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LEGISLATIVE ACTION

Senate

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House

The Committee on Rules (Harrell) recommended the following:

Senate Amendment (with title amendment)

Between lines 368 and 369

insert:

Section 5. Paragraph (f) of subsection (4) and paragraph (e) of subsection (8) of section 381.986, Florida Statutes, are amended to read:

381.986 Medical use of marijuana.—

(4) PHYSICIAN CERTIFICATION.—

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



12 marijuana; ~~or~~ more than six 35-day supply limits of marijuana in
13 a form for smoking; or, to a qualified patient under 21 years of
14 age, marijuana with a concentration of tetrahydrocannabinol
15 which exceeds 10 percent, except that a physician may certify
16 such qualified patient for any concentration of
17 tetrahydrocannabinol if the qualified patient is diagnosed with
18 a terminal condition and the qualified physician indicates this
19 fact on the qualified patient's certification. The department
20 shall quantify by rule a daily dose amount with equivalent dose
21 amounts for each allowable form of marijuana dispensed by a
22 medical marijuana treatment center. The department shall use the
23 daily dose amount to calculate a 70-day supply.

24 1. A qualified physician may request an exception to the
25 daily dose amount limit, the 35-day supply limit of marijuana in
26 a form for smoking, ~~and~~ the 4-ounce possession limit of
27 marijuana in a form for smoking established in paragraph
28 (14) (a), and the tetrahydrocannabinol concentration limits
29 established in this paragraph. The request shall be made
30 electronically on a form adopted by the department in rule and
31 must include, at a minimum:

32 a. The qualified patient's qualifying medical condition.

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

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

37 d. The minimum daily dose amount of marijuana and
38 tetrahydrocannabinol concentration, as applicable, that would be
39 sufficient for the treatment of the qualified patient's
40 qualifying medical condition.



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

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

47 (8) MEDICAL MARIJUANA TREATMENT CENTERS.—

48 (e) A licensed medical marijuana treatment center shall
49 cultivate, process, transport, and dispense marijuana for
50 medical use. A licensed medical marijuana treatment center may
51 not contract for services directly related to the cultivation,
52 processing, and dispensing of marijuana or marijuana delivery
53 devices, except that a medical marijuana treatment center
54 licensed pursuant to subparagraph (a)1. may contract with a
55 single entity for the cultivation, processing, transporting, and
56 dispensing of marijuana and marijuana delivery devices. A
57 licensed medical marijuana treatment center must, at all times,
58 maintain compliance with the criteria demonstrated and
59 representations made in the initial application and the criteria
60 established in this subsection. Upon request, the department may
61 grant a medical marijuana treatment center a variance from the
62 representations made in the initial application. Consideration
63 of such a request shall be based upon the individual facts and
64 circumstances surrounding the request. A variance may not be
65 granted unless the requesting medical marijuana treatment center
66 can demonstrate to the department that it has a proposed
67 alternative to the specific representation made in its
68 application which fulfills the same or a similar purpose as the
69 specific representation in a way that the department can



70 reasonably determine will not be a lower standard than the
71 specific representation in the application. A variance may not
72 be granted from the requirements in subparagraph 2. and
73 subparagraphs (b)1. and 2.

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

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

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

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

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

97
98 Within 30 days after the receipt of a complete application, the



99 department shall approve or deny the application.

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

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

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

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

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

120 a. May use pesticides determined by the department, after
121 consultation with the Department of Agriculture and Consumer
122 Services, to be safely applied to plants intended for human
123 consumption, but may not use pesticides designated as
124 restricted-use pesticides pursuant to s. 487.042.

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

127 c. Must inspect seeds and growing plants for plant pests



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128 that endanger or threaten the horticultural and agricultural
129 interests of the state in accordance with chapter 581 and any
130 rules adopted thereunder.

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

134 7. Each medical marijuana treatment center must produce and
135 make available for purchase at least one low-THC cannabis
136 product.

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



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157 dispensing of edibles.

158 9. Within 12 months after licensure, a medical marijuana
159 treatment center must demonstrate to the department that all of
160 its processing facilities have passed a Food Safety Good
161 Manufacturing Practices, such as Global Food Safety Initiative
162 or equivalent, inspection by a nationally accredited certifying
163 body. A medical marijuana treatment center must immediately stop
164 processing at any facility which fails to pass this inspection
165 until it demonstrates to the department that such facility has
166 met this requirement.

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

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

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

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

180 c. Comply with federal and state laws and regulations and
181 department rules for solid and liquid wastes. The department
182 shall determine by rule procedures for the storage, handling,
183 transportation, management, and disposal of solid and liquid
184 waste generated during marijuana production and processing. The
185 Department of Environmental Protection shall assist the



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186 department in developing such rules.

187 d. Test the processed marijuana using a medical marijuana
188 testing laboratory before it is dispensed. Results must be
189 verified and signed by two medical marijuana treatment center
190 employees. Before dispensing, the medical marijuana treatment
191 center must determine that the test results indicate that low-
192 THC cannabis meets the definition of low-THC cannabis, the
193 concentration of tetrahydrocannabinol meets the potency
194 requirements of this section, the labeling of the concentration
195 of tetrahydrocannabinol and cannabidiol is accurate, and all
196 marijuana is safe for human consumption and free from
197 contaminants that are unsafe for human consumption. The
198 department shall determine by rule which contaminants must be
199 tested for and the maximum levels of each contaminant which are
200 safe for human consumption. The Department of Agriculture and
201 Consumer Services shall assist the department in developing the
202 testing requirements for contaminants that are unsafe for human
203 consumption in edibles. The department shall also determine by
204 rule the procedures for the treatment of marijuana that fails to
205 meet the testing requirements of this section, s. 381.988, or
206 department rule. The department may select a random sample from
207 edibles available for purchase in a dispensing facility which
208 shall be tested by the department to determine that the edible
209 meets the potency requirements of this section, is safe for
210 human consumption, and the labeling of the tetrahydrocannabinol
211 and cannabidiol concentration is accurate. A medical marijuana
212 treatment center may not require payment from the department for
213 the sample. A medical marijuana treatment center must recall
214 edibles, including all edibles made from the same batch of



215 marijuana, which fail to meet the potency requirements of this
216 section, which are unsafe for human consumption, or for which
217 the labeling of the tetrahydrocannabinol and cannabidiol
218 concentration is inaccurate. The medical marijuana treatment
219 center must retain records of all testing and samples of each
220 homogenous batch of marijuana for at least 9 months. The medical
221 marijuana treatment center must contract with a marijuana
222 testing laboratory to perform audits on the medical marijuana
223 treatment center's standard operating procedures, testing
224 records, and samples and provide the results to the department
225 to confirm that the marijuana or low-THC cannabis meets the
226 requirements of this section and that the marijuana or low-THC
227 cannabis is safe for human consumption. A medical marijuana
228 treatment center shall reserve two processed samples from each
229 batch and retain such samples for at least 9 months for the
230 purpose of such audits. A medical marijuana treatment center may
231 use a laboratory that has not been certified by the department
232 under s. 381.988 until such time as at least one laboratory
233 holds the required certification, but in no event later than
234 July 1, 2018.

235 e. Package the marijuana in compliance with the United
236 States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.
237 1471 et seq.

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

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

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



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

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

248 (V) The name of the patient.

249 (VI) The product name, if applicable, and dosage form,
250 including concentration of tetrahydrocannabinol and cannabidiol.
251 The product name may not contain wording commonly associated
252 with products marketed by or to children.

253 (VII) The recommended dose.

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

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

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

- 261 a. Clinical pharmacology.
- 262 b. Indications and use.
- 263 c. Dosage and administration.
- 264 d. Dosage forms and strengths.
- 265 e. Contraindications.
- 266 f. Warnings and precautions.
- 267 g. Adverse reactions.

268 13. In addition to the packaging and labeling requirements
269 specified in subparagraphs 11. and 12., marijuana in a form for
270 smoking must be packaged in a sealed receptacle with a legible
271 and prominent warning to keep away from children and a warning
272 that states marijuana smoke contains carcinogens and may



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273 negatively affect health. Such receptacles for marijuana in a
274 form for smoking must be plain, opaque, and white without
275 depictions of the product or images other than the medical
276 marijuana treatment center's department-approved logo and the
277 marijuana universal symbol.

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

283 15. Each edible shall be individually sealed in plain,
284 opaque wrapping marked only with the marijuana universal symbol.
285 Where practical, each edible shall be marked with the marijuana
286 universal symbol. In addition to the packaging and labeling
287 requirements in subparagraphs 11. and 12., edible receptacles
288 must be plain, opaque, and white without depictions of the
289 product or images other than the medical marijuana treatment
290 center's department-approved logo and the marijuana universal
291 symbol. The receptacle must also include a list of all the
292 edible's ingredients, storage instructions, an expiration date,
293 a legible and prominent warning to keep away from children and
294 pets, and a warning that the edible has not been produced or
295 inspected pursuant to federal food safety laws.

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

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



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302 2017.

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

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

314 d. Must verify that the qualified patient and the
315 caregiver, if applicable, each have an active registration in
316 the medical marijuana use registry and an active and valid
317 medical marijuana use registry identification card, the amount
318 and type of marijuana dispensed matches the physician
319 certification in the medical marijuana use registry for that
320 qualified patient, and the physician certification has not
321 already been filled.

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

326 f. May not dispense marijuana with a concentration of
327 tetrahydrocannabinol which exceeds 10 percent to a qualified
328 patient 18 to 21 years of age, to his or her caregiver, or to
329 the caregiver of a qualified patient under 18 years of age for
330 the qualified patient's medical use. However, if a qualified



331 patient younger than 21 years of age has an exception approved
332 by the department under paragraph (4) (f) relating to the
333 concentration of tetrahydrocannabinol or the qualified patient's
334 certification indicates that he or she is diagnosed with a
335 terminal condition, marijuana with a concentration of
336 tetrahydrocannabinol which exceeds 10 percent may be dispensed
337 to such a qualified patient who is 18 years of age or older or
338 to his or her caregiver or to such a qualified patient's
339 caregiver if the patient is younger than 18 years of age, for
340 the qualified patient's medical use.

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

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

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

355
356 ===== T I T L E A M E N D M E N T =====

357 And the title is amended as follows:

358 Delete line 19

359 and insert:



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360 Program; amending s. 381.986, F.S.; prohibiting
361 qualified physicians from certifying for certain
362 qualified patients marijuana with concentration of
363 tetrahydrocannabinol exceeding a certain amount;
364 providing exceptions; prohibiting medical marijuana
365 treatment centers from dispensing for certain
366 qualified patients marijuana with a concentration of
367 tetrahydrocannabinol exceeding a certain amount;
368 providing exceptions; amending s. 401.35, F.S.;
369 clarifying