

By the Committee on Health Policy; and Senator Brandes

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1 A bill to be entitled
2 An act relating to smoking marijuana for medical use;
3 amending s. 381.986, F.S.; redefining the term
4 "medical use" to include the possession, use, or
5 administration of marijuana in a form for smoking;
6 conforming a provision to changes made by the act;
7 requiring a patient's informed consent form to include
8 the risks specifically associated with smoking
9 marijuana; requiring a certifying physician to make a
10 determination in concurrence with a second physician
11 who meets specified requirements before certifying a
12 patient not diagnosed with a terminal condition to
13 smoke marijuana for medical use; deleting a provision
14 prohibiting a medical marijuana treatment center from
15 dispensing or selling specified products; providing an
16 effective date.

17
18 Be It Enacted by the Legislature of the State of Florida:

19
20 Section 1. Paragraph (j) of subsection (1), paragraph (a)
21 of subsection (4), and paragraph (e) of subsection (8) of
22 section 381.986, Florida Statutes, are amended to read:

23 381.986 Medical use of marijuana.—

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

25 (j) "Medical use" means the acquisition, possession, use,
26 delivery, transfer, or administration of marijuana authorized by
27 a physician certification. The term does not include:

28 1. Possession, use, or administration of marijuana that was
29 not purchased or acquired from a medical marijuana treatment

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30 center.

31 2. Possession, use, or administration of marijuana in a
32 ~~form for smoking, in the form of commercially produced food~~
33 ~~items other than edibles, or of marijuana seeds or flower,~~
34 ~~except for flower in a sealed, tamper-proof receptacle for~~
35 ~~vaping.~~

36 3. Use or administration of any form or amount of marijuana
37 in a manner that is inconsistent with the qualified physician's
38 directions or physician certification.

39 4. Transfer of marijuana to a person other than the
40 qualified patient for whom it was authorized or the qualified
41 patient's caregiver on behalf of the qualified patient.

42 5. Use or administration of marijuana in the following
43 locations:

44 a. On any form of public transportation, except for low-THC
45 cannabis.

46 b. In any public place, except for low-THC cannabis.

47 c. In a qualified patient's place of employment, except
48 when permitted by his or her employer.

49 d. In a state correctional institution, as defined in s.
50 944.02, or a correctional institution, as defined in s. 944.241.

51 e. On the grounds of a preschool, primary school, or
52 secondary school, except as provided in s. 1006.062.

53 f. In a school bus, a vehicle, an aircraft, or a motorboat,
54 except for low-THC cannabis.

55
56 For the purposes of this subparagraph, the exceptions for low-
57 THC cannabis do not include the smoking of low-THC cannabis.

58 (4) PHYSICIAN CERTIFICATION.—

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

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

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

66 3. Determined that the medical use of marijuana would
67 likely outweigh the potential health risks for the patient, and
68 such determination must be documented in the patient's medical
69 record. If a patient is younger than 18 years of age, a second
70 physician must concur with this determination, and such
71 concurrence must be documented in the patient's medical record.

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

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

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

82 7. Registers as the issuer of the physician certification
83 for the named qualified patient on the medical marijuana use
84 registry in an electronic manner determined by the department,
85 and:

86 a. Enters into the registry the contents of the physician
87 certification, including the patient's qualifying condition and

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88 the dosage not to exceed the daily dose amount determined by the
89 department, the amount and forms of marijuana authorized for the
90 patient, and any types of marijuana delivery devices needed by
91 the patient for the medical use of marijuana.

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

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

98 8. Obtains the voluntary and informed written consent of
99 the patient for medical use of marijuana each time the qualified
100 physician issues a physician certification for the patient,
101 which shall be maintained in the patient's medical record. The
102 patient, or the patient's parent or legal guardian if the
103 patient is a minor, must sign the informed consent acknowledging
104 that the qualified physician has sufficiently explained its
105 content. The qualified physician must use a standardized
106 informed consent form adopted in rule by the Board of Medicine
107 and the Board of Osteopathic Medicine, which must include, at a
108 minimum, information related to:

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

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

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

116 d. The potential for addiction.

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

122 f. The potential side effects of marijuana use.

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

124 h. The risks specifically associated with smoking
125 marijuana.

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

129
130 For a patient not diagnosed with a terminal condition, if the
131 certifying physician intends to certify the patient's medical
132 use of marijuana by way of smoking, the certifying physician
133 must determine that smoking is the only means of administering
134 medical marijuana that is likely to benefit the patient and a
135 second physician must concur with that determination. The second
136 physician must not be registered with the department as a
137 certifying physician for any qualified patients. Such
138 determination and concurrence must be documented in the
139 patient's medical record.

140 (8) MEDICAL MARIJUANA TREATMENT CENTERS.—

141 (e) A licensed medical marijuana treatment center shall
142 cultivate, process, transport, and dispense marijuana for
143 medical use. A licensed medical marijuana treatment center may
144 not contract for services directly related to the cultivation,
145 processing, and dispensing of marijuana or marijuana delivery

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146 devices, except that a medical marijuana treatment center
147 licensed pursuant to subparagraph (a)1. may contract with a
148 single entity for the cultivation, processing, transporting, and
149 dispensing of marijuana and marijuana delivery devices. A
150 licensed medical marijuana treatment center must, at all times,
151 maintain compliance with the criteria demonstrated and
152 representations made in the initial application and the criteria
153 established in this subsection. Upon request, the department may
154 grant a medical marijuana treatment center a variance from the
155 representations made in the initial application. Consideration
156 of such a request shall be based upon the individual facts and
157 circumstances surrounding the request. A variance may not be
158 granted unless the requesting medical marijuana treatment center
159 can demonstrate to the department that it has a proposed
160 alternative to the specific representation made in its
161 application which fulfills the same or a similar purpose as the
162 specific representation in a way that the department can
163 reasonably determine will not be a lower standard than the
164 specific representation in the application. A variance may not
165 be granted from the requirements in subparagraph 2. and
166 subparagraphs (b)1. and 2.

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

173 a. The licensed medical marijuana treatment center shall
174 notify the department in writing at least 60 days before the

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175 anticipated date of the change of ownership.

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

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

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

190
191 Within 30 days after the receipt of a complete application, the
192 department shall approve or deny the application.

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

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

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

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

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

213 a. May use pesticides determined by the department, after
214 consultation with the Department of Agriculture and Consumer
215 Services, to be safely applied to plants intended for human
216 consumption, but may not use pesticides designated as
217 restricted-use pesticides pursuant to s. 487.042.

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

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

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

227 7. Each medical marijuana treatment center must produce and
228 make available for purchase at least one low-THC cannabis
229 product.

230 8. A medical marijuana treatment center that produces
231 edibles must hold a permit to operate as a food establishment
232 pursuant to chapter 500, the Florida Food Safety Act, and must

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233 comply with all the requirements for food establishments
234 pursuant to chapter 500 and any rules adopted thereunder.
235 Edibles may not contain more than 200 milligrams of
236 tetrahydrocannabinol, and a single serving portion of an edible
237 may not exceed 10 milligrams of tetrahydrocannabinol. Edibles
238 may have a potency variance of no greater than 15 percent.
239 Edibles may not be attractive to children; be manufactured in
240 the shape of humans, cartoons, or animals; be manufactured in a
241 form that bears any reasonable resemblance to products available
242 for consumption as commercially available candy; or contain any
243 color additives. To discourage consumption of edibles by
244 children, the department shall determine by rule any shapes,
245 forms, and ingredients allowed and prohibited for edibles.
246 Medical marijuana treatment centers may not begin processing or
247 dispensing edibles until after the effective date of the rule.
248 The department shall also adopt sanitation rules providing the
249 standards and requirements for the storage, display, or
250 dispensing of edibles.

251 9. Within 12 months after licensure, a medical marijuana
252 treatment center must demonstrate to the department that all of
253 its processing facilities have passed a Food Safety Good
254 Manufacturing Practices, such as Global Food Safety Initiative
255 or equivalent, inspection by a nationally accredited certifying
256 body. A medical marijuana treatment center must immediately stop
257 processing at any facility which fails to pass this inspection
258 until it demonstrates to the department that such facility has
259 met this requirement.

260 10. When processing marijuana, a medical marijuana
261 treatment center must:

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

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

270 c. Comply with federal and state laws and regulations and
271 department rules for solid and liquid wastes. The department
272 shall determine by rule procedures for the storage, handling,
273 transportation, management, and disposal of solid and liquid
274 waste generated during marijuana production and processing. The
275 Department of Environmental Protection shall assist the
276 department in developing such rules.

277 d. Test the processed marijuana using a medical marijuana
278 testing laboratory before it is dispensed. Results must be
279 verified and signed by two medical marijuana treatment center
280 employees. Before dispensing, the medical marijuana treatment
281 center must determine that the test results indicate that low-
282 THC cannabis meets the definition of low-THC cannabis, the
283 concentration of tetrahydrocannabinol meets the potency
284 requirements of this section, the labeling of the concentration
285 of tetrahydrocannabinol and cannabidiol is accurate, and all
286 marijuana is safe for human consumption and free from
287 contaminants that are unsafe for human consumption. The
288 department shall determine by rule which contaminants must be
289 tested for and the maximum levels of each contaminant which are
290 safe for human consumption. The Department of Agriculture and

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291 Consumer Services shall assist the department in developing the
292 testing requirements for contaminants that are unsafe for human
293 consumption in edibles. The department shall also determine by
294 rule the procedures for the treatment of marijuana that fails to
295 meet the testing requirements of this section, s. 381.988, or
296 department rule. The department may select a random sample from
297 edibles available for purchase in a dispensing facility which
298 shall be tested by the department to determine that the edible
299 meets the potency requirements of this section, is safe for
300 human consumption, and the labeling of the tetrahydrocannabinol
301 and cannabidiol concentration is accurate. A medical marijuana
302 treatment center may not require payment from the department for
303 the sample. A medical marijuana treatment center must recall
304 edibles, including all edibles made from the same batch of
305 marijuana, which fail to meet the potency requirements of this
306 section, which are unsafe for human consumption, or for which
307 the labeling of the tetrahydrocannabinol and cannabidiol
308 concentration is inaccurate. The medical marijuana treatment
309 center must retain records of all testing and samples of each
310 homogenous batch of marijuana for at least 9 months. The medical
311 marijuana treatment center must contract with a marijuana
312 testing laboratory to perform audits on the medical marijuana
313 treatment center's standard operating procedures, testing
314 records, and samples and provide the results to the department
315 to confirm that the marijuana or low-THC cannabis meets the
316 requirements of this section and that the marijuana or low-THC
317 cannabis is safe for human consumption. A medical marijuana
318 treatment center shall reserve two processed samples from each
319 batch and retain such samples for at least 9 months for the

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320 purpose of such audits. A medical marijuana treatment center may
321 use a laboratory that has not been certified by the department
322 under s. 381.988 until such time as at least one laboratory
323 holds the required certification, but in no event later than
324 July 1, 2018.

325 e. Package the marijuana in compliance with the United
326 States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.
327 1471 et seq.

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

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

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

334 (III) The batch number and harvest number from which the
335 marijuana originates and the date dispensed.

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

338 (V) The name of the patient.

339 (VI) The product name, if applicable, and dosage form,
340 including concentration of tetrahydrocannabinol and cannabidiol.
341 The product name may not contain wording commonly associated
342 with products marketed by or to children.

343 (VII) The recommended dose.

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

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

348 11. The medical marijuana treatment center shall include in

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349 each package a patient package insert with information on the
350 specific product dispensed related to:

- 351 a. Clinical pharmacology.
- 352 b. Indications and use.
- 353 c. Dosage and administration.
- 354 d. Dosage forms and strengths.
- 355 e. Contraindications.
- 356 f. Warnings and precautions.
- 357 g. Adverse reactions.

358 12. Each edible shall be individually sealed in plain,
359 opaque wrapping marked only with the marijuana universal symbol.
360 Where practical, each edible shall be marked with the marijuana
361 universal symbol. In addition to the packaging and labeling
362 requirements in subparagraphs 10. and 11., edible receptacles
363 must be plain, opaque, and white without depictions of the
364 product or images other than the medical marijuana treatment
365 center's department-approved logo and the marijuana universal
366 symbol. The receptacle must also include a list all of the
367 edible's ingredients, storage instructions, an expiration date,
368 a legible and prominent warning to keep away from children and
369 pets, and a warning that the edible has not been produced or
370 inspected pursuant to federal food safety laws.

371 13. When dispensing marijuana or a marijuana delivery
372 device, a medical marijuana treatment center:

- 373 a. May dispense any active, valid order for low-THC
374 cannabis, medical cannabis and cannabis delivery devices issued
375 pursuant to former s. 381.986, Florida Statutes 2016, which was
376 entered into the medical marijuana use registry before July 1,
377 2017.

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378 b. May not dispense more than a 70-day supply of marijuana
379 to a qualified patient or caregiver.

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

384 d. Must verify that the qualified patient and the
385 caregiver, if applicable, each have an active registration in
386 the medical marijuana use registry and an active and valid
387 medical marijuana use registry identification card, the amount
388 and type of marijuana dispensed matches the physician
389 certification in the medical marijuana use registry for that
390 qualified patient, and the physician certification has not
391 already been filled.

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

396 f. May not dispense or sell any other type of cannabis,
397 alcohol, or illicit drug-related product, ~~including pipes,~~
398 ~~bongs, or wrapping papers,~~ other than a marijuana delivery
399 device required for the medical use of marijuana and which is
400 specified in a physician certification.

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

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

410 Section 2. This act shall take effect upon becoming a law.