A bill to be entitled

An act relating to the medical use of marijuana; amending s. 381.986, F.S.; prohibiting a physician from certifying certain patients for marijuana other than low-THC cannabis under certain conditions; revising a provision requiring certain information to be entered into the medical marijuana use registry; revising a provision relating to the informed consent form to include the negative health effects of marijuana use on certain persons; providing daily dose amount limits for edibles and marijuana in a form for smoking; waiving the medical marijuana identification card fee for certain qualified patients who can demonstrate veteran status; authorizing the Department of Health to possess and test marijuana samples from medical marijuana treatment centers; authorizing medical marijuana treatment centers to contract with certain medical marijuana testing laboratories; providing limits on the amount of tetrahydrocannabinol content in the dried leaves and flowers of marijuana and edibles dispensed by a medical marijuana treatment center; authorizing the department and certain employees to acquire, possess, test, transport, and dispose of marijuana; amending s. 381.988, F.S.; prohibiting a certified medical marijuana testing

laboratory from having an economic interest in or financial relationship with a medical marijuana treatment center; providing construction; amending ch. 2017-232, Laws of Florida; revising provisions authorizing emergency rulemaking; providing an appropriation; providing an effective date.

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

Section 1. Paragraphs (a) and (f) of subsection (4), paragraph (e) of subsection (8), and paragraph (a) of subsection (14) of section 381.986, Florida Statutes, as amended by section 1 of chapter 2019-1, Laws of Florida, are amended, and paragraph (f) is added to subsection (7) and paragraph (h) is added to subsection (14) of that section, to read:

381.986 Medical use of marijuana.—

(4) PHYSICIAN CERTIFICATION.—

(a) A qualified physician may issue a physician certification only if the qualified physician:

1. Conducted a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would

likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient younger than 18 years of age, unless the qualified physician determines that marijuana other than low-THC cannabis is the most effective treatment for the patient, and a second physician who is a board-certified pediatrician concurs with such determination. Such determination and concurrence must be documented in the patient's medical record and in the medical marijuana use registry ~~If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record~~.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use

registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including all of the patient's qualifying conditions ~~condition~~ and the dosage not to exceed the daily dose amount authorized under paragraph (f) ~~determined by the department~~, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a

minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use, including the negative health risks associated with smoking and the negative health effects of marijuana use on persons under 18 years of age.

g. The risks, benefits, and drug interactions of marijuana.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

(f) A qualified physician may not issue a physician certification for more than three 70-day supply limits of

marijuana, more than six 35-day supply limits of edibles, or more than six 35-day supply limits of marijuana in a form for smoking. The department shall quantify by rule a daily dose amount with equivalent dose amounts for each allowable form of marijuana, other than edibles and marijuana in a form for smoking, dispensed by a medical marijuana treatment center. The department shall use the daily dose amount to calculate a 70-day supply. The daily dose amount for edibles shall not exceed 200 mg of tetrahydrocannabinol. The daily dose amount for marijuana in a form for smoking shall not exceed .08 ounces.

1. A qualified physician may request an exception to the daily dose amount limit, the 35-day supply limit for edibles, the 35-day supply limit of marijuana in a form for smoking, and the 4-ounce possession limit of marijuana in a form for smoking established in paragraph (14)(a). The request shall be made electronically on a form adopted by the department in rule and must include, at a minimum:

a. The qualified patient's qualifying medical condition.

b. The dosage and route of administration that was insufficient to provide relief to the qualified patient.

c. A description of how the patient will benefit from an increased amount.

d. The minimum daily dose amount of marijuana that would be sufficient for the treatment of the qualified patient's qualifying medical condition.

2. A qualified physician must provide the qualified patient's records upon the request of the department.

3. The department shall approve or disapprove the request within 14 days after receipt of the complete documentation required by this paragraph. The request shall be deemed approved if the department fails to act within this time period.

(7) IDENTIFICATION CARDS.—

(f) A qualified patient who is a veteran, as defined in s. 1.01(14), is not required to pay the fee for the issuance or renewal of an identification card. To demonstrate veteran status, a qualified patient must provide the department with a copy of one of the following:

1. The qualified patient's DD Form 214, issued by the United States Department of Defense;

2. The qualified patient's veteran health identification card, issued by the United States Department of Veterans Affairs; or

3. The qualified patient's veteran identification card, issued by the United States Department of Veterans Affairs pursuant to the Veterans Identification Card Act of 2015, Pub. L. No. 114-31.

(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.

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. 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.

12.~~d.~~ A medical marijuana treatment center must 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 ~~a~~ random samples of marijuana, ~~sample from edibles,~~ available in a cultivation facility, processing facility, or for purchase in a dispensing facility, which shall be tested by the department to determine that the marijuana ~~edible~~ meets the potency requirements of this section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall edibles, including all edibles made from the same batch of marijuana, which fail to meet the potency requirements of this section, which are unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. 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, 2020 ~~2018~~.

13. When packaging marijuana, a medical marijuana treatment center must:

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

b.~~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 subparagraph 12 ~~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 marketed by or to children.

(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.

14.~~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.

15.~~13.~~ In addition to the packaging and labeling requirements specified in subparagraphs 12., 13., and 14. ~~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.

16.~~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.

17.~~15.~~ Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 13. and 14. ~~10. and 11.~~, edible receptacles 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. The receptacle must also include a list all of the edible's 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.

18.~~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 a 35-day supply of edibles within any 35-day period to a qualified patient or caregiver. A 35-day supply of edibles may not exceed 7000 mg of tetrahydrocannabinol unless an exception to this amount is approved by the department pursuant to paragraph (4)(f). 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. Beginning January 1, 2020, may not dispense dried leaves and flowers of marijuana with a tetrahydrocannabinol concentration greater than 10 percent.

d.~~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.

e.~~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.

f.~~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.

g.~~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.

h.~~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.

i.~~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.

(14) 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 may purchase from a medical marijuana treatment center for the patient's medical use a marijuana delivery device and up to the amount of marijuana authorized in the physician certification, but may not possess more than a 35-day supply of edibles, a 70-day supply of marijuana, or the greater of 4 ounces of marijuana in a form for smoking or an amount of marijuana in a form for smoking approved by the department pursuant to paragraph (4)(f), at any given time and all marijuana purchased must remain in its original packaging.

(h) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, the department, including an employee of the department acting within the scope of his or her employment, may acquire, possess, test, transport, and lawfully dispose of marijuana as provided in this section.

Section 2. Subsection (12) is added to section 381.988, Florida Statutes, to read:

381.988 Medical marijuana testing laboratories; marijuana

tests conducted by a certified laboratory.—

(12) A certified medical marijuana testing laboratory and its officers, directors, and employees may not have a direct or indirect economic interest in, or financial relationship with, a medical marijuana treatment center. Nothing in this subsection may be construed to prohibit a certified medical marijuana testing laboratory from contracting with a medical marijuana treatment center to provide testing services.

Section 3. Subsection (1) of section 14 of chapter 2017-232, Laws of Florida, is amended to read:

Section 14. Department of Health; authority to adopt rules; cause of action.—

(1) EMERGENCY RULEMAKING.—

(a) The Department of Health and the applicable boards shall adopt emergency rules pursuant to s. 120.54(4), Florida Statutes, and this section necessary to implement ss. 381.986 and 381.988, Florida Statutes. If an emergency rule adopted under this section is held to be unconstitutional or an invalid exercise of delegated legislative authority, and becomes void, the department or the applicable boards may adopt an emergency rule pursuant to this section to replace the rule that has become void. If the emergency rule adopted to replace the void emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department and the applicable boards must follow the

nonemergency rulemaking procedures of the Administrative Procedures Act to replace the rule that has become void.

(b) For emergency rules adopted under this section, the department and the applicable boards need not make the findings required by s. 120.54(4)(a), Florida Statutes. Emergency rules adopted under this section are exempt from ss. 120.54(3)(b) and 120.541, Florida Statutes. The department and the applicable boards shall meet the procedural requirements in s. 120.54(a), Florida Statutes, if the department or the applicable boards have, before July 1, 2019 ~~the effective date of this act~~, held any public workshops or hearings on the subject matter of the emergency rules adopted under this subsection. Challenges to emergency rules adopted under this subsection are subject to the time schedules provided in s. 120.56(5), Florida Statutes.

(c) Emergency rules adopted under this section are exempt from s. 120.54(4)(c), Florida Statutes, and shall remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedures Act. Rules adopted under the nonemergency rulemaking procedures of the Administrative Procedures Act to replace emergency rules adopted under this section are exempt from ss. 120.54(3)(b) and 120.541, Florida Statutes. By July 1, 2020 ~~January 1, 2018~~, the department and the applicable boards shall initiate nonemergency rulemaking pursuant to the Administrative Procedures Act to replace all emergency rules adopted under this section by

publishing a notice of rule development in the Florida Administrative Register. Except as provided in paragraph (a), after July 1, 2020 ~~January 1, 2018~~, the department and applicable boards may not adopt rules pursuant to the emergency rulemaking procedures provided in this section.

Section 4. For the 2019-2020 fiscal year, the sum of $350,000 in nonrecurring funds from the Grants and Donations Trust Fund is appropriated to the Department of Health for the purpose of implementing this act.

Section 5. This act shall take effect July 1, 2019.