

CHAPTER 2014-157

Committee Substitute for Committee Substitute for Senate Bill No. 1030

An act relating to cannabis; providing a short title; creating s. 381.986, F.S.; defining terms; authorizing specified physicians to order low-THC cannabis for use by specified patients; providing conditions; prohibiting specified acts by physicians or persons seeking low-THC cannabis; providing criminal penalties; requiring physician education; providing duties of the Department of Health; requiring the department to create a compassionate use registry; providing requirements for the registry; requiring the department to authorize a specified number of dispensing organizations; authorizing rulemaking; providing requirements and duties for a dispensing organization; providing exceptions to specified laws; creating s. 385.211, F.S.; defining the term “low-THC cannabis”; authorizing certain medical centers to conduct research on cannabidiol and low-THC cannabis; authorizing state or privately obtained research funds to be used to support such research; creating s. 385.212, F.S.; requiring the department to establish an Office of Compassionate Use; authorizing the office to engage in specified activities; authorizing rulemaking; amending s. 893.02, F.S.; revising the term “cannabis” as used in the Florida Comprehensive Drug Abuse Prevention and Control Act and as applicable to certain criminal offenses proscribing the sale, manufacture, delivery, possession, dispensing, distribution, or purchase of cannabis, to which penalties apply; creating s. 1004.441, F.S.; defining the term “low-THC cannabis”; authorizing state universities with both medical and agricultural research programs to conduct specified research on cannabidiol and low-THC cannabis; authorizing state or privately obtained research funds to be used to support such research; providing an appropriation to the department for research of cannabidiol and its effect on intractable childhood epilepsy; specifying how biomedical research funding for research of cannabidiol and its effect on intractable childhood epilepsy shall be awarded; specifying who may apply for such funding; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the “Compassionate Medical Cannabis Act of 2014.”

Section 2. Section 381.986, Florida Statutes, is created to read:

381.986 Compassionate use of low-THC cannabis.—

(1) DEFINITIONS.—As used in this section, the term:

(a) “Dispensing organization” means an organization approved by the department to cultivate, process, and dispense low-THC cannabis pursuant to this section.

(b) “Low-THC cannabis” means 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.

(c) “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.

(d) “Qualified patient” means a resident of this state who has been added to the compassionate use registry by a physician licensed under chapter 458 or chapter 459 to receive low-THC cannabis from a dispensing organization.

(e) “Smoking” means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.

(2) PHYSICIAN ORDERING.—Effective January 1, 2015, a physician licensed under chapter 458 or chapter 459 who has examined and is treating a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may order for the patient’s medical use 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:

(a) The patient is a permanent resident of this state.

(b) The physician determines that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient’s medical record.

(c) The physician registers as the orderer of low-THC cannabis for the named patient on the compassionate use registry maintained by the department and updates the registry to reflect the contents of the order. The physician shall deactivate the patient’s registration when treatment is discontinued.

(d) 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.

(e) 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.

(f) 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.

(3) PENALTIES.—

(a) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders low-THC cannabis for a patient without a reasonable belief that the patient is suffering from:

1. 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

2. 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.

(b) Any person who fraudulently represents that he or she has cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms to a physician for the purpose of being ordered low-THC cannabis by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4) PHYSICIAN EDUCATION.—

(a) Before ordering low-THC cannabis for use by a patient in this state, the appropriate board shall require the ordering physician licensed under chapter 458 or chapter 459 to successfully complete an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis, 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. The first course and examination shall be presented by October 1, 2014, and shall be administered at least annually thereafter. Successful completion of the course may be used by a physician to satisfy 8 hours of the continuing medical education requirements required by his or her respective board for licensure renewal. This course may be offered in a distance learning format.

(b) The appropriate board shall require the medical director of each dispensing organization approved under subsection (5) to successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses appropriate safety procedures and knowledge of low-THC cannabis.

(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders low-THC cannabis each time such physician renews his or her license. In addition, successful completion of the course and examination specified in paragraph (b) is required for the medical director of each dispensing organization each time such physician renews his or her license.

(d) A physician who fails to comply with this subsection and who orders low-THC cannabis may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

(5) DUTIES OF THE DEPARTMENT.—By January 1, 2015, the department shall:

(a) Create a secure, electronic, and online compassionate use registry for the registration of physicians and patients as provided under this section. 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.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. An applicant for approval as a dispensing organization must be able to demonstrate:

1. The technical and technological ability to cultivate and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 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.

2. The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.

3. The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.

4. An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.

5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a \$5 million performance bond.

6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.

7. The employment of a medical director who is a physician licensed under chapter 458 or chapter 459 to supervise the activities of the dispensing organization.

(c) Monitor physician registration and ordering of low-THC cannabis for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis and take disciplinary action as indicated.

(d) Adopt rules necessary to implement this section.

(6) DISPENSING ORGANIZATION.—An approved dispensing organization shall maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) at all times. Before dispensing low-THC cannabis to a qualified patient, the dispensing organization shall 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 the low-THC cannabis, the dispensing organization shall record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.

(7) EXCEPTIONS TO OTHER LAWS.—

(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, 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.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, 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 department rule, of low-THC cannabis. For purposes of this subsection, the terms "manufacture,"

“possession,” “deliver,” “distribute,” and “dispense” have the same meanings as provided in s. 893.02.

(c) An approved dispensing organization and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of low-THC cannabis.

Section 3. Section 385.211, Florida Statutes, is created to read:

385.211 Refractory and intractable epilepsy treatment and research at recognized medical centers.—

(1) As used in this section, the term “low-THC cannabis” means “low-THC cannabis” as defined in s. 381.986 that is dispensed only from a dispensing organization as defined in s. 381.986.

(2) Notwithstanding chapter 893, medical centers recognized pursuant to s. 381.925 may conduct research on cannabidiol and low-THC cannabis. 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. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 4. Section 385.212, Florida Statutes, is created to read:

385.212 Powers and duties of the Department of Health; Office of Compassionate Use.—

(1) The Department of Health shall establish an Office of Compassionate Use under the direction of the Deputy State Health Officer.

(2) The Office of Compassionate Use may enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies. The Office of Compassionate Use may:

(a) Create a network of state universities and medical centers recognized pursuant to s. 381.925.

(b) Make any necessary application to the United States Food and Drug Administration or a pharmaceutical manufacturer to facilitate enhanced access to compassionate use for Florida patients.

(c) Enter into any agreements necessary to facilitate enhanced access to compassionate use for Florida patients.

(3) The department may adopt rules necessary to implement this section.

Section 5. Subsection (3) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(3) “Cannabis” means 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. The term does not include “low-THC cannabis,” as defined in s. 381.986, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986.

Section 6. Section 1004.441, Florida Statutes, is created to read:

1004.441 Refractory and intractable epilepsy treatment and research.

(1) As used in this section, the term “low-THC cannabis” means “low-THC cannabis” as defined in s. 381.986 that is dispensed only from a dispensing organization as defined in s. 381.986.

(2) Notwithstanding chapter 893, state universities with both medical and agricultural research programs, including those that have satellite campuses or research agreements with other similar institutions, may conduct research on cannabidiol and low-THC cannabis. 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 state universities to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities authorized by this section.

Section 7. (1) As used in this section, 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.

(2) For the 2014-2015 fiscal year, \$1 million in nonrecurring general revenue is appropriated to the Department of Health for the James and Esther King Biomedical Research Program and shall be deposited into the Biomedical Research Trust Fund. These funds shall be reserved for research of cannabidiol and its effect on intractable childhood epilepsy.

(3) Biomedical research funding for research of cannabidiol and its effect on intractable childhood epilepsy shall be awarded pursuant to s. 215.5602, Florida Statutes. An application for such funding may be submitted by any research university in the state that has obtained approval from the United States Food and Drug Administration for an exploratory investigational new

drug study of cannabidiol and its effect on intractable childhood epilepsy. For purposes of this section, the Biomedical Research Advisory Council created under s. 215.5602, Florida Statutes, shall 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.

Section 8. This act shall take effect upon becoming a law.

Approved by the Governor June 16, 2014.

Filed in Office Secretary of State June 16, 2014.