

LEGISLATIVE ACTION		
Senate		House
Comm: RCS		
02/13/2019		
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The Committee on Innovation, Industry, and Technology (Brandes) recommended the following:

## Senate Amendment (with title amendment)

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Delete everything after the enacting clause and insert:

5 Section 1. Paragraphs (g) and (j) of subsection (1), 6 paragraph (a) of subsection (4), paragraph (e) of subsection 7 (8), subsection (14), and subsection (15) of section 381.986,

Florida Statutes, are amended to read:

381.986 Medical use of marijuana.-

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

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- (g) "Marijuana delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing marijuana into the human body, and which is dispensed from a medical marijuana treatment center for medical use by a qualified patient, except that delivery devices intended for the medical use of marijuana by smoking need not be dispensed from a medical marijuana treatment center in order to qualify as marijuana delivery devices.
- (j) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does not include:
- 1. Possession, use, or administration of marijuana that was not purchased or acquired from a medical marijuana treatment center.
- 2. Possession, use, or administration of marijuana in a form for smoking, in the form of commercially produced food items other than edibles, or of marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping.
- 3. Use or administration of any form or amount of marijuana in a manner that is inconsistent with the qualified physician's directions or physician certification.
- 4. Transfer of marijuana to a person other than the qualified patient for whom it was authorized or the qualified patient's caregiver on behalf of the qualified patient.
- 5. The smoking of marijuana in an enclosed indoor workplace as defined in s. 386.203(5).
  - 6.5. Use or administration of marijuana in the following



40 locations:

- a. On any form of public transportation, except for low-THC cannabis.
  - b. In any public place, except for low-THC cannabis.
- c. In a qualified patient's place of employment, except when permitted 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, except as provided in s. 1006.062.
- f. In a school bus, a vehicle, an aircraft, or a motorboat, except for low-THC cannabis.

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For the purposes of this subparagraph, the exceptions for low-THC cannabis do not include the smoking of low-THC cannabis.

- (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. 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.

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- 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 the patient's qualifying condition and the dosage not to exceed the daily dose amount 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.
  - g. The risks, benefits, and drug interactions of marijuana.
- h. The risks specifically associated with smoking marijuana.
- i.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.

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For a patient not diagnosed with a terminal condition, if the patient is younger than 18 years of age and the certifying physician intends to certify the patient's medical use of marijuana by way of smoking, the certifying physician must determine that smoking is the most effective means of administering medical marijuana for the patient and a second physician must concur with that determination. The second physician must be a pediatrician. Such determination and concurrence must be documented in the patient's medical record.

- (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

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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.

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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.

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- 214 b. Must grow marijuana within an enclosed structure and in 215 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

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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. 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

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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 a random sample from edibles available for purchase in a dispensing facility which shall be tested by the department to determine that the 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

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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, 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.



330 (III) The batch number and harvest number from which the 331 marijuana originates and the date dispensed. (IV) The name of the physician who issued the physician 332 333 certification. 334 (V) The name of the patient. 335 (VI) The product name, if applicable, and dosage form, 336 including concentration of tetrahydrocannabinol and cannabidiol. 337 The product name may not contain wording commonly associated 338 with products marketed by or to children. 339 (VII) The recommended dose. 340 (VIII) A warning that it is illegal to transfer medical 341 marijuana to another person. 342 (IX) A marijuana universal symbol developed by the 343 department. 344 11. The medical marijuana treatment center shall include in 345 each package a patient package insert with information on the 346 specific product dispensed related to: 347 a. Clinical pharmacology. b. Indications and use. 348 349 c. Dosage and administration. 350 d. Dosage forms and strengths. 351 e. Contraindications. 352 f. Warnings and precautions. 353 q. Adverse reactions. 354 12. In addition to the packaging and labeling requirements 355 in subparagraphs 10. and 11., marijuana in a form for smoking 356 must be packaged in a sealed receptacle with a legible and 357 prominent warning to keep away from children and a warning that

states marijuana smoke contains carcinogens and may negatively

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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.

13.12. 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 10., and 11., and 12., 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.

14.<del>13.</del> 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 to a qualified patient or caregiver.
- c. Must have the medical marijuana treatment center's employee who dispenses the marijuana or a marijuana delivery

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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, bongs, or wrapping papers, 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.
  - (14) EXCEPTIONS TO OTHER LAWS.-

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- (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 70-day supply of marijuana at any given time and all marijuana purchased must remain in its original packaging.
- (b) Notwithstanding paragraph (a), s. 893.13, s. 893.135, s. 893.147, or any other provision of law, a qualified patient and the qualified patient's caregiver may purchase and possess a marijuana delivery device intended for the medical use of marijuana by smoking from a vendor other than a medical marijuana treatment center if such delivery device, or a similar delivery device, is specified in that patient's certification issued by a qualified physician.
- (c) (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 medical marijuana treatment center and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of marijuana or a marijuana delivery device as provided in this section, s. 381.988, and by department rule. For the purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.
- (d)  $\frac{(e)}{(e)}$  Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements

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of this section, a certified marijuana testing laboratory, including an employee of a certified marijuana testing laboratory acting within the scope of his or her employment, may acquire, possess, test, transport, and lawfully dispose of marijuana as provided in this section, in s. 381.988, and by department rule.

(e) (d) A licensed medical marijuana treatment center 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 marijuana or a marijuana delivery device, as provided in this section, in s. 381.988, and by department rule.

(f) (e) This subsection does not exempt a person from prosecution for a criminal offense related to impairment or intoxication resulting from the medical use of marijuana 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.

(g) (f) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section and pursuant to policies and procedures established pursuant to s. 1006.62(8), school personnel may possess marijuana that is obtained for medical use pursuant to this section by a student who is a qualified patient.

(h)  $\frac{1}{2}$  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 research institute established by a public postsecondary educational institution, such as the H. Lee

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Moffitt Cancer Center and Research Institute, Inc., established under s. 1004.43, or a state university that has achieved the preeminent state research university designation under s. 1001.7065 may possess, test, transport, and lawfully dispose of marijuana for research purposes as provided by this section.

- (15) APPLICABILITY.-
- (a) This section does not limit the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy.
- (b) This section does not require an employer to accommodate the medical use of marijuana in any workplace or any employee working while under the influence of marijuana.
- (c) This section does not create a cause of action against an employer for wrongful discharge or discrimination.
- (d) This section does not impair the ability of any party to restrict or limit smoking on his or her private property.
- (e) This section does not prohibit the medical use of marijuana, or a caregiver assisting with the medical use of marijuana, in a nursing home, licensed under part II of chapter 400; in a hospice facility, licensed under part IV of chapter 400; or in an assisted living facility, licensed under part I of chapter 429, if the medical use of marijuana is not prohibited in the facility's policies.
- (f) Marijuana, as defined in this section, is not reimbursable under chapter 440.
- Section 2. The proviso following Specific Appropriation 422 in section 3 of chapter 2018-9, Laws of Florida, and the proviso following Specific Appropriation 424 in section 3 of chapter 2018-9, Laws of Florida, are repealed and the funds appropriated



by those specific appropriations which were affected by those provisos are released from reserve.

Section 3. This act shall take effect upon becoming a law.

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======= T I T L E A M E N D M E N T ========= And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to the safe medical use of marijuana; amending s. 381.986, F.S.; redefining the term "marijuana delivery device" to eliminate the requirement that such devices must be purchased from a medical marijuana treatment center; redefining the term "medical use" to include the possession, use, or administration of marijuana in a form for smoking; restricting smoking of marijuana in enclosed indoor workplaces; conforming a provision to changes made by the act; requiring a patient's informed consent form to include the risks specifically associated with smoking marijuana; requiring a certifying physician to make a determination in concurrence with a second physician who meets specified requirements before certifying a patient under 18 years of age who is not diagnosed with a terminal condition to smoke marijuana for medical use; requiring that marijuana in a form for smoking meet certain packaging and labeling requirements; deleting a provision prohibiting a medical marijuana treatment center from dispensing or

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selling specified products; allowing marijuana delivery devices to be purchased from a vendor other than a medical marijuana treatment center; providing applicability; repealing proviso language in s. 3, ch. 2018-9, Laws of Florida, relating to salaries and benefits positions and other personnel services of the Department of Health; providing an effective date.

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