A bill to be entitled

An act relating to medical marijuana packaging and labeling; amending s. 381.986, F.S.; revising requirements for the packaging and labeling of edibles; providing an effective date.

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

Section 1. Paragraph (e) of subsection (8) of section 381.986, Florida Statutes, is amended to read:

381.986 Medical use of marijuana.—

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(e) A licensed medical marijuana treatment center shall cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices, except that a medical marijuana treatment center licensed pursuant to subparagraph (a)1. may contract with a single entity for the cultivation, processing, transporting, and dispensing of marijuana and marijuana delivery devices. A licensed medical marijuana treatment center must, at all times, maintain compliance with the criteria demonstrated and representations made in the initial application and the criteria established in this subsection. Upon request, the department may

grant a medical marijuana treatment center a variance from the representations made in the initial application. Consideration of such a request shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting medical marijuana treatment center can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application. A variance may not be granted from the requirements in subparagraph 2. and subparagraphs (b)1. and 2.

1. A licensed medical marijuana treatment center may transfer ownership to an individual or entity who meets the requirements of this section. A publicly traded corporation or publicly traded company that meets the requirements of this section is not precluded from ownership of a medical marijuana treatment center. To accommodate a change in ownership:

a. The licensed medical marijuana treatment center shall notify the department in writing at least 60 days before the anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure due to a change of ownership must submit an application that must be received by the department at least 60 days before the

date of change of ownership.

c. Upon receipt of an application for a license, the department shall examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.

d. Requested information omitted from an application for licensure must be filed with the department within 21 days after the department's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.

e. Within 30 days after the receipt of a complete application, the department shall approve or deny the application.

2. A medical marijuana treatment center, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center, may not acquire direct or indirect ownership or control of any voting shares or other form of ownership of any other medical marijuana treatment center.

3. A medical marijuana treatment center may not enter into any form of profit-sharing arrangement with the property owner or lessor of any of its facilities where cultivation, processing, storing, or dispensing of marijuana and marijuana

delivery devices occurs.

4. All employees of a medical marijuana treatment center must be 21 years of age or older and have passed a background screening pursuant to subsection (9).

5. Each medical marijuana treatment center must adopt and enforce policies and procedures to ensure employees and volunteers receive training on the legal requirements to dispense marijuana to qualified patients.

6. When growing marijuana, a medical marijuana treatment center:

a. 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.

b. Must grow marijuana within an enclosed structure and in a room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state in accordance with chapter 581 and any rules adopted thereunder.

d. Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

7. Each medical marijuana treatment center must produce

and make available for purchase at least one low-THC cannabis product.

8. A medical marijuana treatment center that produces edibles must hold a permit to operate as a food establishment pursuant to chapter 500, the Florida Food Safety Act, and must comply with all the requirements for food establishments pursuant to chapter 500 and any rules adopted thereunder. Edibles may not contain more than 200 milligrams of tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles may have a potency variance of no greater than 15 percent. Marijuana products, including edibles, may not be attractive to children; be manufactured in the shape of humans, cartoons, or animals; be manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives. To discourage consumption of edibles by children, the department shall determine by rule any shapes, forms, and ingredients allowed and prohibited for edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date of the rule. The department shall also adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

9. Within 12 months after licensure, a medical marijuana treatment center must demonstrate to the department that all of

its processing facilities have passed a Food Safety Good Manufacturing Practices, such as Global Food Safety Initiative or equivalent, inspection by a nationally accredited certifying body. A medical marijuana treatment center must immediately stop processing at any facility which fails to pass this inspection until it demonstrates to the department that such facility has met this requirement.

10. A medical marijuana treatment center that produces prerolled marijuana cigarettes may not use wrapping paper made with tobacco or hemp.

11. When processing marijuana, a medical marijuana treatment center must:

a. Process the marijuana within an enclosed structure and in a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

c. Comply with federal and state laws and regulations and department rules for solid and liquid wastes. The department shall determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing. The

Department of Environmental Protection shall assist the department in developing such rules.

d. Test the processed marijuana using a medical marijuana testing laboratory before it is dispensed. Results must be verified and signed by two medical marijuana treatment center employees. Before dispensing, the medical marijuana treatment center must determine that the test results indicate that low-THC cannabis meets the definition of low-THC cannabis, the concentration of tetrahydrocannabinol meets the potency requirements of this section, the labeling of the concentration of tetrahydrocannabinol and cannabidiol is accurate, and all marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption. The department shall determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption. The Department of Agriculture and Consumer Services shall assist the department in developing the testing requirements for contaminants that are unsafe for human consumption in edibles. The department shall also determine by rule the procedures for the treatment of marijuana that fails to meet the testing requirements of this section, s. 381.988, or department rule. The department may select samples of marijuana from a medical marijuana treatment center facility which shall be tested by the department to determine whether the marijuana meets the potency requirements of this section, is safe for

human consumption, and is accurately labeled with the tetrahydrocannabinol and cannabidiol concentration or to verify the result of marijuana testing conducted by a marijuana testing laboratory. The department may also select samples of marijuana delivery devices from a medical marijuana treatment center to determine whether the marijuana delivery device is safe for use by qualified patients. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall marijuana, including all marijuana and marijuana products made from the same batch of marijuana, that fails to meet the potency requirements of this section, that is unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. The department shall adopt rules to establish marijuana potency variations of no greater than 15 percent using negotiated rulemaking pursuant to s. 120.54(2)(d) which accounts for, but is not limited to, time lapses between testing, testing methods, testing instruments, and types of marijuana sampled for testing. The department may not issue any recalls for product potency as it relates to product labeling before issuing a rule relating to potency variation standards. A medical marijuana treatment center must also recall all marijuana delivery devices determined to be unsafe for use by qualified patients. The medical marijuana treatment center must retain records of all

testing and samples of each homogenous batch of marijuana for at least 9 months. The medical marijuana treatment center must contract with a marijuana testing laboratory to perform audits on the medical marijuana treatment center's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for human consumption. A medical marijuana treatment center shall reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of such audits. A medical marijuana treatment center may use a laboratory that has not been certified by the department under s. 381.988 until such time as at least one laboratory holds the required certification, but in no event later than July 1, 2018.

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

f. Package the marijuana in a receptacle that has a firmly affixed and legible label stating the following information:

(I) The marijuana or low-THC cannabis meets the requirements of sub-subparagraph d.

(II) The name of the medical marijuana treatment center from which the marijuana originates.

(III) The batch number and harvest number from which the

marijuana originates and the date dispensed.

(IV) The name of the physician who issued the physician certification.

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products that are attractive to children or which promote the recreational use of marijuana.

(VII) The recommended dose.

(VIII) A warning that it is illegal to transfer medical marijuana to another person.

(IX) A marijuana universal symbol developed by the department.

12. The medical marijuana treatment center shall include in each package a patient package insert with information on the specific product dispensed related to:

a. Clinical pharmacology.

b. Indications and use.

c. Dosage and administration.

d. Dosage forms and strengths.

e. Contraindications.

f. Warnings and precautions.

g. Adverse reactions.

13. In addition to the packaging and labeling requirements

specified in subparagraphs 11. and 12., marijuana in a form for smoking must be packaged in a sealed receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a form for smoking must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol.

14. The department shall adopt rules to regulate the types, appearance, and labeling of marijuana delivery devices dispensed from a medical marijuana treatment center. The rules must require marijuana delivery devices to have an appearance consistent with medical use.

15. ~~Each edible must be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol.~~ Where practical, each edible must be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 11. and 12., edible receptacles must be plain, opaque, and white without depictions of the product or images and must include other than the medical marijuana treatment center's department-approved logo, ~~and~~ the marijuana universal symbol, the edible's statement of identity as provided in 21 C.F.R. s. 101.3, and the net quantity of contents as provided in 21 C.F.R. s. 101.105(a), (b), and (c).

The receptacle must also include a list of ~~all~~ the edible's nutrition facts, allergens, ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

16. When dispensing marijuana or a marijuana delivery device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC cannabis, medical cannabis and cannabis delivery devices issued pursuant to former s. 381.986, Florida Statutes 2016, which was entered into the medical marijuana use registry before July 1, 2017.

b. May not dispense more than a 70-day supply of marijuana within any 70-day period to a qualified patient or caregiver. May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver. A 35-day supply of marijuana in a form for smoking may not exceed 2.5 ounces unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

c. Must have the medical marijuana treatment center's employee who dispenses the marijuana or a marijuana delivery device enter into the medical marijuana use registry his or her name or unique employee identifier.

d. Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in

the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled.

e. May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

f. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes or wrapping papers made with tobacco or hemp, other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.

g. Must, upon dispensing the marijuana or marijuana delivery device, record in the registry the date, time, quantity, and form of marijuana dispensed; the type of marijuana delivery device dispensed; and the name and medical marijuana use registry identification number of the qualified patient or caregiver to whom the marijuana delivery device was dispensed.

h. Must ensure that patient records are not visible to anyone other than the qualified patient, his or her caregiver, and authorized medical marijuana treatment center employees.

Section 2. This act shall take effect July 1, 2024.