

## HOUSE OF REPRESENTATIVES FINAL BILL ANALYSIS

<b>BILL #:</b>	CS/CS/HB 843	<b>FINAL HOUSE FLOOR ACTION:</b>	
<b>SPONSOR(S):</b>	Judiciary Committee; Criminal Justice Subcommittee; Gaetz; Edwards and others	111 Y's	7 N's
<b>COMPANION BILLS:</b>	CS/CS/SB 1030	<b>GOVERNOR'S ACTION:</b>	Pending

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### SUMMARY ANALYSIS

CS/CS/HB 843 passed the House on May 1, 2014, as CS/CS/SB 1030 as amended. The Senate concurred in the House amendment to the Senate Bill and subsequently passed the bill as amended on May 2, 2014.

The bill establishes a regulatory scheme overseen by the Department of Health (DOH) that authorizes the use of low-THC cannabis for limited medicinal purposes. The bill defines "low-THC cannabis" as:

A plant of the genus Cannabis, the dried flowers of which contain 0.8 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 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 Florida resident patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms to order low-THC cannabis for the patient's medical use to treat such disease, disorder, or condition or alleviate symptoms of such disease, disorder, or condition if no other satisfactory alternative treatment options exist. "Medical use" means administration of the ordered amount of low-THC cannabis, but does not include the possession, use, or administration by smoking. The bill requires a variety of other conditions to apply before low-THC cannabis can be ordered. For example, physicians must:

- Determine the risks of ordering low-THC cannabis are reasonable in light of the benefit;
- Register as the orderer of low-THC cannabis for the patient on the compassionate use registry created and maintained by DOH, and update the registry to reflect the contents of the order; and
- 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 five dispensing organizations that must meet specified requirements. The bill also:

- Exempts patients, their legal representatives, and dispensing organizations from the legal restrictions on selling, possessing, etc., low-THC cannabis in accordance with the bill's provisions;
- Requires DOH to establish the Office of Compassionate Use;
- Permits medical centers and state universities to research cannabidiol and low-THC cannabis; and
- Appropriates \$1 million in nonrecurring General Revenue funds to DOH's James and Esther King Biomedical Research Program to research 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.

Subject to the Governor's veto powers, the bill is effective upon becoming a law.

### I. SUBSTANTIVE INFORMATION

#### A. EFFECT OF CHANGES:

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0843z.CRJS

DATE: May 13, 2014

## 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.<sup>1</sup>

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,<sup>2</sup> and various acts involving drug paraphernalia.<sup>3</sup>

### 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.<sup>4</sup>

In *Jenks v. State*,<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> The court ordered the Jenks to be acquitted.<sup>8</sup>

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.<sup>9</sup> More recently, the State Attorney's Office in the Twelfth Judicial

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<sup>1</sup> Section 893.02(3), F.S.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991).

<sup>5</sup> 582 So.2d 676 (Fla. 1st DCA 1991).

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> 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 for his wife's medical use.<sup>10</sup>

### Medical Cannabis Laws in Other States

Currently, 21 states<sup>11</sup> 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<sup>12</sup> lists cannabis as a Schedule 1 drug with no accepted medical uses.<sup>13</sup> Just like Florida's Drug Control Act, the Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, etc. cannabis.<sup>14</sup> 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.<sup>15</sup> Selling and cultivating cannabis are subject to even greater penalties.<sup>16</sup>

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.

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<sup>10</sup> *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).

<sup>11</sup> 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 May 8, 2014).

<sup>12</sup> 21 U.S.C. ss. 801-971.

<sup>13</sup> 21 U.S.C. s. 812.

<sup>14</sup> 21 U.S.C. ss. 841-65.

<sup>15</sup> 21 U.S.C. s. 844.

<sup>16</sup> 21 U.S.C. ss. 841-65.

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.”<sup>17</sup> 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.”<sup>18</sup>

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.<sup>19</sup> 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.<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup>

### 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.<sup>23</sup> This strain of marijuana is high in cannabidiol, 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.<sup>24</sup> 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.<sup>25</sup>

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.<sup>26</sup>

### **Effect of the Bill**

#### Low-THC for Medicinal Purposes - Regulatory Scheme

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<sup>17</sup> <http://www.justice.gov/ag/smart-on-crime.pdf>. (last visited on May 5, 2014).

<sup>18</sup> *Id.*

<sup>19</sup> See USDOJ memo on “Guidance Regarding Marijuana Enforcement,” August 29, 2014

<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> (last visited on May 5, 2014).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> 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](http://www.huffingtonpost.com/2014/01/31/cannabis-for-children_n_4697135.html) (last visited on May 5, 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 May 5, 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 May 5, 2014).

<sup>24</sup> *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](http://www.huffingtonpost.com/2014/01/31/cannabis-for-children_n_4697135.html) (last visited on May 5, 2104).

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

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 limited 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*

Effective January 1, 2015, the bill authorizes a physician licensed under chapters 458 or 459, F.S., who has examined and who is treating a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms to order for the patient's medical use low-THC cannabis to treat such disease, disorder, or condition or to alleviate symptoms of such disease, disorder, or condition, 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.

### *Penalties*

The bill makes it a first degree misdemeanor<sup>27</sup> for:

- A physician to order 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 to fraudulently represent to a physician that he or she has cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms for the purpose of being ordered low-THC cannabis by such physician.

#### *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) or the Florida Osteopathic Medical Association (FOMA) 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.<sup>28</sup> 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.

The bill also requires the appropriate board to require the medical director of a dispensing organization to successfully complete a two hour course and subsequent examination offered by the FMA or FOMA that encompasses appropriate safety procedures and knowledge of low-THC cannabis. Successful completion of the course and examination is required each time the medical director renews his or her license.

#### *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.
- Develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering the registry.
- Authorize the establishment of five dispensing organizations<sup>29</sup> to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis. An applicant for approval as a dispensing organization must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131, F.S., that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years. The applicant must also be able to demonstrate:

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<sup>27</sup> A first degree misdemeanor is punishable by up to one year in county jail and a \$1,000 fine. Sections 775.082 and 775.083, F.S.

<sup>28</sup> 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.

<sup>29</sup> One in northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.

- 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, including the provision of certified financials to DOH.<sup>30</sup>
- That all owners and managers have been fingerprinted and have successfully passed a Level 2 background screening pursuant to s. 435.04, F.S.
- The employment of a medical director who is a physician licensed under chapters 458 or 459 to supervise the activities of the dispensing organization.
- 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 that 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 for the patient.
- Specifying that 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" in 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 bill 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.

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<sup>30</sup> Upon approval, the applicant must post a \$5 million performance bond.

### 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 Food and Drug Administration 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<sup>31</sup> to conduct research on cannabidiol and low-THC cannabis.<sup>32</sup> 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.<sup>33</sup>

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.<sup>34</sup>

Any university or established research institute may apply for biomedical research funding under the Program.<sup>35</sup> Grants and fellowships are awarded by the State Surgeon General, after consultation with the Biomedical Research Advisory Council,<sup>36</sup> on the basis of scientific merit, as determined by the competitively open peer-reviewed process to ensure objectivity, consistency, and high quality.<sup>37</sup>

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

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<sup>31</sup> This includes state universities that have satellite campuses or research agreements with other similar institutions.

<sup>32</sup> "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.

<sup>33</sup> Section 215.5602(1), F.S.

<sup>34</sup> Section 215.5602(2), F.S.

<sup>35</sup> Section 215.5602(5)(a), F.S.

<sup>36</sup> 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.

<sup>37</sup> Section 215.5602(5)(b), F.S.



scores are forwarded to the Biomedical Research Advisory Council and are considered in determining which proposals are recommended for funding.<sup>38</sup>

The bill appropriates \$1 million in nonrecurring 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,<sup>39</sup> 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.<sup>40</sup>

## 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 low-THC cannabis. The impact is indeterminate at this time, therefore, the fiscal impact cannot be calculated.

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<sup>38</sup> Section 215.5602(6), F.S.

<sup>39</sup> The Biomedical Research Trust Fund is created in s. 20.435(8), F.S., and is administered by DOH.

<sup>40</sup> 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 May 5, 2014).

- 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 nonrecurring costs for rulemaking, which current budget authority is adequate to absorb.<sup>41</sup>

## B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

### 1. Revenues:

None.

### 2. Expenditures:

This bill creates two new first degree misdemeanor offenses, which may have a negative jail bed impact.

The bill amends s. 893.02, F.S., to exclude low-THC cannabis from the definition of “cannabis” for purposes of the criminal code so long as the low-THC cannabis is possessed, manufactured, etc. in conformance with the newly created medical registry statute. As such, the instances in which a law enforcement officer might arrest a person for possessing, delivering, etc., low-THC cannabis will be limited (e.g., an LEO might arrest a person who is on the registry if the LEO thinks the substance the person possesses is “real” marijuana). FDLE reports that in such instances, their crime labs will not be able to do the quantitative analyses needed to determine whether the substance meets the definition of low-THC cannabis. Instead, local law enforcement agencies will have to hire a private laboratory to conduct such testing.<sup>42</sup> It is unknown how often such testing will be necessary, and how much such testing costs.

## C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

The bill requires FMA and FOMA to offer courses to physicians who order low-THC cannabis and to the medical directors of dispensing organizations. This may have a negative fiscal impact on the FMA and FOMA.

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.

<sup>41</sup> DOH’s analysis of SB 1030, February 17, 2014 (on file with Judiciary Committee staff).

<sup>42</sup> FDLE’s analysis of SB 1030, March 3, 2014 (on file with Judiciary Committee staff).