

THE FLORIDA SENATE
2014 SUMMARY OF LEGISLATION PASSED
Committee on Health Policy

CS/CS/SB 1030 — Cannabis

by Appropriations Committee; Health Policy Committee; and Senators Bradley, Bean, Brandes, Galvano, Sobel, Soto, Gardiner, Stargel, and Simpson

The bill creates the Compassionate Medical Cannabis Act of 2014.

Notwithstanding the criminal prohibitions in ch. 893, F.S., the act allows:

- Patients and their legal representatives to possess and purchase low-THC cannabis;
- Owners, managers, and employees of a dispensing organization to manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of low-THC cannabis;
- Recognized medical centers to conduct research on cannabidiol and low-THC cannabis; and
- State universities, with both medical and agricultural research programs, to conduct research on cannabidiol and low-THC cannabis.

The act also creates an exception from the definition of “cannabis” in s. 893.02, F.S., for low-THC cannabis that is manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with newly created s. 381.986, F.S.

The Medical Use and Ordering of Low-THC Cannabis

The bill creates s. 381.986, F.S., which specifies the conditions under which low-THC cannabis may be ordered and dispensed to, and used by, a patient. Low-THC cannabis is defined as “a plant of the genus *Cannabis* the dried flowers of which contain .8 percent or less of tetrahydrocannabinol (THC) and more than 10 percent of cannabidiol weight for weight.” The definition includes extracted resin and any compound, manufacture, salt, derivative, mixture, or preparation of such a plant. In order to meet the definition low-THC cannabis must also be dispensed only from a dispensing organization. The term “medical use” is also defined to exclude smoking and the transfer of low-THC cannabis to a person other than the patient for whom it was ordered or that patient’s legal representative.

Physician Ordering

Beginning on January 1, 2015, the bill allows allopathic and osteopathic physicians licensed in Florida to order low-THC cannabis for their patients’ medical use. The bill specifies that a physician may only order low-THC cannabis for patients who are Florida residents, suffer from cancer or a physical medical condition that chronically produces seizures or severe and persistent muscle spasms, and have no acceptable alternative treatment options available to them.

The bill establishes a first degree misdemeanor penalty for physicians who order low-THC cannabis for patients without a reasonable belief that the patient suffers from the required conditions or symptoms and for any person who fraudulently represents that he or she has such symptoms. The Department of Health (DOH) is required to monitor physician registration and

ordering of low-THC cannabis for practices that could facilitate unlawful distribution or misuse and take disciplinary action as needed.

Physicians who order low-THC cannabis must obtain the voluntary informed consent of the patient or the patient's legal guardian to the treatment after explaining the current state of medical knowledge on the treatment of the patient's condition with low-THC cannabis, medically acceptable alternatives, and the potential risks and side effects. Physicians must also maintain a treatment plan that includes dose, route of administration, planned duration, and monitoring of their patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis. This treatment plan must be submitted quarterly to the University of Florida, College of Pharmacy, for research on the safety and efficacy of low-THC cannabis.

Physicians who wish to order low-THC cannabis must complete an 8-hour course and examination offered by the Florida Medical Association (FMA) or the Florida Osteopathic Medical Association (FOMA) before ordering for a patient. Physicians who order low-THC cannabis must retake and pass the course and examination upon licensure renewal. The bill requires the first such course to be offered by October 1, 2014, and at least annually afterwards, and allows for the course to be offered in distance learning format. The course must encompass clinical indications for the appropriate use of low-THC cannabis; the appropriate delivery mechanisms, the contraindications for such use; and the relevant state and federal laws governing ordering, possessing and dispensing low-THC cannabis. Failing to comply with these training requirements may subject a physician to disciplinary action against his or her license.

Compassionate Use Registry

The DOH is required to create a compassionate use registry (registry) by January 1, 2015, for the registration of physicians and patients who order or are ordered, respectively, low-THC cannabis. The registry must be secure, online, be able to be accessed by physicians, law enforcement agencies, and dispensing organizations in order to verify patient authorization for low-THC cannabis, to record any low-THC cannabis dispensed, and to prevent active registrations of a single patient by multiple physicians.

Physicians are responsible for registering themselves and the patients for whom they order low-THC cannabis. Physicians must also update the registry to reflect order contents and to deactivate a patient's registration when treatment is discontinued.

Dispensing organizations are responsible for checking the registry before dispensing low-THC cannabis to a patient in order to verify a patient's active registration, that the order presented matches the order recorded in the registry, and that the order has not previously been filled. Dispensing organizations must also update the registry with the date, time, quantity, and form of the low-THC cannabis dispensed after dispensing to a patient.

Dispensing Organizations

By January 1, 2015, the DOH must authorize the establishment of five dispensing organizations to cultivate, process, and dispense low-THC cannabis. The DOH must authorize one dispensing organization in each of northwest, northeast, central, southwest, and southeast Florida. In order to be considered, an applicant must be able to demonstrate:

- Possession of a valid certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants, are operated by a nurseryman, and have been operated as a registered nursery in Florida for at least 30 continuous years;
- Technical and technological ability to cultivate and produce low-THC cannabis;
- Ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization;
- Ability to maintain accountability of all raw materials, finished product, and byproducts;
- Infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide, or regionally, as determined by the DOH;
- Financial ability to maintain operations for a 2-year approval cycle, including the provision of certified financials to the DOH;
- Posting of a \$5 million performance bond, upon approval as a dispensing organization;
- Fingerprinting of all owners and managers and successful passing of a Level 2 background screening;
- The employment of a Florida licensed allopathic or osteopathic physician as a medical director to supervise the activities of the dispensing organization.

Approved dispensing organizations must maintain compliance with all of the above listed criteria. In addition, the dispensing organization's medical director must complete and pass a 2-hour course and examination offered by the FMA or the FOMA upon initially becoming the medical director and upon license renewal. The course and exam must encompass appropriate safety procedures and knowledge of low-THC cannabis.

Dispensing organizations and their owners, managers, and employees are not required to be licensed under ch. 465, F.S., relating to the practice of pharmacy.

The Office of Compassionate Use

The bill creates s. 385.212, F.S. to require the DOH to establish an Office of Compassionate Use (office) under the direction of the Deputy State Health Officer. The office is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies. The office is also authorized to create a network of state universities and medical centers, make necessary applications to the United States Food and Drug Administration (FDA) or pharmaceutical manufacturers to facilitate enhanced access to compassionate use for Florida patients, and enter into any agreements necessary to facilitate

enhanced access for such patients. The DOH may adopt rules necessary to implement the Office of Compassionate Use.

Research

The bill creates ss. 385.211 and 1004.441, F.S., to authorize recognized medical centers and state universities with both medical and agricultural research programs, respectively, to conduct research on cannabidiol and low-THC cannabis notwithstanding ch. 893, F.S. The authorized research includes, but is not limited to, agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment of refractory or intractable epilepsy. The bill allows state or privately obtained research funds to be used to support such research.

The bill also creates a new, unnumbered section of the Florida Statutes which appropriates \$1 million of nonrecurring general revenue funding for Fiscal Year 2014-2015 to the DOH's James and Esther King Biomedical Research Program for the research of cannabidiol and its effects on intractable childhood epilepsy. In order to apply for the funds, the bill requires that a state university must have received approval from the FDA for an exploratory investigational new drug study of cannabidiol and its effects on intractable childhood epilepsy. The Biomedical Research Advisory Council must advise the State Surgeon General as to the direction and scope of such research and the awarding of research funding.

If approved by the Governor, these provisions take effect upon becoming law.

Vote: Senate 30-9; House 111-7