A bill to be entitled

An act relating to the medical use of cannabis; amending s. 381.986, F.S.; providing and revising definitions; revising requirements for physicians ordering low-THC cannabis; providing requirements for physicians ordering medical cannabis; providing penalties; providing that a physician who orders low-THC cannabis or medical 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 legal representative information in its online compassionate use registry; revising requirements for dispensing organizations; revising duties and responsibilities of the department; revising standards to be met and maintained by dispensing organizations; authorizing an independent testing laboratory and its employees to possess, test, transport, and lawfully dispose of low-THC cannabis or medical cannabis under certain circumstances; exempting an approved dispensing organization and related persons from the Florida Drug and Cosmetic Act; providing applicability; amending s. 499.0295, F.S.; defining the term "dispensing organization"; revising the definition of the term "investigational drug, biological product, or device"; authorizing

certain manufacturers to dispense cannabis delivery devices; authorizing certain dispensing organizations to provide low-THC cannabis, medical cannabis, and cannabis delivery devices to eligible patients; providing for dispensing organizations meeting specified criteria to be granted authorization to cultivate certain cannabis and operate as dispensing organizations; providing applicability; providing an effective date.

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

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

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

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

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

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

(c) "Independent testing laboratory" means a laboratory,

including the managers, employees, or contractors of the laboratory, which has no direct or indirect interest in a dispensing organization.

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

(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) "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.

(g) ~~(c)~~ "Medical use" 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 low-THC cannabis or medical cannabis by smoking.

2. ~~The term also does not include the~~ Transfer of low-THC cannabis or medical cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient.

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

a. On any form of public transportation.

b. In any public place.

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

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

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

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

(h) ~~(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 or medical 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. ~~Effective January 1, 2015,~~ A physician is authorized to order ~~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 qualified patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms; order low-THC cannabis ~~such disease, disorder, or condition or~~ to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the qualified ~~that~~ patient; order medical cannabis to treat an eligible patient as defined in s. 499.0295; or order a cannabis delivery device for the medical use of low-THC cannabis or medical cannabis, only if the physician ~~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) Has treated the patient for at least 3 months immediately preceding the patient's registration in the compassionate use registry;

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

~~(a) The patient is a permanent resident of this state.~~

(d) ~~(b)~~ Has determined ~~The physician determines~~ that the risks of treating the patient with ~~ordering~~ low-THC cannabis or medical 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 must concur with this determination, and such determination must be documented in the patient's medical record; ~~.~~

(e) ~~(c) The physician~~ Registers as the orderer of low-THC cannabis or medical cannabis for the named patient on the compassionate use registry maintained by the department and updates the registry to reflect the contents of the order, including the amount of low-THC cannabis or medical cannabis that will provide the patient with not more than a 45-day supply and a cannabis delivery device needed by the patient for the medical use of low-THC cannabis or medical cannabis. The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician shall deactivate the registration of the patient and the patient's legal representative ~~patient's registration~~ when treatment is discontinued; ~~.~~

(f) ~~(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 or medical cannabis; ~~.~~

(g) ~~(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 and medical cannabis on patients;~~.~~

(h)~~(f)~~ ~~The physician~~ Obtains the voluntary written informed consent of the patient or the patient's legal representative ~~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;

(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

(j) Is not a medical director employed by a dispensing organization.

(3) PENALTIES.—

(a) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders low-THC cannabis 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 spasms that can be treated with low-THC cannabis; or

2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and

persistent muscle spasms that can be alleviated with low-THC cannabis.

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

(c) ~~(b)~~ A ~~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, or a terminal condition to a physician for the purpose of being ordered low-THC cannabis, medical cannabis, or a cannabis delivery device by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

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

(e) A physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device and receives compensation from a dispensing organization related to the ordering of low-THC cannabis, medical cannabis, or a cannabis

delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(4) PHYSICIAN EDUCATION.—

(a) Before ordering low-THC cannabis, medical cannabis, or a cannabis delivery device for medical use by a patient in this state, the appropriate board shall require the ordering physician ~~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 and medical cannabis, the appropriate cannabis delivery devices ~~mechanisms~~, the contraindications for such use, and ~~as well as~~ the relevant state and federal laws governing the ordering, dispensing, and possessing of these substances and devices ~~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 as an osteopathic physician under chapter 459 and ~~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, medical cannabis, and cannabis delivery devices.

(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device each time such physician renews his or her license. In addition, successful completion of the course and examination specified in paragraph (b) is required for the medical director of each dispensing organization each time such physician renews his or her license.

(d) A physician who fails to comply with this subsection and 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).

(5) DUTIES OF THE DEPARTMENT. ~~By January 1, 2015,~~ The department shall:

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, ~~and~~ patients, and the legal representatives of patients as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization ~~in order~~ to verify the authorization of a patient or a patient's legal representative to possess ~~patient authorization for~~ low-

THC cannabis, medical cannabis, or a cannabis delivery device and record the low-THC cannabis, medical cannabis, or cannabis delivery device dispensed. The registry must prevent an active registration of a patient by multiple physicians.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis, medical cannabis, or a cannabis delivery device under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. An applicant for approval as 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. However, upon a dispensing organization's serving at least 1,000 qualified patients, the dispensing organization is only required to maintain a $2 million performance bond.

6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.

7. The employment of a medical director ~~who is a physician licensed under chapter 458 or chapter 459~~ to supervise the activities of the dispensing organization.

(c) Upon the registration of 250,000 qualified patients in the compassionate use registry, approve three additional dispensing organizations, which must meet the requirements of subparagraphs (b)2.-7. for such approval.

(d) Allow a dispensing organization to make a wholesale purchase of low-THC cannabis or medical cannabis from, or a

distribution of low-THC cannabis or medical cannabis to, another dispensing organization.

(e) ~~(c)~~ Monitor physician registration and ordering of low-THC cannabis, medical cannabis, or a cannabis delivery device for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis, medical cannabis, or a cannabis delivery device and take disciplinary action as indicated.

~~(d) Adopt rules necessary to implement this section.~~

(6) DISPENSING ORGANIZATION.—An approved dispensing organization must, at all times, ~~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 or medical 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 or medical cannabis within an enclosed structure and in a room separate from any other plant.

3. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and

Consumer Services within 10 calendar days after a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures.

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

(b) When processing low-THC cannabis or medical cannabis, a dispensing organization must:

1. Process the low-THC cannabis or medical cannabis in an enclosure separate from other plants or products.

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

4. Package the low-THC cannabis or medical cannabis in a receptacle that has a firmly affixed and legible label stating the following information:

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

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

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

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

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

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

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

her name or unique employee identifier.

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

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

5. Must ~~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 legal representative holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.

6. Must, upon dispensing the low-THC cannabis, medical cannabis, or cannabis delivery device, ~~the dispensing organization shall~~ record in the registry the date, time, quantity, and form of low-THC cannabis or medical cannabis dispensed and the type of cannabis delivery device dispensed.

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

dispensing organization shall:

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

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

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

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

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

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

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

3. Establish and maintain a tracking system approved by the department that traces the low-THC cannabis or medical cannabis from seed to sale. The tracking system shall include notification of key events as determined by the department,

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

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

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

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

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

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

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

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

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

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

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

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

(7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES.—

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

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

(c) The department shall conduct at least a biennial inspection of each dispensing organization to evaluate the dispensing organization's records, personnel, equipment,

processes, security measures, sanitation practices, and quality assurance practices.

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

(e) The department must make a list of all approved 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 registration cards for patients and their legal representatives, establish the circumstances under which the cards may be revoked by or must be returned to the department, and establish fees to implement such system. The department must require, at a minimum, the registration cards to:

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

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

3. Identify whether the cardholder is a patient or legal

representative.

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

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

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

7. Be resistant to counterfeiting or tampering.

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

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

2. Failing to maintain qualifications for approval.

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

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

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

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

of a dispensing organization.

7. Making or filing a report or record that the 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 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 suspended, revoked, or otherwise acted against by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law.

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

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

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

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

(8) PREEMPTION.—

(a) All matters regarding the regulation of the cultivation and processing of medical cannabis or low-THC cannabis by 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 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 dispensing organizations located within the unincorporated areas of that county.

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

cannabis ordered for the patient, but not more than a 45-day supply, and a cannabis delivery device ordered for the patient.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved dispensing organization and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis, medical cannabis, or a cannabis delivery device. 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 low-THC cannabis or medical cannabis as provided by department rule.

(d) ~~(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 low-THC cannabis, medical cannabis, or a cannabis delivery device.

(e) An approved dispensing organization that continues to meet the requirements for approval is presumed to be registered

with the department and to meet the regulations adopted by the department or its successor agency for the purpose of dispensing medical cannabis or low-THC cannabis under state law. Additionally, the authority provided to a dispensing organization in s. 499.0295 does not impair the approval of a dispensing organization.

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

Section 2. Subsections (2) and (3) of section 499.0295, Florida Statutes, are amended to read:

499.0295 Experimental treatments for terminal conditions.—

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

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

(b) ~~(a)~~ "Eligible patient" means a person who:

1. Has a terminal condition that is attested to by the patient's physician and confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty for that condition;

2. Has considered all other treatment options for the

terminal condition currently approved by the United States Food and Drug Administration;

3. Has given written informed consent for the use of an investigational drug, biological product, or device; and

4. Has documentation from his or her treating physician that the patient meets the requirements of this paragraph.

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

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

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

(d) ~~(c)~~ "Terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

(e) ~~(d)~~ "Written informed consent" means a document that is signed by a patient, a parent of a minor patient, a court-

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

1. An explanation of the currently approved products and treatments for the patient's terminal condition.

2. An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life.

3. Identification of the specific investigational drug, biological product, or device that the patient is seeking to use.

4. A realistic description of the most likely outcomes of using the investigational drug, biological product, or device. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment for the patient's terminal condition.

5. A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless required to do so by law or contract.

6. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the

patient meets hospice eligibility requirements.

7. A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

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

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

(b) Provide an investigational drug, biological product, ~~or~~ 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, ~~or~~ device, or cannabis delivery device as defined in s. 381.986.

Section 3. (1) Notwithstanding s. 381.986(5)(b), Florida Statutes, a dispensing organization that receives notice from the Department of Health that it is approved as a region's dispensing organization; posts a $5 million performance bond in compliance with rule 64-4.002(5)(e), Florida Administrative Code; meets the requirements of and requests cultivation authorization pursuant to rule 64-4.005(2), Florida

Administrative Code; and expends at least $100,000 to fulfill its legal obligations as a dispensing organization shall be granted cultivation authorization by the Department of Health and is authorized to operate as a dispensing organization for the full term of its original approval and all subsequent renewals pursuant to s. 381.986, Florida Statutes.

(2) An action taken before or after the effective date of this section by the Division of Administrative Hearings, the Department of Health, or a court of competent jurisdiction which has the effect of approving, pursuant to s. 381.986(5)(b), Florida Statutes, a dispensing organization that does not meet the criteria of subsection (1) does not impair an authorization granted pursuant to subsection (1) to a dispensing organization meeting the criteria of subsection (1). During the operations of any dispensing organization that meets the criteria of subsection (1), the Department of Health may enforce rule 64-4.005, Florida Administrative Code, as filed on June 17, 2015.

Section 4. This act shall take effect upon becoming a law.