A bill to be entitled

An act relating to low-THC cannabis for medical use; amending s. 381.986, F.S.; providing and revising definitions; revising requirements for physicians ordering low-THC cannabis; providing that a physician who orders low-THC cannabis and receives related compensation from a dispensing organization is subject to disciplinary action; revising requirements relating to physician education; requiring the Department of Health to include caregiver information in the online compassionate use registry; revising requirements for dispensing organizations; specifying duties and responsibilities of the department; authorizing an approved laboratory and its employees to possess, test, transport, and lawfully dispose of low-THC cannabis or paraphernalia in certain circumstances; exempting an approved dispensing organization and related persons from the Florida Drug and Cosmetic Act; 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 read:

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381.986 Compassionate use of low-THC cannabis.

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

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(a) "Caregiver" means an individual who is 21 years of age or older, a permanent resident of the state, and registered with the department to assist a patient with the medical use of low-THC cannabis.

- (b) (a) "Dispensing organization" means an organization approved by the department to cultivate, process, and dispense low-THC cannabis pursuant to this section.
- (c) (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.
- (d) (e) "Medical use" means administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. 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 guardian if the guardian is a registered caregiver, or other registered caregiver representative on behalf of the qualified patient.
- (e) "Paraphernalia" means objects used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis into the human body.
 - (f) (d) "Qualified patient" means a permanent resident of

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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.

- (g) (e) "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.
- physician is authorized to licensed under chapter 458 or chapter 459 who has examined and is treating a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may order for the patient's medical use low-THC cannabis to treat a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms; such disease, disorder, or condition or to order low-THC cannabis to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the that patient; or order paraphernalia for the medical use of low-THC cannabis, only if the physician and all of the following conditions apply:
- (a) Holds an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459;
- (b) Is board-certified as an oncologist, neurologist, or epileptologist or specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle

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spasms;

- (c) Has treated the patient for cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms for at least 3 months immediately preceding the patient's registration in the compassionate use registry;
- (d) Has successfully completed the course and examination required under paragraph (4)(a);
- (e) (b) Has determined The physician determines that the risks of treating the patient with ordering low-THC cannabis are reasonable in light of the potential benefit to the for that patient. If a patient is younger than 18 years of age, a second physician having a board certification or specialization described in paragraph (b) must concur with this determination, and such determination must be documented in the patient's medical record;
- (f) (c) The physician Registers as the orderer of low-THC 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 low-THC cannabis that will provide the patient with not more than a 30-day supply and any paraphernalia needed by the patient for the medical use of low-THC cannabis. The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician shall deactivate the patient's and caregiver's registration when

treatment is discontinued; -

- (g) (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 tolerance or reaction to the low-THC cannabis;
- (h) (e) The physician 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 on patients;
- (i) (f) The physician Obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects; and
- (j) Is not a medical director employed by a dispensing organization.
 - (a) The patient is a permanent resident of this state.
 - (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 low-THC cannabis or paraphernalia for a patient 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

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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) Any person who fraudulently represents that he or she has 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 low-THC cannabis or paraphernalia by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
- (c) A physician who orders low-THC cannabis or paraphernalia and receives compensation from a dispensing organization related to the ordering of low-THC cannabis is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).
 - (4) PHYSICIAN EDUCATION. -
- (a) Before ordering low-THC cannabis or paraphernalia for medical 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 low-THC cannabis, the appropriate delivery mechanisms, the

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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 to hold an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459 and be board-certified as an oncologist, neurologist, or epileptologist or provide proof that he or she specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms. Additionally, the medical director must approved under subsection (5) to successfully complete a 2-hour course and subsequent examination offered by the Florida Medical 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 low-THC cannabis or paraphernalia each time such

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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 or paraphernalia may be subject to disciplinary action under the applicable practice act and under s. 456.072(1) (k).
- (5) DUTIES OF THE DEPARTMENT.—By January 1, 2015, The department shall:
- (a) Create <u>and maintain</u> a secure, electronic, and online compassionate use registry for the registration of physicians, and patients, and caregivers as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization <u>in order</u> to verify patient <u>and caregiver</u> authorization for low-THC cannabis <u>and paraphernalia</u> and record the low-THC cannabis <u>and paraphernalia</u> dispensed. The registry must prevent an active registration of a patient by multiple physicians.
- (b) 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 or paraphernalia under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The

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department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. An applicant for approval as 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 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.

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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 <u>meets the</u> <u>qualifications of paragraph (4)(b)</u> is a physician licensed under chapter 458 or chapter 459 to supervise the activities of the dispensing organization.
- (c) Monitor physician registration and ordering of low-THC cannabis or paraphernalia for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis and take disciplinary action as indicated.
 - (d) Adopt rules necessary to implement this section.
- (6) DISPENSING ORGANIZATION.—An approved dispensing organization, at all times, must shall maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) and the criteria required in this subsection at all times.
- (a) When growing low-THC cannabis, a dispensing organization:
- 1. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.
- 2. Must grow and process low-THC cannabis within an enclosed structure and in a room separate from any other plant.

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

- 4. Must perform fumigation or treatment of plants, or the removal and destruction of infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.
- (b) When processing low-THC cannabis, a dispensing organization must:

- 2. Package the low-THC cannabis in compliance with the United States Poison Prevention Packaging Act, 15 U.S.C. ss. 1471-1477.
- 3. Package the low-THC cannabis in a receptacle that has a firmly affixed and legible label stating the following information:
 - a. The name of the dispensing organization.
- b. The quantity of low-THC cannabis contained in the receptacle.
- $\underline{\text{c.}}$ The cannabinoid profile of the low-THC cannabis, including the THC level.
- 285 <u>d. Any ingredient other than low-THC cannabis contained in</u>
 286 the receptacle.

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287	e.	The	date	that	the	low-THC	is	dispensed.

- $\underline{\text{f. The patient's name and registration identification}} \\ \text{number.}$
- g. A statement that the low-THC cannabis is for medical use and not for resale or transfer to another person.
- h. A unique serial number corresponding to the original batch of low-THC cannabis from which the low-THC cannabis contained in the receptacle was made, to facilitate necessary warnings or recalls by the department.
 - i. A recommended "use by" date or expiration date.
- 4. Reserve two processed samples from each batch, retain such samples for at least 1 year, and make such samples available for testing.
- (c) When dispensing low-THC cannabis or paraphernalia, a dispensing organization:
- 1. May not dispense more than a 30-day supply of low-THC cannabis to a patient or the patient's caregiver.
- 2. Must have the dispensing organization's employee who dispenses the low-THC cannabis or paraphernalia enter into the compassionate use registry his or her name or unique employee identifier.
- 3. Must verify in the compassionate use registry that a physician has ordered the low-THC cannabis or a specific type of paraphernalia for the patient.
- 4. May not dispense or sell any other type of retail product, other than physician-ordered paraphernalia, while

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313 <u>dispensing low-THC cannabis.</u>

- 5. Must Before dispensing low-THC cannabis to a qualified patient, the dispensing organization shall verify that the patient has an active registration in the compassionate use registry, the patient or patient's caregiver holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.
- <u>6. Must,</u> upon dispensing the low-THC cannabis, the dispensing organization shall record in the registry the date, time, quantity, and form of low-THC cannabis and any paraphernalia dispensed.
- (d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate controls against the diversion, theft, and loss of low-THC cannabis, a dispensing organization must:
- 1. 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.
- 2. Maintain a video surveillance system that records continuously 24 hours each day and meets the following minimum criteria:
- <u>a. Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises.</u> Controlled areas include grow rooms, processing

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rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms.

- b. Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points.
- c. Recorded images must clearly and accurately display the time and date.
- 3. Retain video surveillance recordings for a minimum of 45 days or longer upon the request of a law enforcement agency.
- 4. Enclose the perimeter of any buildings used in cultivating, processing, or dispensing low-THC cannabis with a fence or wall at least 6 feet in height.
- 5. Ensure that the organization's outdoor premises have sufficient lighting from dusk until dawn.
- 6. Establish and maintain a tracking system approved by the department that traces the low-THC cannabis from seed to sale. The tracking system shall include notification of key events as determined by the department, including when low-THC cannabis seeds are planted, low-THC cannabis plants are harvested, low-THC cannabis plants are destroyed, low-THC cannabis is transported, low-THC cannabis is sold, or a theft, diversion, or loss of low-THC cannabis occurs.
- 7. Not dispense low-THC cannabis or paraphernalia between the hours of 9 p.m. and 7 a.m., but may perform all other operations 24 hours each day.
 - 8. Store low-THC cannabis in a secured, locked room or a

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365 <u>vault.</u>

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- 9. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the organization's premises at all times.
- 10. Require each employee to wear a photo identification badge at all times while on the premises.
- 11. Require each visitor to wear a visitor's pass at all times while on the premises.
 - 12. Implement an alcohol and drug-free workplace policy.
- 13. Report to local law enforcement within 24 hours after it is notified or becomes aware of the theft, diversion, or loss of low-THC cannabis.
- (e) To ensure the safe transport of low-THC cannabis to dispensing organization facilities, laboratories, or patients, the dispensing organization must:
- 1. Maintain a transportation manifest, which must be retained for at least 1 year.
- 2. Ensure only vehicles in good working order are used to transport low-THC cannabis.
- 3. Lock low-THC cannabis in a separate compartment or container within the vehicle.
- 4. Require at least two persons to be in a vehicle transporting low-THC cannabis, and require at least one person to remain in the vehicle while the low-THC cannabis is being delivered.
 - 5. Provide specific safety and security training to

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employees transporting or delivering low-THC cannabis.

- (f) A dispensing organization may only use an insignia or logo approved by the department to advertise its product.
- laboratory approved by the department for purposes of testing low-THC cannabis for compliance with this section and to detect any mold, bacteria, or other contaminant in the product that may result in adverse effects to human health or the environment. The contract must require the laboratory to report to the dispensing organization, within 48 hours after a test, the cannabinoid composition of the product and whether the laboratory has detected any mold, bacteria, or other contaminant in the product that may result in adverse effects to human health or the environment.
 - (7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES. -
 - (a) The department:

- 1. May conduct announced or unannounced inspections of dispensing organizations to determine compliance with this section or rules adopted pursuant to this section.
- 2. Must inspect a dispensing organization upon complaint or notice provided to the department that the dispensing organization has dispensed low-THC cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.
- 3. Must conduct at least a biennial inspection of each dispensing organization to evaluate the dispensing

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

- (b) The department may inspect laboratories to ensure they are using standardized procedures to test low-THC cannabis.
- (c) The department may adopt standards for the approval of laboratories contracting with dispensing organizations, including standardized procedures, required equipment, and conflict-of-interest provisions.
- (d) The department may enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with the department, to conduct inspections or perform other responsibilities assigned to the department under this section.
- (e) The department must make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.
- (f) The department may establish a system for issuing and renewing patient and caregiver registration cards, 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

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143	registration	cards	to:
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- 1. Provide the name, address, and date of birth of the patient or caregiver.
 - 2. Have a full-face, passport-type, color photograph of the patient or caregiver taken within the 90 days immediately preceding registration.
 - 3. Identify whether the cardholder is a patient or caregiver.
 - 4. List a unique numeric identifier for the patient or caregiver 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.
 - 6. For the caregiver, provide the name and unique numeric identifier of the patient that the caregiver is assisting.
 - 7. Be resistant to counterfeiting or tampering.
 - (g) The department must create a schedule of violations in rule to impose reasonable fines not to exceed \$10,000 on a dispensing organization. In determining the amount of the fine to be levied for a violation, the department shall consider:
 - 1. The severity of the violation.
 - 2. Any actions taken by the dispensing organization to correct the violation or to remedy the complaint.
 - 3. Any previous violations.
 - (h) The department may suspend, revoke, or refuse to renew

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a dispensing organization's approval if the organization has had a license or authority to practice any regulated profession or the authority to conduct any business in any other state or country revoked, suspended, or otherwise acted against, including the denial of licensure by the licensing authority, for a violation that would constitute a violation under Florida law.

- (i) The department may adopt rules necessary to implement this section.
 - (8) (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 caregiver legal representative may purchase and possess for the patient's medical use up to the amount of low-THC cannabis ordered for the patient, but not more than a 30-day supply of low-THC cannabis.
- (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 may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

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()) <u>N</u>	otwith	stand	ing :	s. 89	3.13,	s.	893	.135	, s.	893.147	, or
any oth	ner p	rovisi	on of	law	, but	subj	ect	to	the	requ	irements	of
this se	ectio	n, an	appro	ved	labor	atory	and	dit	s em	ploye	ees may	
possess	, te	st, tr	ranspo	rt,	and l	awful	ly c	disp	ose	of l	ow-THC	
cannabi	s or	parap	herna	lia a	as pr	ovide	d by	, de	part	ment	rule.	

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- (d) 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 low-THC cannabis.
 - Section 2. This act shall take effect July 1, 2016.