

	LEGISLATIVE ACTION	
Senate		House
Comm: UNFAV		
04/09/2015		
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The Committee on Rules (Soto) recommended the following:

## Senate Amendment (with title amendment)

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Delete everything after the enacting clause and insert:

6 read:

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

381.986 Compassionate use of <del>low-THC</del> cannabis.-

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

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(a) "Applicant" means a person that has submitted an application to the department for licensure or renewal as a dispensing organization.

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- (b) "Batch" means a specific quantity of cannabis product that is intended to have uniform character and quality, within specified limits, and is produced at the same time from one or more harvests.
- (c) "Dispensing organization" means an applicant licensed organization approved by the department to cultivate, process, and dispense low-THC cannabis pursuant to this section.
- (d) "Harvest" means a specifically identified and numbered quantity of cannabis cultivated using the same herbicides, pesticides, and fungicides and harvested at the same time from a single facility.
- (e) (b) "Low-THC Cannabis" means a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization.
- (f) "Cannabis product" means any product derived from cannabis, including 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 which is dispensed from a dispensing organization. Cannabis products include, but are not limited to, oils, tinctures, creams, encapsulations, and food products. All cannabis products must maintain concentrations, weight for weight, of more than 10 percent of cannabidiol.
- (q) (e) "Medical use" means administration of the ordered amount of <del>low-THC</del> cannabis. The term does not include:

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- 1. The possession, use, or administration by smoking; -
- 2. The term also does not include The transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative who is registered in the compassionate use registry on behalf of the qualified patient; or-
- 3. The use or administration of cannabis or cannabis products:
  - a. On any form of public transportation.
  - b. In any public place.
- c. In a registered qualified patient's place of work, if restricted by his or her employer.
  - d. In a correctional facility.
- e. On the grounds of any preschool, primary school, or secondary school.
  - f. On a school bus.
- (h) (d) "Qualified patient" means a resident of this state who has been added to the compassionate use registry by a physician licensed under chapter 458 or chapter 459 to receive low-THC cannabis from a dispensing organization.
- (i) (e) "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.
  - (2) PHYSICIAN ORDERING.-
- (a) Effective January 1, 2015, A physician licensed under chapter 458 or chapter 459 who has examined and is treating a patient suffering from cancer, human immunodeficiency virus, acquired immune deficiency syndrome, epilepsy, amyotrophic lateral sclerosis, multiple sclerosis, Crohn's disease,

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Parkinson's disease, paraplegia, quadriplegia, or terminal illness a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may order for the patient's medical use <del>low-THC</del> cannabis to treat such disease, disorder, or condition; or to alleviate symptoms of such disease, disorder, or condition; or to alleviate symptoms caused by a treatment for such disease, disorder, or condition if no other satisfactory alternative treatment options exist for that patient and all of the following conditions apply:

- 1. (a) The patient is a permanent resident of this state.
- 2.(b) The physician determines that the risks of ordering <del>low-THC</del> cannabis are reasonable in light of the potential benefit for that patient. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record.
- 3.(c) The physician registers the patient, the patient's legal representative if requested by the patient, and himself or herself as the orderer of <del>low-THC</del> 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. If the patient is a minor, the physician must register a legal representative on the compassionate use registry. The physician shall deactivate the patient's registration when treatment is discontinued.
- 4. (d) The physician maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of

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tolerance or reaction to the <del>low-THC</del> cannabis.

- 5. (e) The physician submits the patient treatment plan, as well as any other requested medical records, quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis on patients pursuant to subsection (8).
- 6.(f) The physician obtains the voluntary informed consent of the patient or the patient's legal quardian 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 conditions or symptoms condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.
- (b) A physician who improperly orders cannabis is subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).
  - (3) PENALTIES.-
- (a) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders <del>low-THC</del> cannabis for a patient without a reasonable belief that the patient is suffering from at least one of the conditions listed in subsection (2).  $\div$
- 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.

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- (b) Any person who fraudulently represents that he or she has at least one condition listed in subsection (2) cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms to a physician for the purpose of being ordered <del>low-THC</del> cannabis by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
  - (4) PHYSICIAN EDUCATION.-
- (a) Before ordering <del>low-THC</del> cannabis for use by a patient in this state, the appropriate board shall require the ordering physician licensed under chapter 458 or chapter 459 to successfully complete an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of <del>low-THC</del> cannabis, the appropriate delivery mechanisms, the contraindications for such use, as well as the relevant state and federal laws governing the ordering, dispensing, and possessing of this substance. The first course and examination shall be presented by October 1, 2014, and shall be administered at least annually thereafter. Successful completion of the course may be used by a physician to satisfy 8 hours of the continuing medical education requirements required by his or her respective board for licensure renewal. This course may be offered in a distance learning format.
- (b) The appropriate board shall require the medical director of each dispensing organization approved under subsection (5) to successfully complete a 2-hour course and subsequent examination offered by the Florida Medical

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Association or the Florida Osteopathic Medical Association that encompasses appropriate safety procedures and knowledge of low-THC cannabis.

- (c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders <del>low-THC</del> cannabis each time such physician renews his or her license. In addition, successful completion of the course and examination specified in paragraph (b) is required for the medical director of each dispensing organization each time such physician renews his or her license.
- (d) A physician who fails to comply with this subsection and who orders low-THC cannabis may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).
- (5) DUTIES AND POWERS OF THE DEPARTMENT. By January 1, 2015, The department shall:
- (a) The department shall create a secure, electronic, and online compassionate use registry for the registration of physicians and patients as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization in order to verify patient authorization for <del>low-THC</del> cannabis and record the <del>low-THC</del> cannabis dispensed. The registry must prevent an active registration of a patient by multiple physicians.
- (b) 1. Beginning 7 days after the effective date of this act, the department shall accept applications for licensure as a dispensing organization. The department shall review each application to determine whether the applicant meets the criteria in subsection (6) and qualifies for licensure.

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- 2. Within 10 days after receiving an application for licensure, the department shall examine the application, notify the applicant of any apparent errors or omissions, and request any additional information the department is allowed by law to require. An application for licensure must be filed with the department no later than 5 p.m. on the 30th day after the effective date of this act, and all applications must be complete no later than 5 p.m. on the 60th day after the effective date of this act.
- 3. If fewer than 20 applicants meet the criteria specified in subsection (6), the department shall, by the 75th day after the effective date of this act, license each such applicant. If more than 20 applicants meet these criteria, licensure shall be determined by lottery.
- 4. Beginning March 15, 2016, and every 6 months thereafter, if fewer than 20 dispensing organization licenses have been issued in this state, the department may issue additional licenses to qualified applicants up to the 20-organization maximum. The department shall use the same timeframes as set forth in subparagraphs 1.-3., beginning 75 days before the date specified for issuing additional licenses. If the number of qualified applicants under this subparagraph exceeds the number of dispensing organization licenses available for issuance, licensure shall be determined by lottery.
- 5. This section is exempt from s. 120.60 Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis under this section, one in each

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of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.

- (c) The department shall use develop an application form that requires the applicant to state:
- 1. Whether the application is for initial licensure or renewal licensure;
- 2. The name, the physical address, the mailing address, the address listed on the Department of Agriculture and Consumer Services certificate required in paragraph (6)(b), and the contact information for the applicant and for the nursery that holds the Department of Agriculture and Consumer Services certificate, if different from the applicant;
- 3. The name, address, and contact information for the operating nurseryman of the organization that holds the Department of Agriculture and Consumer Services certificate;
- 4. The name, address, license number, and contact information for the applicant's medical director; and
- 5. All information required to be included by subsection (6).
- (d) The department shall and impose an initial application fee of \$50,000, an initial licensure fee of \$125,000, and a biennial renewal fee of \$125,000 that is sufficient to cover the costs of administering this section. An applicant for approval as a dispensing organization must be able to demonstrate:
- 1. The technical and technological ability to cultivate and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be

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operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.

- 2. The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.
- 3. The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.
- 4. An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.
- 5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a \$5 million performance bond.
- 6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.
- 7. The employment of a medical director who is a physician licensed under chapter 458 or chapter 459 to supervise the activities of the dispensing organization.
- (e) The department shall inspect each dispensing organization's properties, cultivation facilities, processing facilities, and retail facilities before they begin operations and at least once every 2 years thereafter. The department may conduct additional announced or unannounced inspections, including followup inspections, at reasonable hours in order to ensure that such property and facilities maintain compliance

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with all applicable requirements in subsections (6) and (7) and to ensure that the dispensing organization has not committed any other act that would endanger the health, safety, or security of a qualified patient, dispensing organization staff, or the community in which the dispensing organization is located. Licensure under this section constitutes permission for the department to enter and inspect the premises and facilities of any dispensing organization. The department may inspect any licensed dispensing organization, and a dispensing organization must make all facility premises, equipment, documents, cannabis, and cannabis products available to the department upon inspection. The department may test any cannabis or cannabis product in order to ensure that it is safe for human consumption and that it meets the requirements in this section.

- (f) The department may suspend or revoke a license, deny or refuse to renew a license, or impose an administrative penalty not to exceed \$10,000 for the following acts or omissions:
  - 1. A violation of this section or department rule.
  - 2. Failing to maintain qualifications for licensure.
- 3. Endangering the health, safety, or security of a qualified patient.
- 4. Improperly disclosing personal and confidential information of the qualified patient.
- 5. Attempting to procure a license by bribery or fraudulent misrepresentation.
- 6. Being convicted or found guilty of, or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the business of a dispensing organization.

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- 302 7. Making or filing a report or record that the licensee 303 knows to be false.
  - 8. Willfully failing to maintain a record required by this section or rule of the department.
  - 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 a dispensing organization.
  - 11. Making misleading, deceptive, or fraudulent representations in or related to the business practices of 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 a dispensing organization revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under state law. A licensing authority's acceptance of a relinquishment of licensure or a stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as an action against the license.
  - 13. Violating a lawful order of the department or an agency of the state, or failing to comply with a lawfully issued subpoena of the department or an agency of the state.
    - (g) The department shall create a permitting process for

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all dispensing organization vehicles used for the transportation of cannabis or cannabis products.

- (h) <del>(c)</del> The department shall monitor physician registration and ordering of <del>low-THC</del> cannabis for ordering practices that could facilitate unlawful diversion or misuse of <del>low-THC</del> cannabis and take disciplinary action as indicated.
- (i) (d) The department shall adopt rules as necessary to implement this section.
  - (6) DISPENSING ORGANIZATION. -
- (a) An applicant seeking licensure as a dispensing organization, or the renewal of its license, must submit an application to the department. The department <u>must review all</u> applications for completeness, including an appropriate inspection of the applicant's property and facilities to verify the authenticity of the information provided in, or in connection with, the application. An applicant authorizes the department to inspect his or her property and facilities for licensure by applying under this subsection.
- (b) In order to receive or maintain licensure as a dispensing organization, an applicant must provide proof that:
- 1. The applicant, or a separate entity that is owned solely by the same persons or entities in the same ratio as the applicant, possesses a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 for the cultivation of more than 400,000 plants, is operated by a nurseryman as defined in s. 581.011, and has been operated as a registered nursery in this state for at least 30 continuous years.
  - 2. The personnel on staff or under contract for the

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360 applicant have experience cultivating and introducing multiple varieties of plants in this state, including plants that are not 361 362 native to Florida; experience with propagating plants; and 363 experience with genetic modification or breeding of plants. 364 3. The personnel on staff or under contract for the 365 applicant include at least one person who: 366 a. Has at least 5 years' experience with United States 367 Department of Agriculture Good Agricultural Practices and Good 368 Handling Practices;

- b. Has at least 5 years' experience with United States Food and Drug Administration Good Manufacturing Practices for food production;
- c. Has a doctorate degree in organic chemistry or microbiology;
- d. Has at least 5 years of experience with laboratory procedures which includes analytical laboratory quality control measures, chain of custody procedures, and analytical laboratory methods;
- e. Has experience with cannabis cultivation and processing, including cannabis extraction techniques and producing cannabis products;
- f. Has experience and qualifications in chain of custody or other tracking mechanisms;
  - g. Works solely on inventory control; and
  - h. Works solely for security purposes.
- 4. The persons who have a direct or indirect interest in the dispensing organization and the applicant's managers, employees, and contractors who directly interact with cannabis or cannabis products have been fingerprinted and have



389 successfully passed a level 2 background screening pursuant to 390 s. 435.04. 5. The applicant owns, or has at least a 2-year lease of, 391 392 all properties, facilities, and equipment necessary for the 393 cultivation and processing of cannabis. The applicant must 394 provide a detailed description of each facility and its 395 equipment, a cultivation and processing plan, and a detailed 396 floor plan. The description must include proof that: 397 a. The applicant is capable of sufficient cultivation and 398 processing to serve at least 15,000 patients with an assumed 399 daily use of 1,000 mg per patient per day of cannabis or 400 cannabis product; 401 b. The applicant has arranged for access to all utilities 402 and resources necessary to cultivate or process cannabis at each 403 listed facility; and 404 c. Each facility is secured and has theft-prevention 405 systems including an alarm system, cameras, and 24-hour security 406 personnel. 407 6. The applicant has diversion and tracking prevention 408 procedures, including: 409 a. A system for tracking material through cultivation, processing, and dispensing, including the use of batch and 410 411 harvest numbers; 412 b. An inventory control system for cannabis and cannabis 413 products; 414 c. A vehicle tracking and security system; and 415 d. A cannabis waste-disposal plan. 416 7. The applicant has recordkeeping policies and procedures

in place.

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- 8. The applicant has a facility emergency management plan.
- 9. The applicant has a plan for dispensing cannabis throughout the state. This plan must include planned retail facilities and a delivery plan for providing cannabis and cannabis products to qualified patients who cannot travel to a retail facility.
  - 10. The applicant has financial documentation, including:
- a. Documentation that demonstrates the applicant's financial ability to operate. If the applicant's assets, credit, and projected revenues meet or exceed projected liabilities and expenses and the applicant provides independent evidence that the funds necessary for startup costs, working capital, and contingency financing exist and are available as needed, the applicant has demonstrated the financial ability to operate. Financial ability to operate must be documented by:
- I. The applicant's audited financial statements. If the applicant is a newly formed entity and does not have a financial history of business upon which audited financial statements may be submitted, the applicant must provide audited financial statements for the separate entity that is owned solely by the same persons or entities in the same ratio as the applicant that possesses the valid certificate of registration issued by the Department of Agriculture and Consumer Services;
- II. The applicant's projected financial statements, including a balance sheet, an income and expense statement, and a statement of cash flow for the first 2 years of operation, which provides evidence that the applicant has sufficient assets, credit, and projected revenues to cover liabilities and expenses; and



III. A statement of the applicant's estimated startup costs and sources of funds, including a break-even projection and documentation demonstrating that the applicant has the ability to fund all startup costs, working capital costs, and contingency financing requirements.

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- All documents required under this sub-subparagraph shall be prepared in accordance with generally accepted accounting principles and signed by a certified public accountant. The statements required by sub-sub-subparagraph II. and III. may be presented as a compilation.
  - b. A list of all subsidiaries of the applicant;
- c. A list of all lawsuits pending and completed within the past 7 years of which the applicant was a party; and

d. Proof of a \$1 million performance and compliance bond, or other equivalent means of security deemed equivalent by the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the department, which must be posted once the applicant is approved as a dispensing organization. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding the dispensing organization license, such as the dispensing organization failing to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the dispensing organization's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this section involving the dispensing organization concludes,

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including any appeal, whichever occurs later.

- 11. The employment of a medical director who is a physician licensed under chapter 458 or chapter 459 to supervise the activities of the dispensing organization.
- (c) An approved dispensing organization shall maintain compliance with the criteria in paragraphs (b), (d), and (e) and subsection (7) demonstrated for selection and approval as a dispensing organization under subsection (5) at all times. Before dispensing <del>low-THC</del> cannabis or cannabis products to a qualified patient or to the qualified patient's legal representative, the dispensing organization shall verify the identity of the qualified patient or the qualified patient's legal representative by requiring the qualified patient or the qualified patient's legal representative to produce a government-issued identification card and shall verify that the qualified patient and the qualified patient's legal representative have has an active registration in the compassionate use registry, that the order presented matches the order contents as recorded in the registry, and that the order has not already been filled. Upon dispensing the <del>low-THC</del> cannabis, the dispensing organization shall record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.
- (d) A dispensing organization may have cultivation facilities, processing facilities, and retail facilities.
- 1. All matters regarding the location of cultivation facilities and processing facilities are preempted to the state. Cultivation facilities and processing facilities must be closed to the public, and cannabis may not be dispensed on the premises



of such facilities.

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- 2. A municipality must determine by ordinance the criteria for the number, location, and other permitting requirements for all retail facilities located within its municipal boundaries. A retail facility may be established in a municipality only after such an ordinance has been created. A county must determine by ordinance the criteria for the number, location, and other permitting requirements for all retail facilities located within the unincorporated areas of that county. A retail facility may be established in the unincorporated areas of a county only after such an ordinance has been created. Retail facilities must have all utilities and resources necessary to store and dispense cannabis and cannabis products. Retail facilities must be secured and have theft-prevention systems, including an alarm system, cameras, and 24-hour security personnel. Retail facilities may not sell, or contract for the sale of, anything other than cannabis or cannabis products on the property of the retail facility. Before a retail facility may dispense cannabis or a cannabis product, the dispensing organization must have a computer network compliant with the federal Health Insurance Portability and Accountability Act of 1996 which is able to access and upload data to the compassionate use registry and which shall be used by all retail facilities.
- (e) Within 15 days of such information becoming available, a dispensing organization must provide the department with updated information, as applicable, including:
- 1. The location and a detailed description of any new or proposed facilities.
  - 2. The updated contact information, including electronic

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534 and voice communication, for all dispensing organization 535 facilities.

- 3. The registration information for any vehicles used for the transportation of cannabis and cannabis product, including confirmation that all such vehicles have tracking and security systems.
- 4. A plan for the recall of any or all cannabis or cannabis product.
- (f) 1. A dispensing organization may transport cannabis or cannabis products in vehicles departing from their places of business only in vehicles that are owned or leased by the licensee or by a person designated by the dispensing organization, and for which a valid vehicle permit has been issued for such vehicle by the department.
- 2. A vehicle owned or leased by the dispensing organization or a person designated by the dispensing organization and approved by the department must be operated by such person when transporting cannabis or products from the licensee's place of business.
- 3. A vehicle permit may be obtained by a dispensing organization upon application and payment of a fee of \$5 per vehicle to the department. The signature of the person designated by the dispensing organization to drive the vehicle must be included on the vehicle permit application. Such permit remains valid and does not expire unless the licensee or any person designated by the dispensing organization disposes of his or her vehicle, or the licensee's license is transferred, canceled, not renewed, or is revoked by the department, whichever occurs first. The department shall cancel a vehicle

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permit upon request of the licensee or owner of the vehicle.

- 4. By acceptance of a license issued under this section, the licensee agrees that the licensed vehicle is, at all times it is being used to transport cannabis or cannabis products, subject to inspection and search without a search warrant by authorized employees of the department, sheriffs, deputy sheriffs, police officers, or other law enforcement officers to determine that the licensee is transporting such products in compliance with this section.
  - (7) TESTING AND LABELING OF CANNABIS.-
- (a) All cannabis and cannabis products must be tested by an independent testing laboratory before the dispensing organization may dispense them. The independent testing laboratory shall provide the dispensing organization with lab results. Before dispensing, the dispensing organization must determine that the lab results indicate that the cannabis or cannabis product meets the definition of cannabis or cannabis product, is safe for human consumption, and is free from harmful contaminants.
- (b) All cannabis and cannabis products must be labeled before dispensing. The label must include, at a minimum:
- 1. A statement that the cannabis or cannabis product meets the requirements in paragraph (a);
- 2. The name of the independent testing laboratory that tested the cannabis or cannabis product;
- 3. The name of the cultivation and processing facility where the cannabis or cannabis product originates; and
- 4. The batch number and harvest number from which the cannabis or cannabis product originates.

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(8) SAFETY AND EFFICACY RESEARCH FOR CANNABIS.—The University of Florida College of Pharmacy must establish and maintain a safety and efficacy research program for the use of cannabis or cannabis products to treat qualifying conditions and symptoms. The program must include a fully integrated electronic information system for the broad monitoring of health outcomes and safety signal detection. The electronic information system must include information from the compassionate use registry; provider reports, including treatment plans, adverse event reports, and treatment discontinuation reports; patient reports of adverse impacts; event-triggered interviews and medical chart reviews performed by University of Florida clinical research staff; information from external databases, including Medicaid billing reports and information in the prescription drug monitoring database for registered patients; and all other medical reports required by the University of Florida to conduct the research required by this subsection. The department must provide access to information from the compassionate use registry and the prescription drug monitoring database, established in s. 893.055, as needed by the University of Florida to conduct research under this subsection. The Agency for Health Care Administration must provide access to registered patient Medicaid records, to the extent allowed under federal law, as needed by the University of Florida to conduct research under this subsection.  $(9) \frac{(7)}{(7)}$  EXCEPTIONS TO OTHER LAWS. (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or

any other provision of law, but subject to the requirements of this section, a qualified patient and the qualified patient's

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legal representative who is registered with the department on the compassionate use registry may purchase and possess for the patient's medical use up to the amount of <del>low-THC</del> cannabis ordered for the patient. Nothing in this section exempts any person from the prohibition against driving under the influence provided in s. 316.193.

- (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved dispensing organization and its owners, managers, and employees and the owners, managers, and employees of contractors who have direct contact with cannabis or cannabis product may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of <del>low-THC</del> cannabis. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.
- (c) An approved dispensing organization and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of <del>low-THC</del> cannabis.
- (d) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other law, but subject to the requirements of this section, a licensed laboratory and its employees may receive and possess cannabis for the sole purpose of testing the cannabis to ensure compliance with this section.
  - (10) Rules adopted by the department under this section are

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exempt from the requirement that they be ratified by the Legislature pursuant to s. 120.541(3).

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

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

- (1) A patient's personal identifying information held by the department in the compassionate use registry established under s. 381.986, including, but not limited to, the patient's name, address, telephone number, and government-issued identification number, and all information pertaining to the physician's order for <del>low-THC</del> 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's order for 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 dispensing organization approved by the department pursuant to s. 381.986 which is attempting to verify the

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authenticity of a physician's order for low-THC cannabis, including whether the order had been previously filled and whether the order was written for the person attempting to have it filled.

- (c) A physician who has written an order for 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 low-THC cannabis, whether another physician has ordered the patient's use of <del>low-THC</del> 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 <del>low-THC</del> cannabis pursuant to s. 381.986.
- (g) Persons engaged in research at the University of Florida pursuant to s. 381.986(8).
- 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 that is dispensed only from a dispensing organization as defined in s. 381.986.
- Section 4. Subsection (3) of section 893.02, Florida Statutes, is amended to read:
- 893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:
- (3) "Cannabis" means all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin



extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. The term does not include "low-THC" cannabis," as defined in s. 381.986, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986.

Section 5. Paragraph (b) of subsection (7) of section 893.055, Florida Statutes, is amended to read:

893.055 Prescription drug monitoring program.-

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(b) A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Persons engaged in research at the University of Florida pursuant to s. 381.986(8) shall have access to information in the prescription drug monitoring program's database which relates to qualified patients as defined in s. 381.986(1) for the purpose of conducting such research. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt

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information in the database shall be released only as provided in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

Section 6. Paragraph (h) is added to subsection (3) of section 893.0551, Florida Statutes, to read:

893.0551 Public records exemption for the prescription drug monitoring program.—

- (3) The department shall disclose such confidential and exempt information to the following persons or entities upon request and after using a verification process to ensure the legitimacy of the request as provided in s. 893.055:
- (h) Persons engaged in research at the University of Florida pursuant to s. 381.986(8).

Section 7. 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 that is dispensed only from a dispensing organization as defined in s.



766 381.986.

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

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769 :========= T I T L E A M E N D M E N T ==============

And the title is amended as follows: 770

> Delete everything before the enacting clause and insert:

> > A bill to be entitled

An act relating to cannabis; amending s. 381.986, F.S.; defining terms; revising the illnesses and symptoms for which a physician may order a patient the medical use of cannabis in certain circumstances; providing that a physician who improperly orders cannabis is subject to specified disciplinary action; revising the duties of the Department of Health; requiring the department to create a secure, electronic, and online compassionate use registry; requiring the department to begin to accept applications for licensure as a dispensing organization according to a specified application process; requiring the department to review all applications, notify applicants of deficient applications, and request any additional information within a specified period; requiring an application for licensure to be filed and complete by specified dates; providing for a lottery for licensure as a dispensing organization in certain circumstances; authorizing the department to issue additional licenses to qualified applicants in certain

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circumstances; providing an exemption for the application process; requiring the department to use an application form that requires specified information from the applicant; requiring the department to impose specified application fees; requiring the department to inspect each dispensing organization's properties, cultivation facilities, processing facilities, and retail facilities before those facilities may operate; authorizing followup inspections at reasonable hours; providing that licensure constitutes permission for the department to enter and inspect the premises and facilities of any dispensing organization; authorizing the department to inspect any licensed dispensing organization; requiring dispensing organizations to make all facility premises, equipment, documents, cannabis, and cannabis products available to the department upon inspection; authorizing the department to test cannabis or cannabis products; authorizing the department to suspend or revoke a license, deny or refuse to renew a license, or impose a maximum administrative penalty for specified acts or omissions; requiring the department to create a permitting process for vehicles used for the transportation of cannabis or cannabis products; authorizing the department to adopt rules as necessary for implementation of specified provisions and procedures, and to provide specified guidance; providing procedures and requirements for an applicant

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seeking licensure as a dispensing organization or the renewal of its license; requiring the dispensing organization to verify specified information of specified persons in certain circumstances; authorizing a dispensing organization to have cultivation facilities, processing facilities, and retail facilities; authorizing a retail facility to be established in a municipality only after such an ordinance has been created; authorizing a retail facility to be established in the unincorporated areas of a county only after such an ordinance has been created; requiring retail facilities to have all utilities and resources necessary to store and dispense and cannabis products; requiring retail facilities to be secured with specified theftprevention systems; requiring a dispensing organization to provide the department with specified updated information within a specified period; authorizing a dispensing organization to transport cannabis or cannabis products in vehicles in certain circumstances; requiring such vehicles to be operated by specified persons in certain circumstances; requiring a fee for a vehicle permit; requiring the signature of the designated driver with a vehicle permit application; providing for expiration of the permit in certain circumstances; requiring the department to cancel a vehicle permit upon the request of specified persons; providing that the licensee authorizes the inspection and search of his or her

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vehicle without a search warrant by specified persons; requiring all cannabis and cannabis products to be tested by an independent testing laboratory before the dispensing organization may dispense it; requiring the independent testing laboratory to provide the lab results to the dispensing organization for a specified determination; requiring all cannabis and cannabis products to be labeled with specified information before dispensing; requiring the University of Florida College of Pharmacy to establish and maintain a specified safety and efficacy research program; providing program requirements; requiring the department to provide information from the prescription drug monitoring program to the University of Florida as needed; requiring the Agency for Health Care Administration to provide access to specified patient records under certain circumstances; providing that the act does not provide an exception to the prohibition against driving under the influence; authorizing specified individuals to manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities of cannabis; authorizing a licensed laboratory and its employees to receive and possess cannabis in certain circumstances; providing that specified rules adopted by the department are exempt from the requirement to be ratified by the Legislature; amending s. 381.987, F.S.; conforming provisions to changes made by the act; requiring the department to allow specified

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persons engaged in research to access the compassionate use registry; amending ss. 385.221 and 893.02, F.S.; conforming provisions to changes made by the act; amending s. 893.055, F.S.; providing that persons engaged in research at the University of Florida shall have access to specified information; amending s. 893.0551, F.S.; providing a specified public records exemption for persons engaged in research at the University of Florida; amending s. 1004.441, F.S.; conforming provisions to changes made by the act; providing an effective date.