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By the Committees on Appropriations; and Health Policy; and Senators Bradley, Young, and Hutson

576-04419-17 2017406c2

A bill to be entitled An act relating to compassionate use of low-THC cannabis and marijuana; amending s. 381.986, F.S.; providing legislative intent; defining and redefining terms; authorizing physicians to issue physician certifications to specified patients who meet certain conditions; authorizing physicians to make specific determinations in certifications; requiring physicians to meet certain conditions to be authorized to issue and make determinations in physician certifications; requiring a physician to conduct a physical examination and make a full assessment of the medical history of a patient and make certain determinations before the physician may certify a patient and specify a delivery device; requiring a physician to review the compassionate use registry and confirm that a patient does not have an active physician certification issued by another physician before the physician may certify a patient and specify a delivery device; specifying certain persons who may assist a qualifying patient under the age of 18 in the purchasing and administering of marijuana; prohibiting qualifying patients under the age of 18 from purchasing marijuana; providing that a physician may in certain circumstances certify an amount greater than a 90-day supply; eliminating the requirement that physicians maintain patient treatment plans and submit the treatment plans to the University of Florida College of Pharmacy; requiring written consent of a parent or

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legal quardian for the treatment of minors; requiring that certain physicians annually reexamine and reassess patients and update patient information in the compassionate use registry; revising criminal penalties; prohibiting a medical marijuana treatment center from advertising services it is not authorized to provide; providing fines; prohibiting a person or entity from advertising or providing medical marijuana treatment center services without being registered with the Department of Health as a medical marijuana treatment center; providing penalties; authorizing a distance learning format for a specified course and reducing the number of hours required for the course; providing that physicians who meet specified requirements are grandfathered for the purpose of specified education requirements; authorizing qualifying patients to designate caregivers; requiring caregivers to meet specified requirements; prohibiting a qualifying patient from designating more than one caregiver at any given time; providing exceptions; requiring the department to register caregivers meeting certain requirements on the compassionate use registry; prohibiting a nursing home or assisted living facility from preventing certain residents from hiring a caregiver; authorizing a nursing home or assisted living facility to prohibit its employees from acting as caregivers to residents; providing that a nursing home or assisted living facility is not required to provide a caregiver to certain residents;

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revising the entities to which the compassionate use registry must be accessible; requiring the department to adopt certain 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; requiring the department to make certain determinations before issuing an identification card to a patient; providing that a patient or the parent or legal guardian of a patient must provide the department with certain documentation to qualify for an identification card; requiring the department to adopt a rule listing documents that a patient may provide to qualify for an identification card; providing requirements for the identification cards; requiring the department to register certain dispensing organizations as medical marijuana treatment centers by a certain date; requiring the department to register additional medical marijuana treatment centers in accordance with a specified schedule; deleting obsolete provisions; revising the operational requirements for medical marijuana treatment centers; authorizing the department to waive certain requirements under specified circumstances; requiring that certain receptacles be childproof; requiring that additional information be included on certain labels; requiring that a medical marijuana treatment center comply with certain standards in the production and dispensing of

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edible or food products; requiring a medical marijuana treatment center to enter additional information into the compassionate use registry; restricting the number of dispensing facilities that may dispense marijuana; providing an exception; requiring a medical marijuana treatment center to keep a copy of a transportation manifest in certain vehicles at certain times; requiring the department to establish a quality control program that requires medical marijuana treatment centers to submit samples from each batch or lot of marijuana to an independent testing laboratory; requiring a medical marijuana treatment center to maintain records of all tests conducted; requiring the department to adopt rules to create and oversee the quality control program; providing that the department must license independent testing laboratories; authorizing an independent testing laboratory to collect and accept samples of, possess, store, transport, and test marijuana; prohibiting a person with an ownership interest in a medical marijuana treatment center from owning an independent testing laboratory; requiring the department to develop rules and a process for licensing requirements; authorizing the department to impose application and renewal fees; specifying that an independent testing laboratory must be certified to perform required tests; requiring the department to suspend or reduce any mandatory testing if the number of licensed and certified independent testing laboratories is insufficient to process the

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tests necessary to meet the patient demand for medical marijuana treatment centers; providing that an independent testing laboratory may only accept certain samples; requiring the department to approve a medical marijuana treatment center's request for a change in ownership, equity structure, or transfer of registration to a new entity if certain criteria are met; providing an exception to a requirement regarding the submission of fingerprints and passing of a background check; providing that a request is deemed approved if not denied by the department within a specified timeframe; requiring the department to adopt rules; requiring the department to establish, maintain, and control a seed-to-sale tracking system for marijuana; providing applicability; conforming provisions to changes made by the act; providing that certain research institutions may possess, test, transport, and dispose of marijuana subject to certain conditions and as provided by department rule; providing for the use of emergency rulemaking procedures by the department; creating s. 1004.4351, F.S.; providing a short title; providing legislative findings; defining terms; establishing the Coalition for Medical Marijuana Research and Education within the H. Lee Moffitt Cancer Center and Research Institute, Inc.; providing a purpose for the coalition; requiring the department to electronically submit to the coalition a data set that includes certain information for each patient registered with

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the compassionate use registry; requiring the coalition to review the data submitted by the department and to make certain determinations and to potentially issue recommendations for changes to state law and rules; establishing the Medical Marijuana Research and Education Board to direct the operations of the coalition; providing for the appointment of board members; providing for terms of office, reimbursement for certain expenses, and the conduct of meetings of the board; authorizing the board to appoint a coalition director; prescribing the duties of the coalition director; requiring the board to advise specified entities and officials regarding medical marijuana research and education in this state; requiring the board to annually adopt a Medical Marijuana Research and Education Plan; providing requirements for the plan; requiring the board to issue an annual report to the Governor and the Legislature by a specified date; specifying responsibilities of the H. Lee Moffitt Cancer Center and Research Institute, Inc.; 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 of Law Revision and Information; providing an effective date.

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

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

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read:

381.986 Compassionate use of low-THC  $\frac{\text{and medical}}{\text{and marijuana.}}$  cannabis and marijuana.

- (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, and dispensing of marijuana, products containing marijuana, related supplies, and 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:
- (a) "Cannabis delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing marijuana low-THC cannabis or medical cannabis into the human body.
- (b) "Caregiver" has the same meaning as provided in s. 29, Art. X of the State Constitution.

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(c) "Chronic nonmalignant pain" means pain that is caused by a debilitating medical condition or that originates from a debilitating medical condition and persists beyond the usual course of that debilitating medical condition.

- (d) "Close relative" means a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half blood, by marriage, or by adoption.
- <u>(e) (b) "Debilitating medical condition" has the same</u>

  <u>meaning as provided in s. 29, Art. X of the State Constitution</u>

  <u>"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.</u>
- $\underline{\text{(f)}}$  "Independent testing laboratory" means a laboratory, including the managers, employees, or contractors of the laboratory, which has no direct or indirect interest in  $\underline{a}$  medical marijuana treatment center  $\underline{a}$  dispensing organization.
- (g) (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.
- (h) (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,

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derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only <u>by a medical marijuana treatment</u> center <del>from a dispensing organization</del>.

- (i) (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
  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.
- (j) "Medical marijuana treatment center" or "MMTC" has the same meaning as provided in s. 29, Art. X of the State Constitution.
- (k) (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. Possession, use, or administration of <u>marijuana</u> <del>low-THC</del> <del>cannabis or medical cannabis</del> by smoking.
- 2. Possession, use, or administration of marijuana that was not purchased or acquired from an MMTC registered with the department.
- 3.2. 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.
  - 4. Use or administration of any type or amount of marijuana

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not specified on the qualifying patient's physician certification.

- 5.3. 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</u> <del>qualified</del> 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.
- (1) (h) "Qualifying Qualified patient" has the same meaning as provided in s. 29, Art. X of the State Constitution but also includes eligible patients, as that term is defined in s. 499.0295, and patients who are issued a physician certification under subparagraph (3) (a) 2. or subparagraph (3) (a) 3. A patient is not a qualifying patient unless he or she is registered with the department and has been issued a compassionate use registry identification card 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.
- $\underline{\text{(m)}}$  "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.
  - (3) (2) PHYSICIAN CERTIFICATION ORDERING. -
  - (a) A physician is authorized to issue a physician

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certification to:

1. A patient suffering from a debilitating medical
condition, which allows the patient to receive marijuana for the
patient's medical use;

- 2. A order low-THC cannabis to treat a qualified patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, which allows the patient to receive low-THC cannabis for the patient's medical use;
- 3. A patient suffering from chronic nonmalignant pain, if the physician has diagnosed an underlying debilitating medical condition as the cause of the pain, which allows the patient to receive marijuana for the patient's medical use order low-THC cannabis to alleviate the patient's pain symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the qualified patient;
- <u>4. order medical cannabis to treat</u> An eligible patient as defined in s. 499.0295, which allows the patient to receive marijuana for the patient's medical use; or
- 5. A patient who is not a resident of this state; who qualifies under subparagraph 1., subparagraph 2., subparagraph 3., or subparagraph 4.; and who can lawfully obtain marijuana through a medical marijuana program in the state that he or she resides in.
- (b) In the physician certification, the physician may also specify one or more or order a cannabis delivery devices to assist with device for the patient's medical use of marijuana. low-THC cannabis or medical cannabis,
  - (c) A physician may certify a patient and specify a

576-04419-17 2017406c2 320 delivery device under paragraphs (a) and (b) only if the 321 physician: 322 1. (a) Holds an active, unrestricted license as a physician 323 under chapter 458 or an osteopathic physician under chapter 459; 324 (b) Has treated the patient for at least 3 months 325 immediately preceding the patient's registration in the 326 compassionate use registry; 327 2.<del>(c)</del> Has successfully completed the course and examination 328 required under paragraph (5) (a)  $\frac{(4)}{(a)}$ ; 329 3. Has conducted a physical examination and made a full 330 assessment of the medical history of the patient; 331 4. Has determined that, in the physician's professional 332 opinion, the patient meets one or more of the criteria specified 333 in paragraph (a); 334 5. (d) Has determined that the medical use of marijuana 335 would likely outweigh the potential health risks to of treating 336 the patient with low-THC cannabis or medical cannabis are 337 reasonable in light of the potential benefit to the patient. If 338 a patient is younger than 18 years of age: 7 339 a. A second physician must concur with this determination, 340 and such determination must be documented in the patient's 341 medical record; 342 b. Only a parent, legal guardian, caregiver, or health care 343 provider may assist the qualifying patient in the purchasing and administering of marijuana for medical use; and 344 345 c. The qualifying patient may not purchase marijuana; 346 6. Has reviewed the compassionate use registry and 347 confirmed that the patient does not have an active physician

certification issued by another physician;

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7.<del>(e)</del> Registers as the patient's physician <del>orderer of low-</del> 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 low-THC cannabis or medical cannabis that will provide the patient with not more than a 90day 45-day supply and 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. If the physician's recommended amount of marijuana for a 90-day supply changes, the physician must also update the registry within 7 days after the 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 legal representative when the physician no longer recommends the medical use of marijuana for the patient treatment is discontinued; and

- (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;
- 8.(h) Obtains the voluntary written informed consent of the patient or the patient's legal representative to treatment with

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marijuana 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 marijuana low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects. If the patient is a minor, the patient's parent or legal guardian must consent to treatment in writing. If the patient is an eligible patient as defined in s. 499.0295, the physician must obtain written informed consent as defined in and required by s. 499.0295.;

- (d) At least annually, a physician must recertify the qualifying patient pursuant to paragraph (c).
- (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
- $\underline{\text{(e)}}$  A physician may not issue a physician certification  $\underline{\text{if the physician}}$  is  $\underline{\text{not}}$  a medical director employed by  $\underline{\text{an MMTC}}$  a dispensing organization.
- (f) 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 the effective date of this act, shall be considered a physician certification issued pursuant to this subsection. 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

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registry identification card.

## (4) (3) PROHIBITED ACTS 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 <u>in a manner other than as required in subsection (3)</u> without a reasonable belief that the patient is suffering from:
- 1. Cancer or A physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be treated with low-THC cannabis; or
- 2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis.
- (b) 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 condition cancer, a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, chronic nonmalignant pain, or a terminal condition as defined in s. 499.0295 to a physician for the purpose of being issued a physician certification for marijuana 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.

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436 775.083.

(c) (d) A qualifying patient 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 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) A qualifying patient or caregiver who cultivates marijuana or who purchases or acquires marijuana from any person or entity other than an MMTC commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
- (e) A caregiver who violates any of the applicable provisions of this section or applicable department rules 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.
- (f) (e) A physician who issues a physician certification for marijuana orders low-THC cannabis, medical cannabis, or a cannabis delivery device and receives compensation from an MMTC a dispensing organization related to issuing the physician certification for marijuana 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).
  - (g) An MMTC that advertises or holds out to the public that

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it may provide services other than services for which it is registered to provide violates this section, and the department may impose a fine on the MMTC pursuant to paragraph (10)(h).

- (h) A person or entity that offers or advertises services as an MMTC without registering as an MMTC with the department violates this section. The operation or maintenance of a facility as an MMTC, or the performance of a service that requires registration, without proper registration is a violation of this section.
- 1. If after receiving notification from the department, such person or entity fails to cease operation, the department may impose an administrative fine of up to \$10,000 per violation. Each day of continued operation is a separate offense.
- 2. The department or any state attorney may, in addition to other remedies provided in this section, bring an action for an injunction to restrain any unauthorized activity or to enjoin the future operation or maintenance of the unauthorized dispensing organization or entity or the performance of any service in violation of this section until compliance with this section and department rules has been demonstrated to the satisfaction of the department.
- 3. If found to be in violation of this paragraph, the department may assess reasonable investigative and legal costs for prosecution of the violation against the person or entity.
  - (5) (4) PHYSICIAN EDUCATION. -
- (a) Before <u>a physician may issue a physician certification</u> <u>pursuant to subsection (3)</u> <del>ordering low-THC cannabis, medical cannabis, or a cannabis delivery device for medical use by a</del>

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patient in this state, the appropriate board shall require the ordering physician to successfully complete a 4-hour 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 marijuana <del>low-THC cannabis and medical cannabis</del>, 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 dispensing  $\tau$  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 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, including an electronic, online format that is available on request. Physicians who have completed an 8-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 are registered in the compassionate use registry on the effective date of this act are 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

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Medical Association which that encompasses appropriate safety procedures and knowledge of marijuana 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 issues a physician certification for marijuana 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 issues a physician certification for marijuana who 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).

## (6) 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 may designate an individual as his or her caregiver to assist him or her with the medical use of marijuana. The designated caregiver must be 21 years of age or older, unless the patient is a close relative of the caregiver; must agree in writing to be the qualifying patient's caregiver; may 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 in

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accordance with subparagraph (c)2.; and must pass a level 2 screening pursuant to chapter 435, unless the patient is a close relative of the caregiver.

- (b) A qualifying patient may have only one designated caregiver at any given time unless all of the 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 is designated by a qualifying patient pursuant to paragraph (a) and meets all of the requirements of this subsection and department rule.
- (e) A nursing home or assisted living facility may not prevent a qualifying patient residing in the nursing home or assisted living facility from hiring a caregiver. A nursing home

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or assisted living facility may prohibit its employees from acting as caregivers to residents of the nursing home or assisted living facility. A nursing home or assisted living facility is not required to provide a caregiver to a resident who is a qualifying patient.

- (7) (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 <u>caregivers</u> the legal representatives of patients as provided under this section. The registry must be accessible to:
- 1. Practitioners 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, to verify the authorization of a qualifying patient or a patient's caregiver to possess marijuana or a cannabis delivery device; and
- 4. MMTCs, to a dispensing organization to verify the authorization of a qualifying patient or a patient's caregiver legal representative to possess marijuana low-THC cannabis, medical cannabis, or a cannabis delivery device and to record the marijuana low-THC cannabis, medical cannabis, or cannabis delivery device dispensed.

The registry must prevent  $\frac{\partial}{\partial x}$  active registration of a patient by multiple physicians.

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(b) By July 3, 2017, adopt rules establishing procedures for the issuance, annual renewal, suspension, and revocation of compassionate use registry identification cards for patients and caregivers. 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 have a physician certification that meets the requirements of subsection (3); minor patients 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 (6).

- 1. Before issuing an identification card to a patient, the department must determine that:
- a. The patient is a permanent resident of the state or, for a patient under the age of 18, the patient's parent or legal guardian is a permanent resident of the state. The patient, or the parent or legal guardian of the patient, must prove permanent residency by providing the department with a copy of a valid Florida driver license or Florida identification card, a copy of a utility bill in his or her name issued within the prior 90 days which shows an address in this state, or a copy of his or her Florida voter information card.
  - b. If the patient is not a permanent resident of the state:
- (I) He or she is eligible to receive marijuana in his or her state of permanent residence; and
- (II) He or she will be remaining in this state for at least 3 consecutive months.
  - (A) An adult patient may provide the department with

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documentation that may include, but is not limited to, a rental
agreement for a property in this state for period of at least 3
months, an employment contract based in this state which
indicates the employment is for a period of at least 3 months,
or a receipt for paid tuition at a school in this state for a
period of at least 3 months.

- (B) A parent or legal guardian of a patient who is under the age of 18 must provide documentation as described in subsub-sub-subparagraph (A) or in department rule and provide additional documentation that the patient is his or her child or ward.
- The department shall adopt in rule a list of documents that a patient may provide to qualify for an identification card under this subparagraph.
- 2. Patient and caregiver identification cards must be resistant to counterfeiting and tampering and must include at least the following:
- <u>a. The name, address, and date of birth of the patient or</u> caregiver, as appropriate;
- b. A full-face, passport-type, color photograph of the patient or caregiver, as appropriate, taken within the 90 days immediately preceding registration;
  - c. Designation of the cardholder as a patient or caregiver;
- d. A unique identification number for the patient or caregiver which is matched to the identification number used for such person in the department's compassionate use registry. A caregiver's identification number and file in the compassionate use registry must be linked to the file of the patient or

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patients the caregiver is assisting so that the caregiver's
status may be verified for each patient individually;

- e. The expiration date, which shall 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
- <u>f. For caregivers who are assisting three or fewer</u>

  <u>qualifying patients, the names and identification number of the</u>

  <u>qualifying patient or patients that the caregiver is assisting.</u>
- (c) As soon as practicable after the effective date of this act, update its records by registering each dispensing organization approved pursuant to chapter 2014-157, Laws of Florida, or chapter 2016-123, Laws of Florida, as an MMTC with an effective registration date that coincides with that dispensing organization's date of approval as a dispensing organization. On the effective date of this act, all dispensing organizations approved pursuant to chapter 2014-157, Laws of Florida, or chapter 2016-123, Laws of Florida, are deemed to be registered MMTCs. The department may not require a dispensing organization approved pursuant to chapter 2014-157, Laws of Florida, or chapter 2016-123, Laws of Florida, to submit an application and may not charge the dispensing organization an application or registration fee for the initial registration of that dispensing organization as an MMTC pursuant to this section. For purposes of the requirement that an MMTC comply with the representations made in its application pursuant to subsection (8), an MMTC registered pursuant to this paragraph shall continue to comply with the representations made in its application for approval as a dispensing organization, including

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any revision authorized by the department before the effective date of this act. After the effective date of this act, the department may grant variances from the representations made in a dispensing organization's application for approval pursuant to subsection (8). For purposes of the definition of the term "marijuana" in s. 29, of Art. X of the State Constitution, an MMTC is deemed to be a dispensing organization as that term is defined in former s. 381.986(1)(a), Florida Statutes 2014

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.

- (d) By October 3, 2017, register five additional MMTCs with at least one of the MMTCs being 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.
- (e) Within 6 months after each instance of the registration of 75,000 qualifying patients with the compassionate use registry, register four additional MMTCs if a sufficient number of MMTC applicants meet the registration requirements established in this section and by department rule.
- (f) Not issue more than one registration as an MMTC to a person or an entity.
  - (g) Identify applicants with strong diversity plans

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reflecting this state's commitment to diversity.

- (h) Implement training programs and other educational programs to enable minority persons and minority business enterprises, as defined in s. 288.703, and veteran business enterprises, as defined in s. 295.187, to compete for MMTC registration and contracts.
- <u>(i)</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>
- 1. That, for the 5 consecutive years before submitting the application, the applicant has been registered to do business in this state.
- 2.1. The technical and technological ability to cultivate and produce low-THC cannabis and marijuana. 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.
- 3.2. The ability to secure the premises, resources, and personnel necessary to operate as an MMTC a dispensing organization.
- $\underline{4.3.}$  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

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substances.

 $\underline{5.4.}$  An infrastructure reasonably located to dispense low-THC cannabis and marijuana to registered qualifying patients statewide or regionally as determined by the department.

- <u>6.5.</u> 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 a dispensing organization's serving at least 1,000 qualifying qualified patients, the MMTC dispensing organization is only required to maintain a \$2 million performance bond.
- 7.6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.
- 8. The ability to implement a diversity plan that promotes and ensures the involvement of minority persons and minority business enterprises, as defined in s. 288.703, or veteran business enterprises, as defined in s. 295.187, in ownership, management, employment, and contracting opportunities.
- $\underline{\text{a. A diversity plan must be submitted with an MMTC}}$  application.
- b. Upon registration renewal the MMTC must show the effectiveness of the diversity plan by including the following:
- (I) Representation of minority persons and veterans in the MMTC's workforce;
- (II) Efforts to recruit minority persons and veterans for employment; and
- (III) A record of contracts for services with minority business enterprises and veteran business enterprises.

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9.7. 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.
- (j)(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.
- (k) (e) Monitor physician registration in the compassionate use registry and the issuance of physician certifications pursuant to subsection (3) 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 cannabis delivery devices device and take disciplinary action as indicated.
- (8) (6) MEDICAL MARIJUANA TREATMENT CENTERS DISPENSING ORGANIZATION.—Each MMTC must register with the department. A registered MMTC An approved dispensing organization must, at all times, maintain compliance with paragraph (7)(i), the criteria demonstrated for selection and approval as a dispensing organization under subsection(5) and the criteria required in

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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 individual 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.

- (a) When growing <u>marijuana</u> <del>low-THC cannabis or medical</del> <del>cannabis</del>, an MMTC <del>a dispensing organization</del>:
- 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 <u>marijuana</u> <del>low-THC cannabis or medical cannabis</del> 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

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removal and destruction of infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

- (b) When processing <u>marijuana</u> <del>low-THC cannabis or medical</del> <del>cannabis</del>, an MMTC <del>a dispensing organization</del> must:
- 1. Process the <u>marijuana</u> <del>low-THC cannabis or medical</del> <del>cannabis</del> within an enclosed structure and in a room separate from other plants or products.
- 2. Have the marijuana tested by an independent testing laboratory to ensure it meets the standards established by the department's quality control program Test the processed low-THC cannabis and medical cannabis before it is they are dispensed. 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.
  - 3. Package the marijuana <del>low-THC cannabis or medical</del>

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cannabis in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

- 4. Package the <u>marijuana</u> <del>low-THC cannabis or medical</del> <del>cannabis</del> in a <u>childproof</u> receptacle that has a firmly affixed and legible label stating the following information:
- a. A statement that the <u>marijuana</u> <del>low-THC cannabis or</del> <del>medical cannabis</del> meets the requirements of subparagraph 2.;
- 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;
- c. The batch number and harvest number from which the <a href="marijuana">marijuana</a> medical cannabis or low-THC cannabis originates; and
- <u>d. The concentration of tetrahydrocannabinol and</u> cannabidiol in the product.
  - e. Any other information required by department rule
- 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 <u>marijuana</u> <del>low-THC cannabis, medical</del> <del>cannabis,</del> or a <u>marijuana</u> <del>cannabis</del> delivery device, <u>an MMTC</u> <del>a</del> <del>dispensing organization</del>:
- 1. May not dispense more than the a 45-day supply of marijuana authorized by a qualifying patient's physician certification low-THC cannabis or medical cannabis to a qualifying patient or caregiver the patient's legal representative.
- 2. Must ensure that the have the dispensing organization's employee who dispenses the marijuana low-THC cannabis, medical cannabis, or marijuana a cannabis delivery device enters enter

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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 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.
- 4. Must label the marijuana with the recommended dose for the qualifying patient receiving the marijuana.
- 5.4. May not dispense or sell any other type of marijuana 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 marijuana which is specified in a physician certification low-THC cannabis or medical cannabis, while dispensing low-THC cannabis or medical cannabis. 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.
- 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,

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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 <u>marijuana</u> low-THC cannabis, medical cannabis, or <u>marijuana</u> cannabis delivery device, record in the registry the date, time, quantity, and form of <u>marijuana</u> low-THC cannabis or medical cannabis dispensed; and the type of <u>marijuana</u> cannabis delivery device dispensed; and the name and compassionate use registry identification number of the qualifying patient or caregiver to whom the marijuana delivery device was dispensed.
- 7. May not dispense marijuana from more than three dispensing facilities. This subparagraph does not apply to MMTC retail facilities that only dispense low-THC cannabis and sell marijuana delivery devices to qualified patients.
- (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 <a href="mailto:marijuana">marijuana</a> low-THC cannabis, medical cannabis, or <a href="mailto:marijuana">marijuana</a> 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

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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  $\underline{\text{MMTC's}}$  organization's outdoor premises have sufficient lighting from dusk until dawn.
- 3. Implement Establish and maintain a tracking system using a vendor 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 cannabis seeds are planted, when 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 <u>marijuana</u> <del>low-THC</del> <del>cannabis, medical cannabis,</del> or a cannabis delivery device between the hours of 9 p.m. and 7 a.m., but may perform all other operations and deliver <u>marijuana</u> <del>low-THC cannabis and medical cannabis</del> to <u>qualifying</u> <del>qualified</del> patients 24 hours each day.
- 5. Store <u>marijuana</u> <del>low-THC cannabis or medical cannabis</del> 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

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premises 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.
- (e) To ensure the safe transport of <u>marijuana</u> <del>low-THC</del> <del>cannabis or medical cannabis</del> to <u>MMTC</u> <del>dispensing organization</del> facilities, independent testing laboratories, or <u>qualifying</u> patients, the MMTC <del>dispensing organization</del> must:
- 1. Maintain a transportation manifest, which must be retained for at least 1 year. A copy of the manifest must be in the vehicle at all times when transporting marijuana.
- 2. Ensure only vehicles in good working order are used to transport <u>marijuana</u> <del>low-THC cannabis or medical cannabis</del>.
- 3. Lock <u>marijuana</u> <del>low-THC cannabis or medical cannabis</del> in a separate compartment or container within the vehicle.
- 4. Require at least two persons to be in a vehicle transporting marijuana low-THC cannabis or medical cannabis, and require at least one person to remain in the vehicle while the marijuana low-THC cannabis or medical cannabis is being delivered.
- 5. Provide specific safety and security training to employees transporting or delivering <u>marijuana</u> <del>low-THC cannabis</del> or medical cannabis.
  - (9) MARIJUANA QUALITY CONTROL PROGRAM AND INDEPENDENT

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## TESTING LABORATORY LICENSURE.-

- (a) The department shall establish a quality control program requiring marijuana to be tested by an independent testing laboratory for potency and contaminants before sale to qualifying patients and caregivers.
- 1. The quality control program must require MMTCs to submit samples from each batch or lot of marijuana harvested or processed to an independent testing laboratory 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 marijuana dispensed to qualifying patients is safe for human consumption.
- 2. An MMTC must maintain records of all tests conducted, including the results of each test and any additional information, as required by the department.
- 3. The department shall adopt all rules necessary to create and oversee the quality control program, which must include, at a minimum:
- <u>a. Permissible levels of variation in potency labeling and standards requiring tetrahydrocannabinol in edible marijuana products to be distributed consistently throughout the product; </u>
- b. Permissible levels of contaminants and mandatory testing for contaminants to confirm that the tested marijuana is safe for human consumption. This testing must include, but is not limited to, testing for microbiological impurity, residual solvents, and pesticide residues;
- c. The destruction of marijuana determined to be inaccurately labeled or unsafe for human consumption after the MMTC has an opportunity to take remedial action;

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d. The collection, storage, handling, recording, and destruction of samples of marijuana by independent testing laboratories; and

- e. Security, inventory tracking, and record retention.
- (b) The department must license all independent testing laboratories to ensure that all marijuana is tested for potency and contaminants in accordance with the department's quality control program. An independent testing laboratory may collect and accept samples of, and possess, store, transport, and test marijuana. An independent testing laboratory may not be owned by a person who also possesses an ownership interest in an MMTC. A clinical laboratory that is licensed by the Agency for Health Care Administration pursuant to part I of chapter 483 and that performs nonwaived clinical tests is exempt from the requirement to be licensed by the department pursuant to this paragraph but must be certified to perform all required tests pursuant to subparagraph 2.
- 1. The department shall develop rules establishing independent testing laboratory license requirements and a process for licensing independent testing laboratories; develop an application form for an independent testing laboratory license; and impose an initial application fee and a biennial renewal fee sufficient to cover the costs of administering this subsection.
- 2. In addition to licensure, an independent testing laboratory must be certified to perform all required tests by the department. The department must issue a certification to an independent testing laboratory that has been certified by a third-party laboratory certification body approved by the

576-04419-17 2017406c2 1074 department. The department shall establish reasonable rules for 1075 the certification and operation of independent testing 1076 laboratories. Rules for certification must, at a minimum, 1077 address standards relating to: 1078 a. Personnel qualifications; 1079 b. Equipment and methodology; 1080 c. Proficiency testing; 1081 d. Tracking; 1082 e. Sampling; 1083 f. Chain of custody; 1084 g. Record and sample retention; 1085 h. Reporting; 1086 i. Audit and inspection; and 1087 j. Security. 1088 3. The department shall suspend or reduce any mandatory 1089 testing requirement specified in its quality control program if 1090 the number of licensed and certified independent testing 1091 laboratories is insufficient to process the tests necessary to 1092 meet the patients' demand for marijuana. 1093 4. An independent testing laboratory may accept only 1094 samples composed of marijuana which are obtained from a sample 1095 source approved by the department. At a minimum, these sources 1096 must include an MMTC, a researcher affiliated with an accredited 1097 university or research hospital, a qualifying patient, and a 1098 caregiver. 1099 (10) <del>(7)</del> DEPARTMENT AUTHORITY AND RESPONSIBILITIES. 1100 (a) The department may conduct announced or unannounced 1101 inspections of MMTCs dispensing organizations to determine

compliance with this section or rules adopted pursuant to this

1103 section.

(b) The department shall inspect <u>an MMTC</u> a dispensing organization upon complaint or notice provided to the department that the <u>MMTC</u> dispensing organization has dispensed <u>marijuana</u> 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  $\underline{\mathsf{MMTC}}$  dispensing organization to evaluate the  $\underline{\mathsf{MMTC's}}$  dispensing organization's records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.
- (d) The department shall approve an MMTC's request for a change in ownership, equity structure, or transfer of registration to a new entity that meets the requirements in paragraph (7)(i) if individuals seeking a 5 percent or greater direct or indirect equity interest in the MMTC are fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04. Individuals who seek or hold less than a 5 percent direct or indirect equity interest in the MMTC are not required to be fingerprinted or pass the background check. A request for a change in MMTC ownership, equity structure, or transfer of registration is deemed approved if not denied by the department within 15 days after receipt of the request. The department shall adopt by rule a process which includes specific criteria for the approval or denial of such requests.
- (e) The department shall establish, maintain, and control a computer software tracking system that traces marijuana from seed to sale and allows real-time, 24-hour access by the

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department to data from all MMTCs and independent testing laboratories. The tracking system must, at a minimum, include notification of when marijuana seeds are planted, when marijuana plants are harvested and destroyed, and when marijuana is transported, sold, stolen, diverted, or lost. Each MMTC shall use the seed-to-sale tracking system selected by the department.

- (f) (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.
- (g) (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 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

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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.
- $\underline{\text{(h)}}$  The department may impose reasonable fines not to exceed \$10,000 on  $\underline{\text{an MMTC}}$  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 <u>registration with</u> the department <del>approval</del>.
- 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

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which directly relates to the business of <u>an MMTC</u> a <u>dispensing</u> organization.

- 7. Making or filing a report or record that the <u>MMTC</u> 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  $\underline{\text{an MMTC}}$  a dispensing 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.
- (i) (h) The department may suspend, revoke, or refuse to renew an MMTC's registration with the department a dispensing organization's approval if the MMTC a dispensing organization commits a violation specified any of the violations in paragraph

1219 (h)  $\frac{(g)}{(g)}$ .

<u>(j) (i)</u> The department shall renew <u>an MMTC's registration</u> with the department the approval of a dispensing organization biennially if the <u>MMTC</u> dispensing organization meets the requirements of this section and pays the biennial renewal fee.

 $\underline{\text{(k)}}$  (j) The department may adopt rules necessary to implement this section.

## $(11) \frac{(8)}{(11)}$ PREEMPTION.—

- (a) All matters regarding the regulation of the cultivation and processing of  $\underline{\text{marijuana}}$   $\underline{\text{medical cannabis}}$  or  $\underline{\text{low-THC cannabis}}$  by MMTCs  $\underline{\text{dispensing organizations}}$  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.

## $(12) \frac{(9)}{(9)}$ 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

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in the physician certification low-THC cannabis or medical cannabis ordered for the patient, but not more than a 90-day 45-day supply, and a 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, administer, and lawfully dispose of reasonable quantities, as established by department rule, of marijuana low-THC cannabis, medical cannabis, or a cannabis delivery device. 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> <del>low-</del>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 cannabis delivery device.
- (e) Exercise by an MMTC of  $\frac{An approved dispensing}{An approved dispensing}$

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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 MMTCs 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 cannabis or medical cannabis</u> 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.
- (g) This section does not limit the ability of an employer to establish, continue, or enforce a drug-free workplace program or substance abuse policy. Notwithstanding any other provision of law, this section does not require an employer to accommodate the ingestion of marijuana in any workplace or any employee working while under the influence of marijuana. Notwithstanding any other provision of law, this section does not create a cause of action against an employer for wrongful discharge or discrimination.
- (h) 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 under 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) RULEMAKING.-

- emergency rules pursuant to s. 120.54(4) and this subsection
  necessary to implement this section. If an emergency rule
  adopted under this subsection is held to be unconstitutional or
  an invalid exercise of delegated legislative authority and
  becomes void, the department and the applicable boards may adopt
  an emergency rule to replace the rule that has become void. If
  the emergency rule adopted to replace the void emergency rule is
  also held to be unconstitutional or an invalid exercise of
  delegated legislative authority and becomes void, the department
  and the applicable boards must follow the nonemergency
  rulemaking procedures of the Administrative Procedures Act to
  replace the rule that has become void.
- (b) For emergency rules adopted under this subsection, the department and the applicable boards need not make the findings required by s. 120.54(4)(a). Emergency rules adopted under this subsection are exempt from ss. 120.54(3)(b) and 120.541. The department and the applicable boards shall meet the procedural requirements in s. 120.54(2)(a) if the department or the applicable boards have, before the effective date of this act, held any public workshops or hearings on the subject matter of emergency rules adopted under this subsection. Challenges to emergency rules adopted under this subsection are subject to the time schedules provided in s. 120.56(5).
- (c) Emergency rules adopted under this section are exempt from s. 120.54(4)(c) and shall remain in effect until replaced

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by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedures Act. By January 1, 2018, the department and the applicable boards shall initiate nonemergency rulemaking pursuant to the Administrative Procedures Act by publishing a notice of rule development in the Florida

Administrative Register. Except as provided in paragraph (a), after January 1, 2018, the department and applicable boards may not adopt rules pursuant to the emergency rulemaking procedures provided in this subsection.

Section 2. Section 1004.4351, Florida Statutes, is created to read:

- 1004.4351 Medical marijuana research and education.
- (1) SHORT TITLE.—This section shall be known and may be cited as the "Medical Marijuana Research and Education Act."
  - (2) LEGISLATIVE FINDINGS.—The Legislature finds that:
- (a) The present state of knowledge concerning the use of marijuana to alleviate pain and treat illnesses is limited because permission to perform clinical studies on marijuana is difficult to obtain, with access to research-grade marijuana so restricted that little or no unbiased studies have been performed.
- (b) Under the State Constitution, marijuana is available for the treatment of certain debilitating medical conditions.
- (c) Additional clinical studies are needed to ensure that the residents of this state obtain the correct dosing, formulation, route, modality, frequency, quantity, and quality of marijuana for specific illnesses.
- (d) An effective medical marijuana research and education program would mobilize the scientific, educational, and medical

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the patient;

576-04419-17 2017406c2 1364 resources that presently exist in this state to determine the 1365 appropriate and best use of marijuana to treat illness. 1366 (3) DEFINITIONS.—As used in this section, the term: 1367 (a) "Board" means the Medical Marijuana Research and 1368 Education Board. 1369 (b) "Coalition" means the Coalition for Medical Marijuana 1370 Research and Education. (c) "Marijuana" has the same meaning as provided in s. 29, 1371 1372 Art. X of the State Constitution. 1373 (4) COALITION FOR MEDICAL MARIJUANA RESEARCH AND 1374 EDUCATION. -1375 (a) There is established within the H. Lee Moffitt Cancer Center and Research Institute, Inc., the Coalition for Medical 1376 1377 Marijuana Research and Education. The purpose of the coalition 1378 is to conduct rigorous scientific research, provide education, 1379 disseminate research, and guide policy for the adoption of a 1380 statewide policy on ordering and dosing practices for the 1381 medicinal use of marijuana. The coalition shall be physically 1382 located at the H. Lee Moffitt Cancer Center and Research 1383 Institute, Inc. 1384 (b) Beginning January 15, 2018, and quarterly thereafter, the Department of Health shall electronically submit to the 1385 coalition a data set that includes, for each patient registered 1386 with the compassionate use registry, as described in s. 381.986: 1387 1. The debilitating medical condition, as defined in s. 1388 1389 381.986, of the patient; 1390 2. The amount of marijuana certified, and the recommended

length of time that the amount of marijuana is certified, for

3. The route of administration of marijuana to the patient and any delivery device for the administration of marijuana to the patient; and

4. The patient's certifying physician.

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The coalition shall review the data submitted by the department.

If, after review of the data, the coalition determines that

state law and rules should be modified to address abuse or fraud

of the system established in s. 29, Art. X of the State

Constitution, s. 381.986, and associated rules, the coalition

must include recommendations for changes to state law and rules

to address such abuse or fraud in the report submitted by the

board pursuant to paragraph (g).

(c) The Medical Marijuana Research and Education Board is established to direct the operations of the coalition. The board shall be composed of seven members appointed by the chief executive officer of the H. Lee Moffitt Cancer Center and Research Institute, Inc. Board members must have experience in a variety of scientific and medical fields, including, but not limited to, oncology, neurology, psychology, pediatrics, nutrition, and addiction. Members shall be appointed to 4-year terms and may be reappointed to serve additional terms. The chair shall be elected by the board from among its members to serve a 2-year term. The board shall meet no less than semiannually, at the call of the chair or, in his or her absence or incapacity, the vice chair. Four members constitute a quorum. A majority vote of the members present is required for all actions of the board. The board may prescribe, amend, and repeal a charter governing the manner in which it conducts its

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business. A board member shall serve without compensation but is entitled to be reimbursed for travel expenses by the coalition or the organization he or she represents in accordance with s. 112.061.

- (d) The coalition shall be administered by a coalition director, who shall be appointed by and serve at the pleasure of the board. The coalition director shall, subject to the approval of the board:
  - 1. Propose a budget for the coalition.
- $\underline{\text{2. Foster}}$  the collaboration of scientists, researchers, and  $\underline{\text{other appropriate personnel in accordance with the coalition's}}$  charter.
- 3. Identify and prioritize the research to be conducted by the coalition.
- $\underline{\text{4. Prepare the Medical Marijuana Research and Education}}$  Plan for submission to the board.
- 5. Apply for grants to obtain funding for research conducted by the coalition.
  - 6. Perform other duties as determined by the board.
- (e) The board shall advise the Board of Governors, the State Surgeon General, the Governor, and the Legislature with respect to medical marijuana research and education in this state. The board shall explore methods of implementing and enforcing medical marijuana laws in relation to cancer control, research, treatment, and education.
- (f) The board shall annually adopt a plan for medical marijuana research, known as the "Medical Marijuana Research and Education Plan," which must be in accordance with state law and coordinate with existing programs in this state. The plan must

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include recommendations for the coordination and integration of medical, nursing, paramedical, community, and other resources connected with the treatment of debilitating medical conditions, research related to the treatment of such medical conditions, and education.

- (g) By February 15 of each year, the board shall issue a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on research projects, community outreach initiatives, and future plans for the coalition.
- (5) RESPONSIBILITIES OF THE H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.—The H. Lee Moffitt Cancer Center and Research Institute, Inc., shall allocate staff and provide information and assistance, as the coalition's budget permits, to assist the board in fulfilling its responsibilities.

Section 3. Paragraph (b) of subsection (3) of section 381.987, Florida Statutes, is amended to read:

- 381.987 Public records exemption for personal identifying information in the compassionate use registry.—
- (3) The department shall allow access to the registry, including access to confidential and exempt information, to:
- (b) A medical marijuana treatment center registered with 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 certification order was written for the person attempting to have it filled.

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Section 4. 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 5. 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. Marijuana Medical cannabis that is manufactured and sold

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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 6. 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 7. 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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1538		Section	8.	This	act	shall	take	effect	upon	becoming	a	law.