:

Treatment of Marijuana in Florida

Florida law defines Cannabis as "all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin"[1] and places it, along with other sources of THC, on the list of Schedule 1 controlled substances.[2] Schedule 1 controlled substances are substances that have a high potential for abuse and no currently accepted medical use in treatment in the United States. As a Schedule 1 controlled substance, possession and trafficking in cannabis carry criminal penalties that vary from a first degree misdemeanor[3] up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a $200,000 fine.[4] Paraphernalia[5] 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.[6]

Medical Marijuana in Florida – the Necessity Defense

Despite the fact that the use, possession, and sale of marijuana is prohibited by state law, Florida courts have found that circumstances can necessitate medical use of marijuana and circumvent the application of any criminal penalties. The necessity defense was successfully applied in a marijuana possession case in *Jenks v. State*[7] 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 First District found that the Jenks met the criteria for

[1] Section 893.02(c), F.S.
[2] Section 893.03(c)7. and 37., F.S.
[3] 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.
[4] 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.
[5] This term is defined in s. 893.145, F.S.
[6] Section 893.147, F.S.
[7] 582 So.2d 676 (Fla. 1st DCA 1991), *review denied*, 589 So.2d 292 (Fla. 1991)

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, 20 states and the District of Columbia[8] 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 has a list of 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.[9] 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 ID card.
- 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 ID card.
- A method for registered patients and caregivers to obtain medical marijuana.
  - There are two general methods by which patients can obtain medical marijuana: either they must 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.

[8] These states include Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois (effective 2014), Maine, Maryland, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and Illinois was the most recent state to pass medical marijuana legislation in August of 2013. Illinois legislation became effective in January, 2014. See http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx. (last visited on March 19, 2014).

[9] 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.[10] Although state 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 should the federal government choose to enforce those laws.

In August of 2013, the United States Justice Department (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century." [11] This document details the federal government's changing stance on low-level drug crimes 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 made clear that the USDOJ considered small-scale marijuana use to be a state matter which the 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 states that have robust regulatory systems for such laws would be far less likely to come under federal scrutiny.[12] These announcements generally indicate the USDOJ's relative unwillingness to prosecute such cases leaving such prosecutions largely up to state authorities.

Tetrahydrocannabinol

Tetrahydrocannabinol, or 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 percent of THC per dry weight of material.

> Average THC concentration in marijuana is 1-5 percent and 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 titer 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.[13]

[10] 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 19, 2014).
[11] See http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on March 19, 2014).
[12] 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 19, 2014).
[13] 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 19, 2014).

Marinol is a currently approved drug[14] that consists of a man-made form of THC known as dornabinol.[15] 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."[16]

Cannabidiol

Cannabidiol, or 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.[17] There is some evidence that shows that CBD is effective in treating seizure disorders,[18,19] although much of this evidence is anecdotal. Currently, the drug Epidiolex, which is a liquid form of highly purified CBD extract, has been approved by the FDA in November 2013, as an orphan drug[20] that may be used to treat Dravet syndrome.[21,22]

III. Effect of Proposed Changes:

Section 1 of the bill creates s. 456.60, F.S., to allow the compassionate use of low-THC marijuana. The bill:

- Defines the terms:
  - "Dispensing organization" to mean an organization approved by the DOH to cultivate, process, and dispense low-THC marijuana;
  - "Low-THC marijuana" to mean a substance that contains no more than .5 percent of any THC and at least 15 percent of CBD and which is dispensed from a dispensing organization;
  - "Medical use" to mean the administration of the ordered amount of low-THC marijuana with the exception of possession, use, or administration by smoking and the transfer of low-THC marijuana to a person other than the qualified patient or his or her legal representative;
  - "Qualified patient" to mean a Florida resident who has been added to the compassionate use registry by a Florida licensed physician; and
  - "Smoking" to mean burning or igniting a substance and inhaling the smoke. The term smoking does not include the use of a vaporizer.

[14] The drug is approved by the US Food and Drug Administration.
[15] See http://www.marinol.com/about-marinol.cfm (last visited on March 19, 2014).
[16] For Marinol prescribing information, see http://www.rxabbvie.com/pdf/marinol_PI.pdf (last visited on March 19, 2014).
[17] This information is from GW Pharmaceuticals, see http://www.gwpharm.com/FAQ.aspx (last visited on March 19, 2014).
[18] See http://www.cnn.com/2013/08/07/health/charlotte-child-medical-marijuana/ (last visited on March 19, 2014).
[19] See also the presentation to the Florida House Criminal Justice Subcommittee on the Charlotte's Web strain of marijuana on January 9, 2014.
[20] 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 19, 2014).
[21] See http://www.gwpharm.com/LGS%20Orphan%20Designation.aspx (last visited on March 19, 2014).
[22] 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 19, 2014).

- Allows Florida licensed physicians to order low-THC marijuana for a patient suffering from a physical medical condition, or treatment for a medical condition, that chronically produces symptoms of seizure or severe and persistent muscle spasms. The physician may only order low-THC marijuana if:
  - The physician has tried alternate treatment options and there are no satisfactory alternative treatments to eliminate the patient's symptoms;
  - The patient is a permanent resident of Florida;
  - The physician has treated the patient for his or her symptoms for at least 6 months;
  - The physician, along with a second physician for patients under the age of 18, determines the risk of ordering low-THC marijuana are reasonable;
  - The physician registers as the orderer for the named patient on the registry, updates the registry with the order's contents, and deactivates the patient's registration 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 marijuana; and
  - The physician submits the treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of the low-THC marijuana.
- Requires the DOH to:
  - Create a secure, electronic, and online registry for the registration of physicians and patients which must be able to be accessed by law enforcement and the dispensing organization in order to verify patient orders. The dispensing organization must be able to record the low-THC marijuana dispensed and the registry 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 marijuana as necessary. The DOH must develop an application form and impose initial and biennial renewal fees that are sufficient to cover the costs of administering their responsibilities under this section. An applicant for approval as a dispensing organization must be able to show:
    - The technical and technological ability to cultivate and produce low-THC marijuana;
    - The ability to secure the premises, resources, and personnel necessary to operate;
    - The ability to maintain accountability of all marijuana related products and to prevent diversion of those substances;
    - An infrastructure reasonably located to dispense low-THC marijuana statewide or regionally as determined by the DOH;
    - The financial ability to maintain operations for the duration of the 2-year cycle;
    - That all owners, managers, and employees have been fingerprinted and passed a level II background screening; and,
    - Any additional criteria determined by the DOH to be needed to safely implement the section.
    - Monitor physician registration and ordering of low-THC marijuana in order to be able to take disciplinary action as needed.
- Requires a dispensing organization to maintain compliance with all listed criteria for approval at all times and to verify before dispensing any low-THC marijuana that a patient has an active registration and that the patient's order matches the one recorded on the registry

and has not already been filled. When the dispensing organization dispenses any low-THC marijuana it must record the date, time, quantity, and form of the marijuana dispensed.

- Creates exceptions from all other sections of law for:
  - Qualified patients and their legal representatives to purchase, acquire, and possess for that patient's medical use up to the ordered amount of low-THC marijuana;
  - Dispensing organizations, including their owners, managers, and employees to acquire, possess, cultivate, and dispose of excess product in reasonable quantities to produce low-THC marijuana and for such organizations to possess, process, and dispense low-THC marijuana. The bill also clarifies that dispensing organizations and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.

Section 2 of the bill amends s. 893.02, F.S., to exempt from the definition of "cannabis" any plant of the genus *Cannabis* that contains 0.5 percent or less of THC and more than 15 percent of CBD; the seeds of such plant; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such a plant or it's seeds or resin, if possessed or used in conformance with the newly created s. 456.60, F.S. This exemption, in effect, legalizes the plants, seeds, resins, and materials that conform to the exemption.

Section 3 of the bill establishes an effective date of July 1, 2014.

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:

None.

B. Private Sector Impact:

The bill may have a positive fiscal impact on the private sector organizations that are approved by the DOH to become dispensing organizations.

C. Government Sector Impact:

DOH Impact

The DOH will require $120,000 to fund the creation of the compassionate use registry and will require further funds to maintain the registry, as well as approve and monitor the dispensing organizations.[23] However, these costs should be funded from the initial and license renewal fees charged to the dispensing organizations.

The DOH will incur a recurring increase in workload associated with monitoring physician registration and prescribing of medical-grade marijuana. The impact is indeterminate at this time, therefore, the fiscal impact cannot be calculated.

The DOH may experience a recurring increase in workload associated with the enforcement and regulation of this legislation. The impact is indeterminate at this time, therefore, the fiscal impact cannot be calculated.

The DOH will incur non-recurring costs for rulemaking, which current budget authority is adequate to absorb.

FDLE and County Crime Lab Impact

The Florida Department of Law Enforcement (FDLE) states that the definition change to the term "cannabis" in Section 2 of the bill will require the FDLE to analyze all cannabis samples confiscated in order to prove that they are not exempt under the new definition. To do so will create an increased workload and the FDLE will require 25 new Crime Lab Analysts and at least 10 additional Gas Chromatographs to perform the additional analyses. The FDLE will incur an estimated $1,832,700 recurring costs for the new personnel and a one-time cost of $650,000 for new Gas Chromatographs.[24]

The FDLE also believes the bill would have a fiscal impact on county crime laboratories. Information assessing that impact was not available.

Section 1 of the bill may generate additional revenue for the FDLE due to an increase in the number of criminal history checks performed. The current cost for a state record check is $24.[25] It is unknown how many criminal history record checks will be submitted.

VI. Technical Deficiencies:

None.

[23] Analysis of SB 1030 (July 1, 2014), Florida Department of Health (on file with Senate Committee on Health Policy and the Senate Committee on Criminal Justice). All information in the "Fiscal Impact" section of this analysis relevant to the DOH is from the DOH analysis.

[24] Analysis of SB 1030 (July 1, 2014), Florida Department of Law Enforcement (on file with Senate Committee on Health Policy and the Senate Committee on Criminal Justice). All information in the "Fiscal Impact" section of this analysis relevant to the FDLE is from the FDLE analysis.

[25] The cost for a state and national criminal history record check is $40.50 ($24 goes into the FDLE Operating Trust Fund and $16.50 from each request is forwarded to the Federal Bureau of Investigation).

VII. Related Issues:

Compassionate Use Registry

Consideration should be given to creating a public records exemption for the personal identifying information in the compassionate use registry.

Background Screening of Owners, Managers, and Employees of a Dispensing Organization Applicant

The FDLE states that participation in the state's and federal fingerprint retention program would ensure that all arrests of owners, managers, and employees of a dispensing organization applicant occurring after the initial criminal history screening of those persons (lines 114-116 of the bill) are made known to the licensing agency.[26]

VIII. Statutes Affected:

This bill substantially amends section 893.02 of the Florida Statutes.

This bill creates section 456.60 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

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

CS by Health Policy on March 11, 2014:
The CS amends SB 1030 to:

- Change the name of "medical-grade marijuana" to "low-THC marijuana" throughout the bill;
- Amend a typo in the definition of "low-THC marijuana"; and,
- Change "prescribe" to "order" throughout the bill to avoid a conflict with other statutes that define "prescriptions" as being filled at a pharmacy.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

[26] Analysis of SB 1030 (July 1, 2014), Florida Department of Law Enforcement.