By Senator Artiles

40-01186-17 20171388__

A bill to be entitled

An act relating to medical cannabis; amending s. 381.986, F.S.; defining, redefining, and deleting terms; authorizing physicians to issue physician certifications for medical cannabis or cannabis delivery devices, instead of ordering low-THC cannabis, for patients suffering from a debilitating medical condition; authorizing physicians to make specific determinations in certifications; requiring physicians to meet certain conditions to be authorized to issue such physician certifications; providing criminal penalties; deleting provisions requiring successful completion of a specified course and examination by a physician who orders low-THC cannabis and by a medical director of a dispensing organization; requiring the Department of Health to register medical marijuana treatment centers, rather than to authorize the establishment of dispensing organizations; requiring the department to register additional medical marijuana treatment centers under certain circumstances; requiring the department to authorize the establishment of medical marijuana testing facilities; prohibiting a medical marijuana testing facility from being owned by certain persons; providing rulemaking authority; conforming provisions to changes made by the act; deleting provisions relating to the department's issuance of registration cards for patients and their legal representatives; requiring the department to establish a quality

control program that requires medical cannabis to be tested by a medical marijuana testing facility; requiring medical marijuana treatment centers to submit samples of medical cannabis to a medical marijuana testing facility; providing testing specifications; requiring retention of testing records; providing rulemaking authority; conforming provisions to changes made by the act; amending ss. 381.987, 385.211, 499.0295, 893.02, and 1004.441, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Section 381.986, Florida Statutes, is amended to read:

381.986 Compassionate use of ~~low-THC and~~ medical cannabis.—

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

(a) "Cannabis delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing ~~low-THC cannabis or~~ medical cannabis into the human body.

(b) "Caregiver" means a person who is at least 21 years old, who has agreed to assist with a qualifying patient's medical use of marijuana, and who has obtained a valid caregiver identification card issued by the department.

(c) "Debilitating medical condition" means cancer, epilepsy, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS),

posttraumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis, or other debilitating medical conditions of the same kind or class as or comparable to those enumerated and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient

~~"Dispensing organization" means an organization approved by the department to cultivate, process, transport, and dispense low-THC cannabis or medical cannabis pursuant to this section~~.

~~(c) "Independent testing laboratory" means a laboratory, including the managers, employees, or contractors of the laboratory, which has no direct or indirect interest in a dispensing organization.~~

~~(d) "Legal representative" means the qualified patient's parent, legal guardian acting pursuant to a court's authorization as required under s. 744.3215(4), health care surrogate acting pursuant to the qualified patient's written consent or a court's authorization as required under s. 765.113, or an individual who is authorized under a power of attorney to make health care decisions on behalf of the qualified patient.~~

~~(e) "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.~~

(d) ~~(f)~~ "Medical 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, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a medical marijuana treatment center ~~dispensing organization~~ for medical use by a qualifying ~~an eligible~~ patient ~~as defined in s. 499.0295~~.

(e) "Medical marijuana treatment center" or "MMTC" means an entity that is registered with the department and that:

1. Acquires, cultivates, possesses, or processes marijuana or products containing marijuana, including developing related products such as food, tinctures, aerosols, oils, or ointments, for sale to qualifying patients or their caregivers; or

2. Transfers, transports, sells, distributes, or dispenses marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers.

(f) "Medical marijuana testing facility" means an entity that is licensed by the department and that is certified by the department, or by an accredited, third-party laboratory certification body that meets department standards, to obtain, transport, store, analyze, and dispose of samples of medical cannabis for the purpose of certifying the safety and potency of medical cannabis.

(g) "Medical use" means the acquisition, transportation, possession, use, or administration of an amount of medical cannabis in accordance with department rules, or of related supplies, by a qualifying patient or a caregiver for use for the treatment of a debilitating medical condition of the qualifying patient ~~administration of the ordered amount of low-THC cannabis~~

~~or medical cannabis~~. ~~The term does not include the:~~

~~1. Possession, use, or administration of low-THC cannabis or medical cannabis by smoking.~~

~~2. Transfer of low-THC cannabis or medical 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.~~

~~3. Use or administration of low-THC cannabis or medical cannabis:~~

~~a. On any form of public transportation.~~

~~b. In any public place.~~

~~c. In a qualified patient's place of employment, if restricted by his or her employer.~~

~~d. In a state correctional institution as defined in s. 944.02 or a correctional institution as defined in s. 944.241.~~

~~e. On the grounds of a preschool, primary school, or secondary school.~~

~~f. On a school bus or in a vehicle, aircraft, or motorboat.~~

(h) "Person" means a natural person, partnership, association, company, corporation, limited liability company, or organization. The term does not include a governmental organization.

(i) ~~(h)~~ "Qualifying patient" means a person who has been diagnosed to have a debilitating medical condition and who has a physician certification and a valid qualifying patient identification card ~~"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 or medical cannabis from a dispensing~~

~~organization~~.

~~(i) "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.~~

(2) PHYSICIAN CERTIFICATION ~~ORDERING~~.—A physician is authorized to issue a physician certification for medical ~~order low-THC~~ cannabis or a cannabis delivery device to treat a qualifying ~~qualified~~ patient suffering from a debilitating ~~cancer or a physical~~ medical condition ~~that chronically produces symptoms of seizures or severe and persistent muscle spasms; order low-THC cannabis to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the qualified patient; order medical cannabis to treat an eligible patient as defined in s. 499.0295; or order a cannabis delivery device for the medical use of low-THC cannabis or medical cannabis,~~ only if the physician:

(a) Holds an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459;

(b) Has treated the patient for at least 3 months immediately preceding the patient's registration in the compassionate use registry;

(c) Has successfully completed the course and examination required under paragraph (4)(a);

(d) Has determined that the risks of treating the patient with ~~low-THC cannabis or~~ medical cannabis are reasonable in light of the potential benefit to the 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;

(e) Registers as the patient's physician ~~orderer of low-THC cannabis or medical 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 of medical cannabis, including the amount of ~~low-THC cannabis or~~ medical cannabis which ~~that~~ will provide the patient with not more than a 45-day supply and a cannabis delivery device needed by the patient for the medical use of ~~low-THC cannabis or~~ medical cannabis. The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician shall deactivate the registration of the patient and the patient's caregiver ~~legal representative~~ when the physician no longer recommends the medical use of marijuana for the patient ~~treatment is discontinued~~;

(f) 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 or~~ medical cannabis;

(g) 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 and~~ medical cannabis on patients;

(h) Obtains the voluntary written informed consent of the patient or the patient's caregiver ~~legal representative~~ to treatment with medical ~~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 medical ~~low-THC~~ cannabis, the medically

acceptable alternatives, and the potential risks and side effects;

~~(i) Obtains written informed consent as defined in and required under s. 499.0295, if the physician is ordering medical cannabis for an eligible patient pursuant to that section; and~~

(i) ~~(j)~~ Is not a medical director employed by an MMTC ~~a dispensing organization~~.

(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 issues a physician certification for medical ~~orders low-THC~~ cannabis or a cannabis delivery device for a patient without a reasonable belief that the patient is suffering from a debilitating medical condition~~:~~

~~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) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders medical cannabis for a patient without a reasonable belief that the patient has a terminal condition as defined in s. 499.0295~~.

(b) ~~(c)~~ A person who fraudulently represents that he or she has a debilitating medical ~~cancer, a physical medical condition that chronically produces symptoms of seizures or severe and~~

~~persistent muscle spasms, or a terminal~~ condition to a physician for the purpose of being issued a physician certification for ~~ordered low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c)~~(d)~~ A qualifying ~~An eligible~~ patient ~~as defined in s. 499.0295~~ who uses medical cannabis, and such patient's caregiver ~~legal representative~~ who administers medical cannabis, in plain view of or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(d)~~(e)~~ A physician who issues a physician certification for ~~orders low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device and receives compensation from an MMTC ~~a dispensing organization~~ related to the ordering of ~~low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(4) PHYSICIAN EDUCATION.—

(a) Before a physician may issue a physician certification for ~~ordering low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device for medical use by a patient in this state, the appropriate board shall require the ~~ordering~~ physician to successfully complete an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which ~~that~~ encompasses the clinical indications for the appropriate use of ~~low-THC~~

~~cannabis and~~ medical cannabis, the appropriate cannabis delivery devices, the contraindications for such use, and the relevant state and federal laws governing the issuance of physician certifications ~~ordering~~, as well as the dispensing~~,~~ and possessing of these substances and devices. The course and examination shall be administered at least annually. 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 MMTC ~~dispensing organization~~ to hold an active, unrestricted license as a physician under chapter 458 or as an osteopathic physician under chapter 459 and successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which ~~that~~ encompasses appropriate safety procedures and knowledge of ~~low-THC cannabis,~~ medical cannabis~~,~~ and cannabis delivery devices.

~~(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device 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.~~

(c) ~~(d)~~ A physician who fails to comply with this subsection and who issues a physician certification for ~~orders low-THC~~

~~cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

(5) DUTIES OF THE DEPARTMENT.—The department shall:

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, patients, and caregivers ~~the legal representatives~~ of patients as provided under this section. The registry must be accessible to law enforcement agencies and to MMTCs ~~a dispensing organization~~ to verify the authorization of a patient or a patient's caregiver ~~legal representative~~ to possess ~~low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device and record the ~~low-THC cannabis,~~ medical cannabis~~,~~ or cannabis delivery device dispensed. The registry must prevent an active registration of a patient by multiple physicians.

(b) Within 6 months after the registration of 250,000 active qualifying patients in the compassionate use registry, register five additional MMTCs, including, but not limited to, an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and that is a member of the Black Farmers and Agriculturalists Association. Additionally, the department must register an additional five MMTCs within 6 months after the registration of each of the following totals of the number of patients in the compassionate use registry: 350,000 qualifying patients; 400,000 qualifying patients; 500,000 qualifying patients; and then the registration of each additional 100,000 qualifying patients above 500,000, if a sufficient number of MMTC applicants meet the registration

requirements established in this section and by department rule ~~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, medical cannabis, or a cannabis delivery device 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 an MMTC ~~a dispensing organization~~ must be able to demonstrate:

1. The technical and technological ability to cultivate and produce medical ~~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 an MMTC ~~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 medical

~~low-THC~~ cannabis to qualifying ~~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. However, upon ~~a dispensing organization's~~ serving at least 1,000 qualifying ~~qualified~~ patients, the MMTC ~~dispensing organization~~ is ~~only~~ required to maintain only a $2 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 to supervise the activities of the MMTC ~~dispensing organization~~.

~~(c) Upon the registration of 250,000 active qualified patients in the compassionate use registry, approve three dispensing organizations, including, but not limited to, an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association, which must meet the requirements of subparagraphs (b)2.-7. and demonstrate the technical and technological ability to cultivate and produce low-THC cannabis.~~

(c) ~~(d)~~ Allow an MMTC ~~a dispensing organization~~ to make a wholesale purchase of ~~low-THC cannabis or~~ medical cannabis from, or a distribution of ~~low-THC cannabis or~~ medical cannabis to, another MMTC ~~dispensing organization~~.

(d) ~~(e)~~ Monitor physician registration in the compassionate

use registry and the issuance of physician certifications ~~ordering of low-THC cannabis, medical cannabis, or a cannabis delivery device for ordering practices~~ that could facilitate unlawful diversion or misuse of ~~low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device and take disciplinary action as indicated.

(e) Authorize the establishment of medical marijuana testing facilities to ensure that all medical cannabis is tested for potency and contaminants in accordance with the department's quality control program. A medical marijuana testing facility may collect and accept samples of, and possess, store, transport, and test medical cannabis. A medical marijuana testing facility may not be owned by a person who also possesses an ownership interest in an MMTC.

1. The department shall develop regulations concerning medical marijuana testing facility license requirements, suitability, and processes; develop an application form for a medical marijuana testing facility license; and impose an initial application fee and a biennial renewal fee sufficient to cover the costs of administering this section.

2. In addition to licensure, a medical marijuana testing facility must be certified to perform all required tests by the department or by an accredited, third-party laboratory certification body that meets department standards. The department shall establish reasonable rules for the certification and operation of medical marijuana testing facilities. Rules for certification must, at a minimum, address standards relating to:

a. Personnel qualifications;

b. Equipment and methodology;

c. Proficiency testing;

d. Tracking;

e. Sampling;

f. Chain of custody;

g. Record and sample retention;

h. Reporting;

i. Audit and inspection; and

j. Security.

3. The department shall suspend or reduce any mandatory testing requirement specified in its quality control program if the number of licensed and certified medical marijuana testing facilities is insufficient to process the tests necessary to meet the current and anticipated market for MMTCs.

4. A medical marijuana testing facility may accept only samples composed of medical cannabis which are obtained from a sample source approved by the department, including an MMTC, a researcher affiliated with an accredited university or research hospital, a qualifying patient, a caregiver, and any entity authorized by the department.

(6) MEDICAL MARIJUANA TREATMENT CENTERS ~~DISPENSING ORGANIZATION~~.—An approved MMTC ~~dispensing organization~~ must, at all times, maintain compliance with the criteria demonstrated for selection and approval as an MMTC ~~a dispensing organization~~ under subsection (5) and the criteria required in this subsection.

(a) When growing ~~low-THC cannabis or~~ medical cannabis, an MMTC ~~a dispensing organization~~:

1. May use pesticides determined by the department, after

consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

2. Must grow ~~low-THC cannabis or~~ medical cannabis within an enclosed structure and in a room separate from any other plant.

3. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days after a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures.

4. Must perform fumigation or treatment of plants, or the removal and destruction of infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

(b) Before transferring medical cannabis to other licensed premises or selling or transferring medical cannabis to a qualifying patient or caregiver, an MMTC ~~When processing low-THC cannabis or medical cannabis, a dispensing organization~~ must:

1. Have the ~~Process the low-THC cannabis or medical cannabis within an enclosed structure and in a room separate from other plants or products.~~

~~2. Test the processed low-THC cannabis and~~ medical cannabis tested by a medical marijuana testing facility to ensure it meets the standards established by the department's quality control program before it is ~~they are~~ dispensed in accordance with department rule. ~~Results must be verified and signed by two dispensing organization employees. Before dispensing low-THC cannabis, the dispensing organization must determine that the~~

~~test results indicate that the low-THC cannabis meets the definition of low-THC cannabis and, for medical cannabis and low-THC cannabis, that all medical cannabis and low-THC cannabis is safe for human consumption and free from contaminants that are unsafe for human consumption. The dispensing organization must retain records of all testing and samples of each homogenous batch of cannabis and low-THC cannabis for at least 9 months. The dispensing organization must contract with an independent testing laboratory to perform audits on the dispensing organization's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the low-THC cannabis or medical cannabis meets the requirements of this section and that the medical cannabis and low-THC cannabis is safe for human consumption.~~

2.~~3.~~ Package the ~~low-THC cannabis or~~ medical cannabis in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

3.~~4.~~ Package the ~~low-THC cannabis or~~ medical cannabis in a receptacle that has a firmly affixed and legible label stating the following information, and any other information required by department rule:

a. A statement that the ~~low-THC cannabis or~~ medical cannabis meets the requirements of subparagraph 1. ~~2.~~;

b. The name of the medical marijuana treatment center ~~dispensing organization~~ from which the medical cannabis ~~or low-THC cannabis~~ originates; and

c. The batch number, lot number, or other unique identification ~~and harvest~~ number from which the medical cannabis ~~or low-THC cannabis~~ originates.

~~5. Reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of testing pursuant to the audit required under subparagraph 2.~~

(c) When dispensing ~~low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device, an MMTC ~~a dispensing organization~~:

1. May not dispense more than a 45-day supply of ~~low-THC cannabis or~~ medical cannabis to a patient or the patient's caregiver ~~legal representative~~.

2. Must have the MMTC's ~~dispensing organization's~~ employee who dispenses the ~~low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device enter into the compassionate use registry his or her name or unique employee identifier.

3. Must verify in the compassionate use registry that a physician has ordered the ~~low-THC cannabis,~~ medical cannabis~~,~~ or a specific type of a cannabis delivery device for the patient.

4. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes, bongs, or wrapping papers, other than a physician-ordered cannabis delivery device required for the medical use of ~~low-THC cannabis or~~ medical cannabis, while dispensing ~~low-THC cannabis or~~ medical cannabis.

5. Must verify that the patient has an active registration in the compassionate use registry, the patient or patient's caregiver ~~legal representative~~ holds a valid and active identification ~~registration~~ card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.

6. Must, upon dispensing the ~~low-THC cannabis,~~ medical cannabis~~,~~ or cannabis delivery device, record in the registry

the date, time, quantity, and form of ~~low-THC cannabis or~~ medical cannabis dispensed and the type of cannabis delivery device dispensed.

(d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate controls against the diversion, theft, and loss of ~~low-THC cannabis,~~ medical cannabis~~,~~ or cannabis delivery devices, an MMTC ~~a dispensing organization~~ shall:

1.a. Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms; or

b. Maintain a video surveillance system that records continuously 24 hours each day and meets at least one of the following criteria:

(I) Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises. Controlled areas include grow rooms, processing rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms;

(II) Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points;

(III) Recorded images must clearly and accurately display the time and date; or

(IV) Retain video surveillance recordings for a minimum of 45 days or longer upon the request of a law enforcement agency.

2. Ensure that the MMTC's ~~organization's~~ outdoor premises have sufficient lighting from dusk until dawn.

3. Establish and maintain a tracking system approved by the department which ~~that~~ traces the ~~low-THC cannabis or~~ medical cannabis from seed to sale. The tracking system must ~~shall~~ include notification of key events as determined by the department, including when cannabis seeds are planted, when cannabis plants are harvested and destroyed, and when ~~low-THC cannabis or~~ medical cannabis is transported, sold, stolen, diverted, or lost.

4. Not dispense from its premises ~~low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device between the hours of 9 p.m. and 7 a.m., but may perform all other operations and deliver ~~low-THC cannabis and~~ medical cannabis to qualifying ~~qualified~~ patients 24 hours each day.

5. Store ~~low-THC cannabis or~~ medical cannabis in a secured, locked room or a vault.

6. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the premises at all times.

7. Require each employee to wear a photo identification badge at all times while on the premises.

8. Require each visitor to wear a visitor’s pass at all times while on the premises.

9. Implement an alcohol and drug-free workplace policy.

10. Report to local law enforcement within 24 hours after it is notified or becomes aware of the theft, diversion, or loss of ~~low-THC cannabis or~~ medical cannabis.

(e) To ensure the safe transport of ~~low-THC cannabis or~~ medical cannabis to medical marijuana testing facilities, MMTCs, caregivers ~~dispensing organization facilities, independent~~

~~testing laboratories~~, or qualifying patients, an MMTC or medical marijuana testing facility that transports medical cannabis ~~the dispensing organization~~ must:

1. Maintain a transportation manifest, which must be retained for at least 1 year.

2. Ensure only vehicles in good working order are used to transport ~~low-THC cannabis or~~ medical cannabis.

3. Lock ~~low-THC cannabis or~~ medical cannabis in a separate compartment or container within the vehicle.

4. Require at least two persons to be in a vehicle transporting ~~low-THC cannabis or~~ medical cannabis, and require at least one person to remain in the vehicle while the ~~low-THC cannabis or~~ medical cannabis is being delivered.

5. Provide specific safety and security training to employees transporting or delivering ~~low-THC cannabis or~~ medical cannabis.

(7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES.—

(a) The department may conduct announced or unannounced inspections of MMTCs ~~dispensing organizations~~ to determine compliance with this section or rules adopted pursuant to this section.

(b) The department shall inspect an MMTC ~~a dispensing organization~~ upon complaint or notice provided to the department that the MMTC ~~dispensing organization~~ has dispensed ~~low-THC cannabis or~~ medical cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.

(c) The department shall conduct at least a biennial inspection of each MMTC ~~dispensing organization~~ to evaluate the

MMTC's ~~dispensing organization's~~ records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.

(d) The department may enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with the department, to conduct inspections or perform other responsibilities assigned to the department under this section.

(e) The department must make a list of all approved MMTCs, physicians who are ~~dispensing organizations and~~ qualified to issue physician certifications, ~~ordering physicians~~ and medical directors of MMTCs publicly available on its website.

~~(f) The department may establish a system for issuing and renewing registration cards for patients and their legal representatives, establish the circumstances under which the cards may be revoked by or must be returned to the department, and establish fees to implement such system. The department must require, at a minimum, the registration cards to:~~

~~1. Provide the name, address, and date of birth of the patient or legal representative.~~

~~2. Have a full-face, passport-type, color photograph of the patient or legal representative taken within the 90 days immediately preceding registration.~~

~~3. Identify whether the cardholder is a patient or legal representative.~~

~~4. List a unique numeric identifier for the patient or legal representative that is matched to the identifier used for such person in the department's compassionate use registry.~~

~~5. Provide the expiration date, which shall be 1 year after the date of the physician's initial order of low-THC cannabis or medical cannabis.~~

~~6. For the legal representative, provide the name and unique numeric identifier of the patient that the legal representative is assisting.~~

~~7. Be resistant to counterfeiting or tampering.~~

(f) ~~(g)~~ The department may impose reasonable fines not to exceed $10,000 on an MMTC ~~a dispensing organization~~ for any of the following violations:

1. Violating this section, s. 499.0295, or department rule.

2. Failing to maintain qualifications for approval.

3. Endangering the health, safety, or security of a qualifying ~~qualified~~ patient.

4. Improperly disclosing personal and confidential information of the qualifying ~~qualified~~ patient.

5. Attempting to procure MMTC ~~dispensing organization~~ approval by bribery, fraudulent misrepresentation, or extortion.

6. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the business of an MMTC ~~a dispensing organization~~.

7. Making or filing a report or record that the MMTC ~~dispensing organization~~ knows to be false.

8. Willfully failing to maintain a record required by this section or department rule.

9. Willfully impeding or obstructing an employee or agent of the department in the furtherance of his or her official duties.

10. Engaging in fraud or deceit, negligence, incompetence, or misconduct in the business practices of an MMTC ~~a dispensing organization~~.

11. Making misleading, deceptive, or fraudulent representations in or related to the business practices of an MMTC ~~a dispensing organization~~.

12. Having a license or the authority to engage in any regulated profession, occupation, or business that is related to the business practices of an MMTC ~~a dispensing organization~~ suspended, revoked, or otherwise acted against by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law.

13. Violating a lawful order of the department or an agency of the state, or failing to comply with a lawfully issued subpoena of the department or an agency of the state.

(g) ~~(h)~~ The department may suspend, revoke, or refuse to renew the ~~a dispensing organization's~~ approval of an MMTC if the MMTC ~~a dispensing organization~~ commits any of the violations in paragraph (f) ~~(g)~~.

(h) ~~(i)~~ The department shall renew the approval of an MMTC ~~a dispensing organization~~ biennially if the MMTC ~~dispensing organization~~ meets the requirements of this section and pays the biennial renewal fee.

(i)1. The department shall establish a quality control program requiring medical cannabis to be tested by a medical

marijuana testing facility for potency and contaminants before sale to qualifying patients and caregivers.

a. The quality control program must require MMTCs to submit samples from each batch or lot of medical cannabis harvested or manufactured to a medical marijuana testing facility for testing to ensure, at a minimum, that the labeling of the potency of tetrahydrocannabinol and all other marketed cannabinoids or terpenes is accurate and that the medical cannabis dispensed to qualifying patients is safe for human consumption.

b. All samples submitted for testing to satisfy a test required under the quality control program must be collected by the medical marijuana testing facility or its certified agent in accordance with department rules.

c. An MMTC must maintain records of all tests conducted on medical cannabis, including the results of each test and any additional information as required by the department.

2. The department shall adopt all rules necessary to create and oversee the quality control program, which must include, at a minimum:

a. Permissible levels of variation in potency labeling and standards requiring tetrahydrocannabinol in edible medical cannabis products to be distributed homogenously throughout the product;

b. Permissible levels of contaminants and mandatory testing for contaminants to confirm that the tested medical cannabis is safe for human consumption, which must include, but is not limited to, testing for microbiological impurity, residual solvents, and pesticide residues;

c. The destruction of medical cannabis determined to be

inaccurately labeled or unsafe for human consumption after the MMTC has an opportunity to take remedial action;

d. The collection, storage, handling, recording, and destruction of samples of medical cannabis by medical marijuana testing facilities; and

e. Security, inventory tracking, and record retention.

(j) The department may adopt rules necessary to implement and administer this section.

(8) PREEMPTION.—

(a) All matters regarding the regulation of the cultivation and processing of medical cannabis ~~or low-THC cannabis~~ by MMTCs ~~dispensing organizations~~ are preempted to the state.

(b) A municipality may determine by ordinance the criteria for the number and location of, and other permitting requirements that do not conflict with state law or department rule for, dispensing facilities of MMTCs ~~dispensing organizations~~ located within its municipal boundaries. A county may determine by ordinance the criteria for the number, location, and other permitting requirements that do not conflict with state law or department rule for all dispensing facilities of MMTCs ~~dispensing organizations~~ located within the unincorporated areas of that county.

(9) 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 qualifying ~~qualified~~ patient or a caregiver ~~and the qualified patient's legal representative~~ may purchase and possess for the qualifying patient's medical use up to the amount of ~~low-THC cannabis or~~ medical cannabis ordered for the

patient, but not more than a 45-day supply, and a cannabis delivery device 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 MMTC ~~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,~~ medical cannabis~~,~~ or a cannabis delivery device. As used in ~~For purposes of~~ this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) 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 medical marijuana testing facility ~~an approved independent testing laboratory~~ may possess, test, transport, and lawfully dispose of ~~low-THC cannabis or~~ medical cannabis as provided by department rule.

(d) An approved MMTC ~~dispensing organization~~ and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of ~~low-THC cannabis,~~ medical cannabis~~,~~ or a cannabis delivery device.

(e) An approved MMTC ~~dispensing organization~~ that continues to meet the requirements for approval is presumed to be registered with the department and to meet the regulations adopted by the department or its successor agency for the

purpose of dispensing medical cannabis ~~or low-THC cannabis~~ under Florida law. Additionally, the authority provided to an MMTC ~~a dispensing organization~~ in s. 499.0295 does not impair its registration with the department ~~the approval of a dispensing organization~~.

(f) This subsection does not exempt a person from prosecution for a criminal offense related to impairment or intoxication resulting from the medical use of ~~low-THC cannabis or~~ medical cannabis or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

Section 2. Subsections (1) and (2) of section 381.987, Florida Statutes, are amended, and paragraphs (b) and (c) of subsection (3) of that section are amended, to read:

381.987 Public records exemption for personal identifying information in the compassionate use registry.—

(1) A patient's personal identifying information held by the department in the compassionate use registry established under s. 381.986, including, but not limited to, the patient's name, address, telephone number, and government-issued identification number, and all information pertaining to the physician certification ~~physician's order~~ for medical ~~low-THC~~ cannabis and the dispensing thereof are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(2) A physician's identifying information held by the department in the compassionate use registry established under s. 381.986, including, but not limited to, the physician's name, address, telephone number, government-issued identification

number, and Drug Enforcement Administration number, and all information pertaining to the physician certification ~~physician's order~~ for medical ~~low-THC~~ cannabis and the dispensing thereof are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(3) The department shall allow access to the registry, including access to confidential and exempt information, to:

(b) A medical marijuana treatment center ~~dispensing organization~~ approved by the department pursuant to s. 381.986 which is attempting to verify the authenticity of a physician certification ~~physician's order~~ for medical ~~low-THC~~ cannabis, including whether the physician certification ~~order~~ had been previously filled and whether the physician certification ~~order~~ was written for the person attempting to have it filled.

(c) A physician who has issued a physician certification ~~written an order~~ for medical ~~low-THC~~ cannabis for the purpose of monitoring the patient's use of such cannabis or for the purpose of determining, before issuing an order for medical ~~low-THC~~ cannabis, whether another physician has ordered the patient's use of medical ~~low-THC~~ cannabis. The physician may access the confidential and exempt information only for the patient for whom he or she has ordered or is determining whether to order the use of medical ~~low-THC~~ cannabis pursuant to s. 381.986.

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

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

(1) As used in this section, the term "medical cannabis" has the same meaning ~~"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, or an academic medical research institution legally affiliated with a licensed children's specialty hospital as defined in s. 395.002(28) which ~~that~~ contracts with the Department of Health, may conduct research on cannabidiol and medical ~~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 medical ~~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. Present paragraphs (b) and (c) of subsection (2) of section 499.0295, Florida Statutes, are redesignated as paragraphs (a) and (b), respectively, present paragraphs (a) and (c) of that subsection are amended, a new paragraph (c) is added to that subsection, and subsection (3) of that section is amended, to read:

499.0295 Experimental treatments for terminal conditions.—

(2) As used in this section, the term:

~~(a) "Dispensing organization" means an organization approved by the Department of Health under s. 381.986(5) to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices.~~

(b) ~~(c)~~ "Investigational drug, biological product, or

device" means:

1. A drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration; or

2. Medical cannabis that is manufactured and sold by an MMTC ~~a dispensing organization~~.

(c) "Medical marijuana treatment center" or "MMTC" means an organization registered with the Department of Health under s. 381.986.

(3) Upon the request of an eligible patient, a manufacturer may, or, upon the issuance of a physician certification ~~a physician's order~~ pursuant to s. 381.986, an MMTC ~~a dispensing organization~~ may:

(a) Make its investigational drug, biological product, or device available under this section.

(b) Provide an investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986 to an eligible patient without receiving compensation.

(c) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986.

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 "medical cannabis," ~~"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 amended to read:

1004.441 Refractory and intractable epilepsy treatment and research.—

(1) As used in this section, the term "medical cannabis" has the same meaning ~~"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 medical ~~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 medical ~~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. This act shall take effect July 1, 2017.