By Senator Braynon

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A bill to be entitled An act relating to medical use of marijuana; amending s. 381.986, F.S.; providing legislative intent; defining, redefining, and deleting terms; authorizing physicians to issue physician certifications to specified patients for the provision of marijuana and marijuana delivery devices; requiring physicians to meet certain conditions to be authorized to issue and make determinations in physician certifications; requiring certain physicians to annually reexamine and reassess patients and update patient information in the compassionate use registry; providing requirements for physician certification for patients who are non-Florida residents; providing that a prior order for low-THC cannabis or medical cannabis issued is considered a physician certification under certain circumstances; providing requirements for such certifications; revising criminal penalties; reducing the number of hours of coursework required of physicians who issue physician certifications; providing that physicians who meet specified requirements are grandfathered for the purpose of specified education requirements; authorizing qualifying patients over the age of 21 to designate or remove caregivers; requiring caregivers to meet specified requirements, including a 1-hour course on the administration of marijuana; authorizing a qualifying patient to designate only one caregiver at any given time; providing exceptions; authorizing a

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caregiver to assist only one qualifying patient at any given time; providing exceptions; requiring the Department of Health to register on the compassionate use registry a caregiver and to issue him or her a caregiver identification card if the caregiver meets certain requirements; providing requirements for assisting a qualifying patient who is under the age of 18; revising the list of entities that have access to the compassionate use registry; requiring the department to adopt rules by a specified date; authorizing the department to charge a fee for identification cards; requiring the department to begin issuing identification cards to qualified registrants by a specific date; providing requirements for the identification cards; requiring the department to register certain dispensing organizations as medical marijuana treatment centers (MMTCs) by a certain date; deleting provisions to conform to changes made by the act; requiring the department to register additional MMTCs in accordance with a specified schedule; prohibiting an entity from being issued more than one MMTC registration; requiring the department to review the number of qualifying patients every 6 months; limiting the number of MMTCs; decreasing the required performance bond amount under certain circumstances; requiring the department to create a 30-minute educational program for qualifying patients; revising the operational requirements for MMTCs; authorizing the department to waive certain

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requirements in the MMTC registration application under specified circumstances; providing requirements for MMTCs to grow, process, and dispense marijuana, rather than requirements for dispensing organizations to grow, process, and dispense low-THC cannabis or medical cannabis; providing a contract option that requires an independent testing laboratory to directly test an MMTC's marijuana final product; requiring that marijuana receptacles be opaque, childproof, and tamper-evident; reducing the time that samples are required to be retained; requiring verification of patient and caregiver identification cards, rather than registration cards, and amount and type of marijuana before dispensing; requiring compliance with certain standards in the production and dispensing of edibles or food products; requiring an MMTC to enter additional information into the compassionate use registry; providing requirements to ensure the safety and security of premises and facilities of MMTCs, rather than the safety and security of premises and facilities of dispensing organizations; requiring an MMTC to register all owners and employees with the department; requiring an MMTC to present a floor plan to the department; defining terms to provide criteria on visitor access to MMTC areas; providing requirements to ensure the safe and sanitary transport of marijuana, rather than the safe transport of low-THC cannabis and medical cannabis; requiring a vehicle transporting marijuana to be legally parked under

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certain circumstances; revising the department's authority and responsibilities; requiring the department to adopt rules relating to ownership changes or changes in an owner's investment interest; conforming provisions to changes made by the act; providing circumstances under which the department may suspend, revoke, or refuse to renew an MMTC's registration; providing rulemaking authority; authorizing an MMTC employee to administer marijuana under certain circumstances; providing construction; conforming provisions to changes made by the act; providing that a physician who issues a physician certification is immune to civil claims and claims for medical malpractice under certain circumstances; providing that a health insurance provider or a governmental agency or authority is not required to reimburse expenses related to the use of marijuana; authorizing certain institutes or state universities to possess, test, transport, or dispose of marijuana for research purposes; prohibiting a person from offering, advertising, or performing services, and from owning, operating, and maintaining certain facilities, without registration; providing penalties; prohibiting the importation of marijuana; authorizing the exportation of marijuana and products containing marijuana under certain circumstances; providing severability; amending ss. 381.987, 385.211, 499.0295, and 1004.441, F.S.; conforming provisions to changes made by the act; providing a directive to the Division 35-01039-17 20171666

of Law Revision and Information; 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 marijuana low-THC and medical cannabis.

- (1) LEGISLATIVE INTENT.—
- (a) It is the intent of the Legislature to implement s. 29,
 Art. X of the State Constitution by creating a unified
 regulatory structure within the framework of this section for
 the acquisition, cultivation, possession, processing, transfer,
 transportation, sale, distribution, or dispensing of marijuana,
 products containing marijuana, related supplies, or educational
 materials to qualifying patients or their caregivers.
- (b) The Legislature intends that all rules adopted by the Department of Health to implement this section be adopted pursuant to s. 120.536(1) or s. 120.54. The Legislature intends that the department use emergency rulemaking procedures pursuant to s. 120.54(4) to adopt rules under this section if necessary to meet any deadline for rulemaking established in s. 29, Art. X of the State Constitution.
- (c) Further, the Legislature intends that all registrations for the purposes specified in paragraph (a) be issued solely in accordance with the requirements of this section and all rules adopted under this section.
 - (2) DEFINITIONS.—As used in this section, the term:

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- (a) "Caregiver" means a person who:
- 1. Is at least 21 years old unless he or she is a close relative of the qualifying patient and the patient demonstrates a need for assistance with the medical use of marijuana;
- 2. Has agreed in writing to assist the qualifying patient with the qualifying patient's medical use of marijuana; and
- 3. Does not receive compensation, other than actual expenses incurred, for assisting the qualifying patient with the medical use of marijuana unless the caregiver is acting pursuant to employment in a licensed facility "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) "Close relative" means a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half blood, by marriage, or by adoption.
- (c) (b) "Debilitating medical condition" means cancer, epilepsy, glaucoma, a positive status for human immunodeficiency virus, acquired immune deficiency syndrome, posttraumatic stress disorder, amyotrophic lateral sclerosis, Crohn's disease, Parkinson's disease, multiple sclerosis, a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, a terminal condition, or any other debilitating medical condition of the same kind or class as, or comparable to, those conditions enumerated in this paragraph and for which a physician believes that the use of medical cannabis would likely outweigh the potential health risks to a patient "Dispensing organization" means an

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

- $\underline{\text{(d)}}$ "Independent testing laboratory" means a laboratory, including the managers, employees, or contractors of the laboratory:
- $\underline{1.}$ Which has no direct or indirect interest in a $\underline{\text{medical}}$ marijuana treatment center; and
- 2. In which no medical marijuana treatment center has any direct or indirect interest dispensing organization.
- (e) (d) "Legal representative" means the qualifying 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 qualifying 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 qualifying qualified patient.
- <u>(f) (e)</u> "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 by a medical marijuana treatment center from a dispensing organization.
- (g) (f) "Marijuana" has the same meaning as provided in s.

 29, Art. X of the State Constitution "Medical cannabis" means

 all parts of any plant of the genus Cannabis, whether growing or

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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 dispensing organization for medical use by an eligible patient as defined in s. 499.0295.

- (h) "Marijuana delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing marijuana or low-THC cannabis into the human body.
- (i) "Medical marijuana treatment center" or "MMTC" has the same meaning as provided in s. 29, Art. X of the State Constitution.
- (j) (g) "Medical use" has the same meaning as provided in s. 29, Art. X of the State Constitution means administration of the ordered amount of low-THC cannabis or medical cannabis. The term does not include the:
- 1. The possession, use, or administration of marijuana low-THC cannabis or medical cannabis by smoking. As used in this subparagraph, the term "smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.
- 2. The possession, use, or administration of marijuana that is not purchased or acquired from a medical marijuana treatment center.
- 3. The transfer of marijuana low-THC cannabis or medical cannabis to a person other than the qualifying qualified patient for whom it was ordered or the qualifying qualified patient's caregiver legal representative on behalf of the qualifying qualified patient.

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4.3. The use or administration of marijuana low-THC cannabis or medical cannabis:

- a. On any form of public transportation.
- b. In any public place.
- c. In a <u>qualifying qualified</u> 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.
- (k) (h) "Qualifying patient" has the same meaning as provided in s. 29, Art. X of the State Constitution. The term also includes eligible patients, as defined in s. 499.0295. A patient is not a qualifying patient unless he or she is registered with the department and has been issued a "Qualified patient" means a resident of this state who has been added to the compassionate use registry identification card 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.
- (3)(2) PHYSICIAN <u>CERTIFICATION</u> ORDERING.—A physician is authorized to <u>issue a physician certification for the provision</u> of marijuana and marijuana delivery devices order low-THC cannabis to treat a qualified patient suffering from cancer or a physical medical condition that chronically produces symptoms of

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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 a qualifying 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 (6)(a) (4)(a);
- (c) Has conducted a physical examination and made a full assessment of the medical history of the patient;
- (d) Has determined that the <u>medical use of marijuana would</u> likely outweigh the potential health 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 <u>patient's physician</u> 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, including the amount of marijuana which low-THC cannabis or

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medical cannabis that will provide the patient with not more than a 90-day 45-day supply and any marijuana a cannabis delivery device needed by the patient for the medical use of marijuana low-THC cannabis or medical cannabis. A physician may certify an amount greater than a 90-day supply of marijuana if the physician has a reasonable belief that the patient will use the additional marijuana in a medically appropriate way. The physician must also update the registry within 7 days after any change is made to the physician certification original order to reflect the change. The physician shall deactivate the registration of the patient and the patient's legal representative when the physician no longer recommends the medical use of marijuana for the patient treatment is discontinued;

- (f) At least annually, recertifies the qualifying patient pursuant to this subsection. The physician must require that a non-Florida resident be physically present during the initial exam and all followup exams. Before being issued a physician certification, a qualifying patient who is a non-Florida resident must:
- 1. Affirm that his or her stay in this state is for at least 30 days;
- 2. Provide proof that he or she holds a state-issued identification card or certification in another state with a medical marijuana program; or
- 3. Elect to wait 2 weeks after the date of receiving a physician certification to obtain marijuana. A non-Florida resident who elects to wait under this subparagraph may not be issued a physician certification for marijuana for more than 6

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months; and

(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 legal representative 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;
- (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
- $\underline{\text{(g)}}$ Is not a medical director employed by $\underline{\text{an MMTC}}$ $\underline{\text{a}}$ dispensing organization.
- (4)(3) GRANDFATHERING.—An order for low-THC cannabis or medical cannabis issued pursuant to former s. 381.986, Florida Statutes 2016, and registered with the compassionate use registry on or before the effective date of this act shall be considered a physician certification issued pursuant to this section. The details and expiration date of such certification must be identical to the details and expiration date of the order as logged in the compassionate use registry. Until the department begins issuing compassionate use registry identification cards, all patients with such orders shall be considered qualifying patients, notwithstanding the requirement that a qualifying patient have a compassionate use registry

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identification card.

(5) 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 <u>issues a physician certification for marijuana to orders low-THC cannabis for</u> a patient without a reasonable belief that the patient is suffering from <u>a debilitating medical condition</u>:
- 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.
- (c) A person who fraudulently represents that he or she has a debilitating 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 marijuana ordered low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

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

- (d) Except as provided in paragraph (c), a caregiver who violates any provision of this section or applicable department rule commits, upon the first offense, a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, and, upon the second and subsequent offenses, a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
- (e) A physician who <u>issues a physician certification for marijuana orders low-THC cannabis</u>, medical cannabis, or a <u>marijuana cannabis</u> delivery device and receives compensation from <u>an MMTC a dispensing organization</u> related to <u>issuing the physician certification for marijuana the ordering of low-THC cannabis</u>, medical cannabis, or a <u>marijuana cannabis</u> delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).
 - (6) (4) PHYSICIAN EDUCATION.—
- (a) Before a physician may issue a physician certification pursuant to subsection (3) 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 a 4-hour an 8-hour

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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 marijuana low-THC cannabis and medical cannabis, the appropriate marijuana cannabis delivery devices, the contraindications for such use, and the relevant state and federal laws governing the issuance of physician certifications, as well as the ordering, dispensing, and possessing of these substances and devices. The course and examination shall be administered at least quarterly annually. Successful completion of the course may be used by a physician to satisfy 4 hours $\frac{8}{3}$ 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. A physician who has completed a 4-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompasses the clinical indications for the appropriate use of marijuana and who is registered in the compassionate use registry on the effective date of this act is deemed to meet the requirements of this paragraph.

(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 marijuana low-THC cannabis, medical

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cannabis, and marijuana 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.

(d) A physician who fails to comply with this subsection and who issues a physician certification for marijuana orders low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

(7) CAREGIVERS.—

(a) During the course of registration with the department for inclusion on the compassionate use registry, or at any time while registered, a qualifying patient over the age of 21 may designate or remove an individual as his or her caregiver to assist him or her with the medical use of marijuana. The designated caregiver must pass a level 2 screening pursuant to chapter 435 unless the patient is a close relative of the caregiver and the patient demonstrates a need for assistance with the medical use of marijuana. The department shall create a 1-hour course for caregivers and a subsequent examination that encompass basic information on the procedure and administration of marijuana. The department shall require the designated caregiver to successfully complete the course and pass the subsequent examination before registering an individual as a

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caregiver.

(b) A qualifying patient may have only one designated caregiver at any given time unless all of the qualifying patient's caregivers are his or her close relatives or legal representatives.

- (c) A caregiver may assist only one qualifying patient at any given time unless:
- 1. All qualifying patients the caregiver is assisting are close relatives of each other and the caregiver is the legal representative of at least one of the patients; or
- 2. All qualifying patients the caregiver is assisting are receiving hospice services, or are residents in the same assisted living facility, nursing home, or other licensed facility and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice or licensed facility; and the caregiver provides personal care or services directly to clients of the hospice or licensed facility as a part of his or her employment duties at the hospice or licensed facility.
- (d) The department must register a caregiver on the compassionate use registry and issue him or her a caregiver identification card if he or she:
- 1. Is designated by a qualifying patient, provides hospice services to a qualifying patient, or is requested by a qualifying patient in a licensed facility for assistance with the medical use of marijuana; and
- 2. Meets all of the requirements of this subsection and department rules.
 - (e) If a qualifying patient is under the age of 18, only a

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parent, legal guardian, caregiver, or health care provider may
assist the patient in the purchasing and administering of
marijuana for medical use. A qualifying patient under the age of
may not purchase marijuana.

- (8) (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, qualifying patients, and caregivers the legal representatives of patients as provided under this section. The registry must be accessible to:
- 1. Physicians licensed under chapter 458 or chapter 459, to ensure proper care for patients requesting physician certifications;
- 2. Practitioners licensed to prescribe prescription drugs, to ensure proper care for patients before prescribing medications that may interact with the medical use of marijuana;
- 3. Law enforcement agencies, only for the purpose of verifying the authorization of a qualifying patient or a qualifying patient's caregiver to possess marijuana or a marijuana delivery device; and
- 4. MMTCs, to a dispensing organization to verify the authorization of a qualifying patient or a qualifying patient's caregiver legal representative to possess marijuana low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device and to record the marijuana low-THC cannabis, medical cannabis, or marijuana cannabis delivery device dispensed. The registry must prevent an active registration of a qualifying patient by multiple physicians.
 - (b) By July 3, 2017, adopt rules, pursuant to s. 120.536(1)

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or s. 120.54, establishing procedures for the issuance, annual renewal, suspension, and revocation of compassionate use registry identification cards for qualifying patients and caregivers who are residents of this state. The department may use emergency rulemaking procedures pursuant to s. 120.54(4) to adopt rules under this section as necessary to ensure that rules are adopted on or before July 3, 2017. The department may charge a reasonable fee associated with the issuance and renewal of patient and caregiver identification cards. By October 3, 2017, the department shall begin issuing identification cards to adult patients who are residents of this state and who have a physician certification that meets the requirements of subsection (3); minor patients who are residents of this state and who have a physician certification that meets the requirements of subsection (3) and the written consent of a parent or legal guardian; and caregivers registered pursuant to subsection (7). Patient and caregiver identification cards must be resistant to counterfeiting and tampering and must include at least the following:

- 1. The name, address, and date of birth of the patient or caregiver, as appropriate;
 - 2. Designation of the cardholder as a patient or caregiver;
- 3. A unique numeric identifier for the patient or caregiver which is matched to the identifier used for such person in the department's compassionate use registry. A caregiver's numeric identifier and file in the compassionate use registry must be linked to the file of the patient or patients the caregiver is assisting so that the caregiver's status may be verified for each patient individually;

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4. The expiration date, which must be 1 year after the date of issuance of the identification card or the date treatment ends as provided in the patient's physician certification, whichever occurs first; and

- 5. For a caregiver who is assisting three or fewer qualifying patients, the name and unique numeric identifier, or the names and unique numeric identifiers, of the qualifying patient, or the qualifying patients, that the caregiver is assisting.
- (c) Deem a dispensing organization approved under s. 2, chapter 2014-157, Laws of Florida, or s. 3, chapter 2016-123, Laws of Florida, before June 1, 2017, to meet the requirements for approval as an MMTC under this section. The department shall presume such dispensing organization to be registered with the department as an MMTC and shall authorize such dispensing organization to acquire, cultivate, possess, or process marijuana or products containing marijuana, including developing related products such as food, tinctures, aerosols, oils, or ointments, for sale to qualifying patients and their caregivers; or to transfer, transport, sell, distribute, or dispense marijuana, products containing marijuana, related supplies, and educational materials to qualifying patients or their caregivers. If holding a valid certificate of registration by the Department of Agriculture and Consumer Services pursuant to s. 581.131 is not required for the renewal of the registration approval, the Department of Health shall renew the approval of such dispensing organization as an MMTC biennially upon payment by the dispensing organization of the biennial renewal fee Authorize the establishment of five dispensing organizations to

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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.

- (d) Register 10 additional MMTCs before October 3, 2017, including, but not limited to, 1 applicant per occurrence which 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 which is a member of the Black Farmers and Agriculturalists Association. All applicants must meet the requirements in this subsection and in subsection (9) and be an entity registered to do business in this state for at least 5 consecutive years as of the date of the application. Upon the registration of every additional 25,000 active qualified patients in the compassionate use registry after January 1, 2018, the department shall register 4 additional MMTCs.
 - 1. An entity may not be issued more than 1 registration.
- 2. The department shall review the number of qualifying patients every 6 months.
- 3. The department may not register more than 1 MMTC for every 10 pharmacies licensed in this state.
- <u>(e)</u> The department shall Develop an application form <u>for</u> registration as an MMTC and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. <u>To be registered as an MMTC, the An applicant for approval as a dispensing organization must be able to demonstrate:</u>

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1. The technical and technological ability to cultivate and produce marijuana 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 $\frac{\text{an MMTC}}{\text{a dispensing}}$
- 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 marijuana low-THC cannabis to registered qualifying 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 an MMTC's a dispensing organization's serving at least 1,000 qualifying qualified patients, the dispensing organization is only required to maintain only a \$1 \$2 million performance bond, to apply retroactively to all registrations.
- 6. That all owners with a 5 percent or greater share and all managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.

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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.
- (f) (d) Allow an MMTC a dispensing organization to make a wholesale purchase of marijuana low-THC cannabis or medical cannabis from, or a distribution of marijuana low-THC cannabis or medical cannabis to, another MMTC dispensing organization.
- <u>(g) (e)</u> Monitor physician registration <u>in the compassionate</u> use registry and the issuance of physician certifications pursuant to subsection (3) and ordering of low-THC cannabis, medical cannabis, or a cannabis delivery device for ordering practices that could facilitate unlawful diversion or misuse of marijuana low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device and take disciplinary action as indicated.
- (h) Create a 30-minute educational program for qualifying patients on the responsible use of marijuana. The program must address the safe consumption of edible marijuana products and keeping the patient's marijuana from children and unauthorized users.

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(9) (6) MEDICAL MARIJUANA TREATMENT CENTERS DISPENSING ORGANIZATION. - In order to be an MMTC, an entity must register with the department. An MMTC An approved dispensing organization must, at all times, maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) and the criteria required in this subsection and all representations made to the department in the MMTC's application for registration. Upon request, the department may grant an MMTC one or more variances from the representations made in the MMTC's application. Consideration of such a variance shall be based upon the facts and circumstances surrounding the request. A variance may not be granted unless the requesting MMTC can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application. An MMTC is not required to obtain a variance for deviations from the MMTC's application for registration which do not materially affect the MMTC's operations or the quality of the marijuana dispensed by the MMTC or for deviations from the MMTC's application which are needed to conform to current statutes or rules.

- (a) When growing <u>marijuana</u> 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

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restricted-use pesticides pursuant to s. 487.042.

2. Must grow $\underline{\text{marijuana}}$ $\underline{\text{low-THC cannabis}}$ within an enclosed structure $\underline{\text{and in a room separate from any}}$ $\underline{\text{other plant}}$.

- 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) When processing <u>marijuana</u>, an <u>MMTC</u> low-THC cannabis or medical cannabis, a dispensing organization must:
- 1. Follow health and safety standards established by the department. The department shall require the use of food grade solvents, equipment, and procedures in the processing of marijuana to ensure safe consumption.
- $\underline{2.}$ Process the <u>marijuana</u> low-THC cannabis or medical cannabis within an enclosed structure and in a room separate from other plants or products.
- 3.2. Test the processed <u>marijuana</u> low-THC cannabis and medical cannabis before <u>it is</u> they are dispensed. Results must be verified and signed by two <u>MMTC dispensing organization</u> employees. Before dispensing <u>marijuana</u> low-THC cannabis, the <u>MMTC dispensing organization</u> must determine that the <u>marijuana</u> test results indicate that the low-THC cannabis meets the definition of low-THC cannabis and, for medical cannabis and

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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 MMTC dispensing organization must retain records of all testing and samples of each homogenous batch of marijuana cannabis and low-THC cannabis for at least 6 9 months. The MMTC dispensing organization must contract with an independent testing laboratory to:

- <u>a.</u> Perform audits on the <u>MMTC's</u> <u>dispensing organization's</u> standard operating procedures, testing records, and samples and provide the results to the department to confirm that the <u>marijuana low-THC cannabis or medical cannabis</u> meets the requirements of this section and that the <u>marijuana medical cannabis and low-THC cannabis</u> is safe for human consumption; or
- b. Directly test the marijuana final product to ensure that it meets the requirements of this section and is safe for human consumption before it is dispensed or distributed.
- 4.3. Directly package the marijuana 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.
- 5.4. Package the <u>marijuana</u> low-THC cannabis or medical cannabis in <u>an opaque</u>, childproof, and tamper-evident a receptacle that has a firmly affixed and legible label stating the following information:
- a. A statement that the <u>marijuana</u> low-THC cannabis or medical cannabis meets the requirements of <u>subparagraphs 1.,</u> subparagraph 2. and 3.;
- b. The name of the $\underline{\text{MMTC}}$ dispensing organization from which the $\underline{\text{marijuana}}$ $\underline{\text{medical cannabis or low-THC cannabis}}$ originates and the MMTC's registration number; and

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c. The batch number and harvest number from which the marijuana medical cannabis or low-THC cannabis originates;

- d. A universal symbol indicating that marijuana is contained in the package; and
 - e. Warning statements.
- $\underline{6.5.}$ Reserve two processed samples from each batch and retain such samples for at least $\underline{6}$ 9 months for the purpose of testing pursuant to the audit required under subparagraph 3. $\underline{2.}$
- (c) When dispensing <u>marijuana</u> low-THC cannabis, medical cannabis, or a <u>marijuana</u> cannabis delivery device, <u>an MMTC</u> a dispensing organization:
- 1. May not dispense more than the a 45-day supply of marijuana low-THC cannabis or medical cannabis to a qualifying patient or the qualifying patient's caregiver which is indicated on the qualifying patient's physician certification legal representative.
- 2. Must ensure that have the dispensing organization's employee who dispenses the marijuana low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device enters enter into the compassionate use registry his or her name or unique employee identifier.
- 3. Must verify that the qualifying patient and the caregiver, if applicable, both have an active and valid compassionate use registry identification card and that the amount and type of marijuana dispensed match the physician's certification in the compassionate use registry for that qualifying patient that a physician has ordered the low-THC cannabis, medical cannabis, or a specific type of a cannabis delivery device for the patient.

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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 marijuana cannabis delivery device required for the medical use of marijuana which is specified in the physician certification.

An MMTC may produce and dispense marijuana as an edible or food product but may not produce such items in a format designed to be attractive to children. In addition to the requirements of this section and department rule, food products produced by an MMTC must meet all food safety standards established in state and federal law, including, but not limited to, the identification of the serving size and the amount of tetrahydrocannabinol in each serving 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 legal representative holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.
- 5.6. Must, upon dispensing the marijuana low-THC cannabis, medical cannabis, or marijuana cannabis delivery device, record in the registry the date, time, quantity, and form of marijuana low-THC cannabis or medical cannabis dispensed; and the type of marijuana cannabis delivery device dispensed; and the name and compassionate use registry numeric identifier of the qualifying patient or caregiver to whom the marijuana delivery device was dispensed.
- (d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate

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controls against the diversion, theft, and loss of <u>marijuana</u> low-THC cannabis, medical cannabis, or <u>marijuana</u> 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 $\underline{\mathsf{MMTC's}}$ 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 marijuana 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 marijuana cannabis seeds are planted,

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when marijuana cannabis plants are harvested and destroyed, and when marijuana low-THC cannabis or medical cannabis is transported, sold, stolen, diverted, or lost.

- 4. Not dispense from its premises marijuana low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device between the hours of 9 p.m. and 7 a.m., but may perform all other operations and deliver marijuana low-THC cannabis and medical cannabis to qualifying qualified patients 24 hours each day.
- 5. Store marijuana 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 of any cultivation or processing facilities at all times.
- 7. Require each employee or contractor 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 marijuana low-THC cannabis or medical cannabis.
- 11. Register all MMTC owners and employees with the department.
- 867 12. Present a floor plan to the department which designates 868 each area of the facility as a "limited access area," 869 "restricted access area," or "general access area." As used in this subparagraph, the term:

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a. "Limited access area" means the area within an MMTC where marijuana is cultivated, processed, stored, packaged, and sold to other MMTCs. This area is accessible only to employees and visitors escorted by an employee.

- b. "Restricted access area" means the area within an MMTC where marijuana is sold to qualifying patients and caregivers.

 This area is accessible only to employees, qualifying patients, and caregivers and to visitors escorted by an employee.

 Individuals admitted into a restricted access area must provide a photo identification as required by the department.
- c. "General access area" means the area within an MMTC where marijuana is not grown, cultivated, processed, stored, packaged, processed for sale, or sold. This area is accessible to visitors.
- (e) To ensure the safe <u>and sanitary</u> transport of <u>marijuana</u> low-THC cannabis or medical cannabis to <u>MMTC</u> dispensing organization facilities, independent testing laboratories, or <u>qualifying</u> patients, the <u>MMTC</u> 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 marijuana low-THC cannabis or medical cannabis.
- 3. Lock <u>marijuana</u> 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 <u>marijuana</u> low-THC cannabis or medical cannabis, and require at least one person to remain in the vehicle while the <u>marijuana</u> low-THC cannabis or medical cannabis is being delivered.

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5. Ensure that any vehicle transporting marijuana to a qualifying patient or caregiver is legally parked while marijuana is being delivered to the qualifying patient or caregiver.

- $\underline{6.5.}$ Provide specific safety and security training to employees transporting or delivering $\underline{\text{marijuana}}$ $\underline{\text{low-THC cannabis}}$ or $\underline{\text{medical cannabis}}$.
 - (10) (7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES. -
- (a) The department may conduct announced or unannounced inspections of $\underline{\text{MMTCs}}$ 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 marijuana low-THC cannabis or medical cannabis containing any mold, bacteria, or other contaminant at a level 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 shall adopt by rule a process for approving changes in MMTC ownership or a change in an MMTC owner's investment interest of 5 percent or more. This process must include specific criteria for the approval or denial of an application for change of ownership or a change in investment interest and procedures for screening applicants' criminal and

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financial histories.

(e) 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 Law Enforcement, 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.

<u>(f)</u> (e) The department must make a list of all approved MMTCs, dispensing organizations and qualified ordering physicians who are qualified to issue physician certifications, 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

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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.
- (g) The department may impose reasonable fines not to exceed \$10,000 on <u>an MMTC</u> a dispensing organization for any of the following violations:
 - 1. Violating this section, s. 499.0295, or department rule.
- 2. Failing to maintain qualifications <u>registration</u> with the department for approval.
- 3. Endangering the health, safety, or security of a qualifying qualified patient.
- 4. Improperly disclosing personal and confidential information of a qualifying the qualified patient.
- 5. Attempting to procure MMTC registration with the department dispensing organization approval by bribery, fraudulent misrepresentation, or extortion.
- 6. Any owner or manager of the MMTC 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 $\underline{\text{MMTC}}$ dispensing organization knows to be false.

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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 <u>an MMTC</u> a <u>dispensing</u> organization.
- 11. Making misleading, deceptive, or fraudulent representations in or related to the business practices of \underline{an} MMTC \underline{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.
- (h) The department may suspend, revoke, or refuse to renew an MMTC's registration with the department a dispensing organization commits approval if the MMTC a dispensing organization commits repeated violations specified any of the violations in paragraph (g) which remain uncured after 30 days' notice from the department. The department may not suspend, revoke, or refuse to renew an MMTC's registration due to an uncured violation if the MMTC begins taking action to cure the violation

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within 30 days after receiving a notice of the violation from the department and such action is pursuant to a corrective action plan filed by the MMTC with the department or if the MMTC takes reasonable steps to ensure that a future violation of a similar nature does not occur.

- (i) The department shall renew <u>an MMTC's registration with the department</u> the <u>approval of a dispensing organization</u> biennially if the <u>MMTC dispensing organization</u> meets the requirements of this section and pays the biennial renewal fee.
- (j) The department may adopt rules necessary to implement this section <u>pursuant to s. 120.536(1) or s. 120.54. The department may use emergency rulemaking procedures pursuant to s. 120.54(4) to adopt rules under this section if necessary to meet any deadline for rulemaking established in s. 29, Art. X of the State Constitution.</u>
- (k) The department may adopt rules authorizing an MMTC to have specified employees administer marijuana. Marijuana may be administered only at an MMTC that is registered with the department as an administration facility.

$(11) \frac{(8)}{(11)}$ PREEMPTION.—

- (a) All matters regarding the regulation of the cultivation and processing of marijuana 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,

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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. This section does not preempt any law or ordinance of any county or municipality which imposes restrictions on the location of an MMTC if the law or ordinance does not unreasonably interfere with the availability of marijuana to qualifying patients.

(12) (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 who has obtained a valid compassionate use registry identification card from the department, and the qualified patient's legal representative may purchase from an MMTC and possess for the qualifying patient's medical use, up to the amount of marijuana in the physician certification low-THC cannabis or medical cannabis ordered for the patient, but not more than a 90-day 45-day supply, except as provided in (3)(e), and a marijuana cannabis delivery device specified in the physician certification ordered for the qualifying 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, contractors, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of marijuana low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device. As used in

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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, an approved independent testing laboratory may possess, test, transport, and lawfully dispose of <u>marijuana</u> low- THC cannabis or medical cannabis as provided by department rule.
- (d) An MMTC approved dispensing organization and its owners, managers, contractors, 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 marijuana low-THC cannabis, medical cannabis, or a marijuana cannabis delivery device.
- (e) Exercise by an MMTC of An approved 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 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 <u>marijuana low-THC</u> cannabis or medical cannabis or relieve a person from any requirement under law to submit to a breath, blood, urine, or

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other test to detect the presence of a controlled substance.

- (g) This section does not affect or repeal laws relating to negligence or professional malpractice on the part of a caregiver, a physician, or an MMTC or its agents and employees.

 However, a physician who issues a physician certification and who fully complies with the requirements of this section is immune from liability in civil actions and claims for medical malpractice.
- (h) This section does not require a health insurance provider or a governmental agency or authority to reimburse a person for expenses related to the use of marijuana.
- (i) 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 research institute established by a public postsecondary educational institution, such as the H. Lee Moffitt Cancer Center and Research Institute established in s. 1004.43, or a state university that has achieved the preeminent state research university designation pursuant to s. 1001.7065, may possess, test, transport, and lawfully dispose of marijuana for research purposes as provided by department rule.

(13) PROHIBITED ACTIVITIES.—

- (a) A person or entity may not offer or advertise services as an MMTC without registering as an MMTC with the department.

 An MMTC may not advertise or hold out to the public that it holds a registration for other than that for which it actually holds the registration.
- (b) The ownership, operation, or maintenance of an unauthorized dispensing organization or entity or the performance of a service that requires registration without

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1132 proper registration is a violation of this section. The 1133 department or any state attorney may, in addition to other 1134 remedies provided in this section, bring an action for an 1135 injunction to restrain any unauthorized activity or to enjoin 1136 the future operation or maintenance of the unauthorized 1137 dispensing organization or entity or the performance of any 1138 service in violation of this section, until compliance with this 1139 section and department rules has been demonstrated to the 1140 satisfaction of the department.

- (c) If after receiving notification from the department, such person, organization, or entity fails to cease operation, the person, organization, or entity is subject to penalties as prescribed by this section. Each day of continued operation is a separate offense.
 - (14) IMPORTATION AND EXPORTATION OF MARIJUANA.-
 - (a) Marijuana may not be imported from outside this state.
- (b) Marijuana and products containing marijuana which are cultivated and produced in accordance with this section may be exported as authorized by federal law and the laws of the states or countries to which they are exported.
- or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this section which can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.
- 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:

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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's order for marijuana 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 marijuana 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 marijuana 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.

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written an order for marijuana 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 marijuana low-THC cannabis, whether another physician has ordered the patient's use of marijuana 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 marijuana low-THC cannabis pursuant to s. 381.986.

Section 3. Subsection (1) of 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 "low-THC cannabis" means "low-THC cannabis" as defined in s. 381.986 which that is dispensed only from a medical marijuana treatment center dispensing organization as defined in s. 381.986.

Section 4. Subsections (2) and (3) of section 499.0295, Florida Statutes, are 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.
 - (a) (b) "Eligible patient" means a person who:
- 1217 1. Has a terminal condition that is attested to by the 1218 patient's physician and confirmed by a second independent

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evaluation by a board-certified physician in an appropriate specialty for that condition;

- 2. Has considered all other treatment options for the terminal condition currently approved by the United States Food and Drug Administration;
- 3. Has given written informed consent for the use of an investigational drug, biological product, or device; and
- 4. Has documentation from his or her treating physician that the patient meets the requirements of this paragraph.
- (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 a dispensing organization.
- (c) (d) "Terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of lifesustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.
- (d) (e) "Written informed consent" means a document that is signed by a patient, a parent of a minor patient, a court-

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appointed guardian for a patient, or a health care surrogate designated by a patient and includes:

- 1. An explanation of the currently approved products and treatments for the patient's terminal condition.
- 2. An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life.
- 3. Identification of the specific investigational drug, biological product, or device that the patient is seeking to use.
- 4. A realistic description of the most likely outcomes of using the investigational drug, biological product, or device. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment for the patient's terminal condition.
- 5. A statement that the patient's health plan or thirdparty administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless required to do so by law or contract.
- 6. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements.
- 7. A statement that the patient understands he or she is liable for all expenses consequent to the use of the

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investigational drug, biological product, or device and that liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

- (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 (1) of 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 "low-THC cannabis" means "low-THC cannabis" as defined in s. 381.986 which that is dispensed only from a medical marijuana treatment center dispensing organization as defined in s. 381.986.

Section 6. The Division of Law Revision and Information is directed to replace the phrase "the effective date of this act" wherever it occurs in this act with the date the act becomes a law.

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1306		Section	7.	This	act	shall	take	effect	upon	becoming	a law	•