HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for CS/HB 843 Cannabis
SPONSOR(S): Judiciary Committee
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1030

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Judiciary Committee		Cunningham	Havlicak

SUMMARY ANALYSIS

The bill creates s. 381.986, F.S., entitled “Compassionate use of low-THC cannabis.” This statute establishes a regulatory scheme overseen by the Department of Health (DOH) that authorizes the use of low-THC cannabis for medicinal purposes. The bill defines "low-THC cannabis" as:

- A plant of the genus Cannabis, the dried flowers of which contain .8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; 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 and that is dispensed only from a dispensing organization.

The bill authorizes a Florida licensed physician who has complied with specified education requirements and who has examined and is treating a patient suffering from a serious medical condition to order low-THC cannabis for the patient's medical use to treat such condition or alleviate symptoms of such condition if no other satisfactory alternative treatment options exist for that patient. The bill requires a variety of other conditions to apply before low-THC cannabis can be ordered. For example, the physician must:

- Determine that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit;
- Register as the orderer of low-THC cannabis for the named patient on the compassionate use registry created and maintained by DOH, and update the registry to reflect the contents of the order.
- Maintain a patient treatment plan and submit it quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis on patients.
- Obtain the voluntary informed consent of the patient or the patient's legal guardian.

In addition to creating and maintaining the compassionate use registry, the bill requires DOH to authorize the establishment of a dispensing organization in northwest Florida, northeast Florida, central Florida, and south Florida. Dispensing organizations must meet and continue to adhere to specified requirements. The bill also exempts patients, their legal representatives, and dispensing organizations from the legal restrictions on selling, manufacturing, possessing, etc., low-THC cannabis in accordance with the bill’s provisions.

The bill also requires DOH to establish the Office of Compassionate Use (Office). The Office, which is under the direction of the Deputy State Health Officer, is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies.

The bill also:

- Authorizes certain medical centers and state universities to conduct research on cannabidiol and low-THC cannabis; and
- Appropriates $1 million in non-recurring funds from the General Revenue Fund to DOH for FY 2014-2015 for the James and Esther King Biomedical Research Program. The funds must be deposited into the Biomedical Research Trust Fund, and are reserved for research of cannabidiol and its effect on intractable childhood epilepsy.

The bill may have a negative fiscal impact on DOH and the Florida Department of Law Enforcement.

The bill is effective upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Florida Cannabis Laws

Florida's drug control laws are contained in ch. 893, F.S., entitled the Florida Comprehensive Drug Abuse Prevention and Control Act (Drug Control Act). The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V. Cannabis is currently a Schedule I controlled substance, which means it has a high potential for abuse and has no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Cannabis is defined 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]

The Drug Control Act contains a variety of provisions criminalizing behavior related to cannabis. The majority of these penalties are found in s. 893.13, F.S., which makes it a crime to sell, manufacture, deliver, purchase, and possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies. The Drug Control Act also criminalizes trafficking in cannabis,[2] and various acts involving drug paraphernalia.[3]

Florida's Medical Necessity Defense

While the sale, manufacture, possession, etc., of cannabis remains a criminal offense, Florida courts have held that persons charged with such offenses can use the medical necessity defense, which requires a defendant to prove that:

- He or she did not intentionally bring about the circumstance which precipitated the unlawful act;
- He or she could not accomplish the same objective using a less offensive alternative; and
- The evil sought to be avoided was more heinous than the unlawful act.[4]

In *Jenks v. State,*[5] the defendants, a married couple, were suffering from uncontrollable nausea due to AIDS treatment and had testimony from their physician that they could find no effective alternative treatment. The defendants tried cannabis, and after finding that it successfully treated their symptoms, decided to grow two cannabis plants.[6] They were subsequently charged with manufacturing and possession of drug paraphernalia. Under these facts, Florida's First District Court of Appeal found that "section 893.03 does not preclude the defense of medical necessity" and that the Jenks met the criteria for the medical necessity defense. The court ordered the Jenks to be acquitted.[7]

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.[8] More recently, the State Attorney's Office in the Twelfth Judicial

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[1] Section 893.02(3), F.S.

[2] Section 893.135, F.S., makes it a first degree felony for a person to knowingly sell, purchase, manufacture, deliver, bring into this state, or possess more than 25 pounds of cannabis or 300 or more cannabis plants (known as "trafficking in cannabis"). A person convicted of trafficking in cannabis must be sentenced to minimum mandatory terms of imprisonment that vary from 3-15 years depending on the amount of cannabis involved in the offense.

[3] Drug paraphernalia is defined in s. 893.145, F.S., as:

> All equipment, products, and materials of any kind which are used, intended for use, or designed for use in the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.

[4] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991).

[5] 582 So.2d 676 (Fla. 1st DCA 1991).

[6] *Id*.

[7] *Id*.

[8] 739 So.2d 333 (Fla. 1st DCA 1998).

Circuit cited the medical necessity defense as the rationale for not prosecuting a person arrested for cultivating a small amount of cannabis in his home.[9]

Medical Cannabis Laws in Other States

Currently, 20 states[10] and the District of Columbia have laws that permit the use of cannabis for medicinal purposes. While these laws vary widely, most include the following:

- A list of medical conditions for which a practitioner can order medical cannabis for a patient.
  - While nearly every state has a list of medical conditions, 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. Most states require that the patient receive certification from at least one, but often two, physicians designating that the patient has a qualifying condition.
- Provisions allowing the patient to designate one or more caregivers who can possess the medical cannabis and assist the patient in preparing and using the medical cannabis.
- Provisions specifying the number of caregivers allowed and the qualifications to become a caregiver. Most states allow one or two caregivers, require that they be at least 21, and prohibit the caregiver from being the patient's physician. Caregivers are generally allowed to purchase or grow cannabis for the patient, be in possession of a specified quantity of cannabis, and aid the patient in using cannabis, but are strictly prohibited from using cannabis themselves.
- A requirement that the patient or caregiver have an ID card, typically issued by a state agency.
- The creation of a registry of people who have been issued an identification card.
- A method for registered patients and caregivers to obtain medical cannabis.
  - There are two general methods by which patients can obtain medical cannabis. They must either self-cultivate the cannabis in their homes, or buy cannabis from specified points of sale or dispensaries. Regulations governing such dispensaries vary widely.
- General restrictions on where medical cannabis may be used.
  - Typically, medical cannabis 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.

Federal Cannabis Laws

The Federal Controlled Substances Act[11] lists cannabis as a Schedule 1 drug with no accepted medical uses.[12] Just like Florida's Drug Control Act, the Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, etc. cannabis.[13] A first misdemeanor offense for possession of cannabis in any amount can result in a $1,000 fine and up to year in prison, climbing for subsequent offenses to as much as $5,000 and three years.[14] Selling and cultivating cannabis are subject to even greater penalties.[15]

Although state medical cannabis laws protect patients from prosecution for the legitimate use of cannabis 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. However, in recent years, the federal government appears to have softened its stance on cannabis.

[9] *Interdepartmental Memorandum*, State Attorney's Office for the Twelfth Judicial Circuit of Florida, SAO Case # 13CF007016AM, April 2, 2013 (on file with Judiciary Committee staff).

[10] These states include Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, 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. http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx (last visited on April 17, 2014).

[11] 21 U.S.C. ss. 801-971.

[12] 21 U.S.C. s. 812.

[13] 21 U.S.C. ss. 841-865.

[14] 21 U.S.C. s. 844.

[15] 21 U.S.C. ss. 841-865.

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."[16] 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."[17]

On August 29, 2013, United States Deputy Attorney General James Cole issued a memorandum to federal attorneys that appeared to relax the federal government's cannabis-related offense enforcement policies.[18] The memo stated that the USDOJ was committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational ways, and outlined eight areas of enforcement priorities.[19] These enforcement priorities focused on offenses that would result in cannabis being distributed to minors, cannabis sale revenues going to criminal gangs or other similar organizations, and cannabis being grown on public lands.[20] The memo indicated that outside of the listed enforcement priorities, the federal government would not enforce federal cannabis-related laws in states that have legalized the drug and that have a robust regulatory scheme in place.[21]

Charlotte's Web

In recent months, a particular strain of cannabis has gained national attention as a way to treat certain seizure disorders in children.[22] This strain of marijuana is high in cannabidiol (CBD), a non-psychoactive ingredient known for treating seizures, and low in tetrahydrocannabinol (THC), which causes cannabis users to feel "high."

Currently, more than 180 Colorado children are being treated with a special strain of medical cannabis that's helping to combat their extreme seizures and other debilitating conditions.[23] The strain, known as "Charlotte's Web," was developed by a group of brothers who run the Realm of Caring Foundation in Colorado Springs, and is named for 7 year-old Charlotte Figi, who was successfully treated with the strain.[24]

Charlotte's Web and similar strains of cannabis are administered in liquid or capsule form and are reported to produce little to no side effects. Because of the low THC count, users don't experience a traditional marijuana high.[25]

Effect of the Bill

Low-THC for Medicinal Purposes - Regulatory Scheme

The bill creates s. 381.986, F.S., entitled "Compassionate use of low-THC cannabis." This statute establishes a regulatory scheme overseen by the Department of Health (DOH) that authorizes the use

[16] http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on April 17, 2014).
[17] *Id*.
[18] See USDOJ memo on "Guidance Regarding Marijuana Enforcement," August 29, 2014 http://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf (last visited on April 17, 2014).
[19] *Id*.
[20] *Id*.
[21] *Id*.
[22] *See, e.g., Meet The Children Who Rely On Marijuana To Survive*, January 31, 2014, http://www.huffingtonpost.com/2014/01/31/cannabis-for-children_n_4697135.html (last visited on April 18, 2104); *Moving for marijuana: Families with seizure-stricken kids relocating to Colorado for strain of pot*, February 18, 2014, http://www.nydailynews.com/life-style/health/kids-seizure-charlotte-web-pot-treatment-article-1.1619066 (last visited on April 18, 2014); *Marijuana stops child's severe seizures*, August 7, 2013, http://www.cnn.com/2013/08/07/health/charlotte-child-medical-marijuana/ (last visited on April 18, 2014).
[23] *Meet The Children Who Rely On Marijuana To Survive*, January 31, 2014, http://www.huffingtonpost.com/2014/01/31/cannabis-for-children_n_4697135.html (last visited on April 18, 2104).
[24] *Id*.
[25] *Id*.

of low-THC cannabis for medicinal purposes. The details of the regulatory scheme are described below.

Definitions
The bill creates the following definitions:

- "Dispensing organization" means an organization approved by DOH to cultivate, process, and dispense low-THC cannabis.
- "Low-THC cannabis" means a plant of the genus Cannabis, the dried flowers of which contain .8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; 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 and that is dispensed only from a dispensing organization.
- "Medical use" means administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include 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 on behalf of the qualified patient.
- "Qualified patient" means a resident of this state who has been added to the compassionate use registry by a physician licensed under chapters 458 or 459, F.S., to receive low-THC cannabis from a dispensing organization.
- "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.

Physicians Ordering low-THC Cannabis for Patients
The bill authorizes a physician licensed under chapters 458 or 459, F.S., who has examined and who is treating a patient suffering from a serious medical condition, including but not limited to, treatment for cancer or neurological conditions, to order for the patient's medical use low-THC cannabis to treat such condition or alleviate symptoms of such condition, such as seizures or severe and persistent muscle spasms, if no other satisfactory alternative treatment options exist for that patient and all of the following conditions apply:

- The patient is a permanent resident of this state.
- The physician determines 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 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 named patient on the compassionate use registry maintained by DOH and updates the registry to reflect the contents of the order. The physician must deactivate 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 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.
- 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.

Physician Education
The bill also specifies that prior to ordering low-THC cannabis for a patient, the appropriate board must require the ordering physician to successfully complete an eight hour course and subsequent examination offered by the Florida Medical Association (FMA) that encompasses the clinical indications for the appropriate use of low-THC cannabis, the appropriate delivery mechanisms, the contraindications for such use, as well as the relevant state and federal laws governing the ordering, dispensing, and possessing of low-THC cannabis. Successful completion of the course and

examination is required for every physician who orders low-THC cannabis each time such physician renews his or her license. Such physicians must submit confirmation of having completed the course and examination on a form provided by the board, when submitting fees for every licensure renewal.[26] Failure to comply constitutes grounds for disciplinary action under each respective practice act and under s. 456.072(1)(k), F.S.

The first course and examination must be presented by October 1, 2014, must be administered at least annually thereafter, and may be offered in a distance learning format.

Duties of the Department of Health
The bill requires DOH, by January 1, 2015, to:

- Create a secure, electronic, and online compassionate use registry for the registration of physicians and patients. The registry must be accessible to law enforcement agencies and to a dispensing organization in order to verify patient authorization for low-THC cannabis and record the low-THC cannabis dispensed. The registry must prevent an active registration of a patient by multiple physicians.
- Authorize the establishment of a dispensing organization in northwest Florida, northeast Florida, central Florida, and south Florida, to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis.
- Develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering the registry. An applicant for approval as a dispensing organization must be able 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 dispensing organization.
    - The ability to maintain accountability of all raw materials, finished product, 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 DOH.
    - The financial ability to maintain operations for the duration of the 2-year approval cycle.
    - That all owners, managers, and employees have been fingerprinted and have successfully passed a Level 2 background screening pursuant to s. 435.04, F.S.
- Monitor physician registration and ordering of low-THC cannabis for ordering practices which could facilitate unlawful diversion or misuse of low-THC cannabis, and take disciplinary action as indicated.

Dispensing Organizations
The bill requires approved dispensing organizations to maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization at all times. Before dispensing low-THC cannabis to a qualified patient, the dispensing organization must verify that the patient has an active registration in the compassionate use registry, the order presented matches the order contents as recorded in the registry, and the order has not already been filled. Upon dispensing low-THC cannabis, the dispensing organization must record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.

Exceptions
As noted above, ch. 893, F.S., contains a variety of criminal penalties related to cannabis. The bill addresses this by specifying the following:

- Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other section of law, but subject to the requirements of s. 381.986, F.S., a qualified patient and the qualified patient's legal representative may purchase and possess for the patient's medical use up to the amount of low-THC cannabis ordered to the patient.

[26] Successful completion of the course may be used by a physician to satisfy eight hours of the continuing medical education requirements required by their respective board for licensure renewal.

- Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other section of law, but subject to the requirements of s. 381.986, F.S., an approved dispensing organization and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by DOH rule, of low-THC cannabis. For purposes of this subsection, the terms manufacture, possess, sell, deliver, distribute, dispense have the same meaning as provided in s. 893.02, F.S.
- Amending the definition of "cannabis" is s. 893.02, F.S., to exclude:
    - Any plant of the genus Cannabis the dried flowers of which contain .8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; 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, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986, F.S.

The also provides that an approved dispensing organization and its owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S., for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by DOH rule, of low-THC cannabis.

Office of Compassionate Use

The bill also creates s. 385.212, F.S., which requires DOH to establish the Office of Compassionate Use (Office). The Office, which is under the direction of the Deputy State Health Officer, is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies. The Office may also:

- Create a network of state universities and medical centers recognized pursuant to s. 381.925, F.S.
- Make any necessary application to the FDA or pharmaceutical manufacturer to facilitate enhanced access to compassionate use for Florida patients; and
- Enter into any agreements necessary to facilitate enhanced access to compassionate use for Florida patients.

Low-THC and Cannabidiol Research

The bill also creates ss. 385.211 and 1004.441 F.S., to authorize medical centers recognized pursuant to s. 381.925, F.S., and state universities with both medical and agricultural research programs[27] to conduct research on cannabidiol and low-THC cannabis.[28] This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. 312 and 316. Current state or privately obtained research funds may be used to support such research activities

Research of Cannabidiol and its effect on Intractable Childhood Epilepsy.

Section 215.5602, F.S., establishes the James and Esther King Biomedical Research Program (Program) within DOH. The purpose of the Program is to provide an annual and perpetual source of funding in order to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.[29]

Funds appropriated for the Program are used to award grants and fellowships for research relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. Priority is given to research designed to prevent or cure disease.[30]

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[27] This includes state universities that have satellite campuses or research agreements with other similar institutions.

[28] "Low-THC cannabis" means a plant of the genus Cannabis, the dried flowers of which contain .8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; 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 and that is dispensed only from a dispensing organization as defined in s. 381.986, F.S..

[29] Section 215.5602(1), F.S.

[30] Section 215.5602(2), F.S.

Any university or established research institute may apply for biomedical research funding under the Program.[31] Grants and fellowships are awarded by the State Surgeon General, after consultation with the Biomedical Research Advisory Council,[32] on the basis of scientific merit, as determined by the competitively open peer-reviewed process to ensure objectivity, consistency, and high quality.[33]

To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, DOH appoints peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal and establish its scientific priority score. The priority scores are forwarded to the Biomedical Research Advisory Council and are considered in determining which proposals are recommended for funding.[34]

The bill appropriates $1 million in non-recurring general revenue to DOH for FY 2014-2015 for the James and Esther King Biomedical Research Program. The funds must be deposited into the Biomedical Research Trust Fund,[35] and are reserved for research of cannabidiol and its effect on intractable childhood epilepsy.

The bill requires any biomedical research funding for research of cannabidiol and its effect on intractable childhood epilepsy to be awarded pursuant to s. 215.5602, F.S. Application for such funding may be submitted by any research university in the state which has obtained approval from the U.S. Food and Drug Administration for an exploratory investigational new drug study of cannabidiol and its effect on intractable childhood epilepsy. The bill requires the Biomedical Research Advisory Council to advise the State Surgeon General as to the direction and scope of research of cannabidiol and its effect on intractable childhood epilepsy and the award of research funding.

For purposes of this section of the bill, the term "cannabidiol" means an extract from the cannabis plant that has less than 0.8 percent tetrahydrocannabinol and the chemical signature 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol, or a derivative thereof, as determined by the International Union of Pure and Applied Chemistry.[36]

This section of the bill takes effect July 1, 2014, and expires June 30, 2015.

B. SECTION DIRECTORY:

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

Section 2. Creates s. 385.211, F.S., relating to refractory and intractable epilepsy treatment and research at recognized medical centers.

Section 3. Creates s. 385.212, F.S., relating to powers and duties of the Department of Health; Office of Compassionate Use.

Section 4. Amends s. 893.02, F.S., relating to definitions.

Section 5. Creates s. 1004.441, F.S., relating to refractory and intractable epilepsy treatment and research.

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[31] Section 215.5602(5)(a), F.S.

[32] The Biomedical Research Advisory Council, created within DOH, consists of 11 members and is tasked with advising the State Surgeon General as to the direction and scope of the Program. This includes providing advice on Program priorities, developing criteria and standards for the award of research grants, and making recommendations for research grants and fellowships. Section 215.5602(3) and (4), F.S.

[33] Section 215.5602(5)(b), F.S.

[34] Section 215.5602(6), F.S.

[35] The Biomedical Research Trust Fund is created in s. 20.435(8), F.S., and is administered by DOH.

[36] The International Union of Pure and Applied Chemistry (IUPAC) is a non-governmental organization of member countries that encompass more than 85% of the world's chemical sciences and industries. IUPAC addresses international issues in the chemical sciences utilizing expert volunteers from its member countries. http://www.iupac.org/home/about/strategic-plan.html (last visited on April 18, 2014).

Section 6. Appropriates $1 million to DOH to fund research of cannabidiol and its effect on intractable childhood epilepsy.

Section 7. Makes the bill effective upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill authorizes DOH to impose initial application and biennial renewal fees that are sufficient to cover the costs of administering the compassionate use registry.

The bill appropriates $1 million from the General Revenue Fund to the James and Esther King Biomedical Research Program through the Department of Health. The general revenue funds will be transferred to the Biomedical Research Trust Fund to fund research of cannabidiol and its effect on intractable childhood epilepsy.

2. Expenditures:

DOH Impact
DOH reports the following fiscal impact:

- 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. However, these costs may be fully funded from the initial and license renewal fees charged to the dispensing organizations.
- 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.
- DOH may experience a recurring increase in workload associated with the enforcement and regulation requirements of the bill. The impact is indeterminate at this time, therefore, the fiscal impact cannot be calculated.
- DOH will incur non-recurring costs for rulemaking, which current budget authority is adequate to absorb.[37]

FDLE Impact
According to the Florida Department of Law Enforcement (FDLE), the change to the definition of the term "cannabis" will require 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 will require 25 new Crime Lab Analysts and at least 10 additional Gas Chromatographs to perform the additional analyses. 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.[38]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not appear to have an impact on local government revenues.

2. Expenditures:

[37] DOH's analysis of SB 1030, February 17, 2014 (on file with Judiciary Committee staff).
[38] FDLE's analysis of SB 1030, March 3, 2014 (on file with Judiciary Committee staff).

According to FDLE, the change to the definition of the term "cannabis" may have a fiscal impact on county crime laboratories, which are funded by county dollars.[39]

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

The bill requires physicians who order low-THC cannabis to complete an 8 hour course and subsequent examination, offered by the FMA, that encompasses the clinical indications for the appropriate use of low-THC cannabis, the appropriate delivery mechanisms, the contraindications for such use, as well as the relevant state and federal laws governing the ordering, dispensing, and possessing of this substance. This may have a negative fiscal impact on the FMA.

The bill appropriates $1 million to the Department of Health to fund research of cannabidiol and its effect on intractable childhood epilepsy. Applications for such funding may be submitted by Florida research universities.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable because the bill does not appear to require the counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with counties and municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill gives DOH rulemaking authority to implement the compassionate use registry and to establish the Office of Compassionate Use.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[39] *Id.*