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LEGISLATIVE ACTION

Senate

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House

The Committee on Rules (Harrell) recommended the following:

1 **Senate Substitute for Amendment (850798) (with title**
2 **amendment)**

3
4 Between lines 368 and 369
5 insert:

6 Section 5. Paragraphs (a) and (f) of subsection (4) and
7 paragraph (e) of subsection (8) of section 381.986, Florida
8 Statutes, are amended, and paragraph (i) is added to subsection
9 (14) of that section, to read:

10 381.986 Medical use of marijuana.—

11 (4) PHYSICIAN CERTIFICATION.—



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12 (a) A qualified physician may issue a physician
13 certification only if the qualified physician:
14 1. Conducted a physical examination while physically
15 present in the same room as the patient and a full assessment of
16 the medical history of the patient.
17 2. Diagnosed the patient with at least one qualifying
18 medical condition.
19 3. Determined that the medical use of marijuana would
20 likely outweigh the potential health risks for the patient, and
21 such determination must be documented in the patient's medical
22 record. If a patient is younger than 18 years of age, a second
23 physician must concur with this determination, and such
24 concurrence must be documented in the patient's medical record.
25 4. Determined whether the patient is pregnant and
26 documented such determination in the patient's medical record. A
27 physician may not issue a physician certification, except for
28 low-THC cannabis, to a patient who is pregnant.
29 5. Reviewed the patient's controlled drug prescription
30 history in the prescription drug monitoring program database
31 established pursuant to s. 893.055.
32 6. Reviews the medical marijuana use registry and confirmed
33 that the patient does not have an active physician certification
34 from another qualified physician.
35 7. Registers as the issuer of the physician certification
36 for the named qualified patient on the medical marijuana use
37 registry in an electronic manner determined by the department,
38 and:
39 a. Enters into the registry the contents of the physician
40 certification, including all of the patient's qualifying



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41 conditions for which the qualified physician is issuing the
42 certification ~~condition~~ and the dosage not to exceed the daily
43 dose amount determined by the department, the amount and forms
44 of marijuana authorized for the patient, and any types of
45 marijuana delivery devices needed by the patient for the medical
46 use of marijuana.

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

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

53 8. Obtains the voluntary and informed written consent of
54 the patient for medical use of marijuana each time the qualified
55 physician issues a physician certification for the patient,
56 which shall be maintained in the patient's medical record. The
57 patient, or the patient's parent or legal guardian if the
58 patient is a minor, must sign the informed consent acknowledging
59 that the qualified physician has sufficiently explained its
60 content. The qualified physician must use a standardized
61 informed consent form adopted in rule by the Board of Medicine
62 and the Board of Osteopathic Medicine, which must include, at a
63 minimum, information related to:

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

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

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



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70 section.

71 d. The potential for addiction.

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

77 f. The potential side effects of marijuana use, including
78 the negative health risks associated with smoking marijuana and
79 the negative health effects of marijuana use on persons under 21
80 years of age.

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

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

85 (f) A qualified physician may not issue a physician
86 certification for more than three 70-day supply limits of
87 marijuana; ~~or~~ more than six 35-day supply limits of marijuana in
88 a form for smoking; or, to a qualified patient under 21 years of
89 age, marijuana with a concentration of tetrahydrocannabinol
90 which exceeds 10 percent, except that a physician may certify
91 such qualified patient for any concentration of
92 tetrahydrocannabinol if the qualified patient is diagnosed with
93 a terminal condition and the qualified physician indicates this
94 fact on the qualified patient's certification. The department
95 shall quantify by rule a daily dose amount with equivalent dose
96 amounts for each allowable form of marijuana dispensed by a
97 medical marijuana treatment center. The department shall use the
98 daily dose amount to calculate a 70-day supply.



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99 1. A qualified physician may request an exception to the
100 daily dose amount limit, the 35-day supply limit of marijuana in
101 a form for smoking, ~~and~~ the 4-ounce possession limit of
102 marijuana in a form for smoking established in paragraph
103 (14) (a), and the tetrahydrocannabinol concentration limits
104 established in this paragraph. The request shall be made
105 electronically on a form adopted by the department in rule and
106 must include, at a minimum:

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

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

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

112 d. The minimum daily dose amount of marijuana and
113 tetrahydrocannabinol concentration, as applicable, that would be
114 sufficient for the treatment of the qualified patient's
115 qualifying medical condition.

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

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

122 (8) MEDICAL MARIJUANA TREATMENT CENTERS.—

123 (e) A licensed medical marijuana treatment center shall
124 cultivate, process, transport, and dispense marijuana for
125 medical use. A licensed medical marijuana treatment center may
126 not contract for services directly related to the cultivation,
127 processing, and dispensing of marijuana or marijuana delivery



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128 devices, except that a medical marijuana treatment center
129 licensed pursuant to subparagraph (a)1. may contract with a
130 single entity for the cultivation, processing, transporting, and
131 dispensing of marijuana and marijuana delivery devices. A
132 licensed medical marijuana treatment center must, at all times,
133 maintain compliance with the criteria demonstrated and
134 representations made in the initial application and the criteria
135 established in this subsection. Upon request, the department may
136 grant a medical marijuana treatment center a variance from the
137 representations made in the initial application. Consideration
138 of such a request shall be based upon the individual facts and
139 circumstances surrounding the request. A variance may not be
140 granted unless the requesting medical marijuana treatment center
141 can demonstrate to the department that it has a proposed
142 alternative to the specific representation made in its
143 application which fulfills the same or a similar purpose as the
144 specific representation in a way that the department can
145 reasonably determine will not be a lower standard than the
146 specific representation in the application. A variance may not
147 be granted from the requirements in subparagraph 2. and
148 subparagraphs (b)1. and 2.

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

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



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157 anticipated date of the change of ownership.

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

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

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

172
173 Within 30 days after the receipt of a complete application, the
174 department shall approve or deny the application.

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

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



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

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

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

195 a. May use pesticides determined by the department, after
196 consultation with the Department of Agriculture and Consumer
197 Services, to be safely applied to plants intended for human
198 consumption, but may not use pesticides designated as
199 restricted-use pesticides pursuant to s. 487.042.

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

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

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

209 7. Each medical marijuana treatment center must produce and
210 make available for purchase at least one low-THC cannabis
211 product.

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



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215 | comply with all the requirements for food establishments
216 | pursuant to chapter 500 and any rules adopted thereunder.
217 | Edibles may not contain more than 200 milligrams of
218 | tetrahydrocannabinol, and a single serving portion of an edible
219 | may not exceed 10 milligrams of tetrahydrocannabinol. Edibles
220 | may have a potency variance of no greater than 15 percent of the
221 | 10 milligrams of tetrahydrocannabinol per single serving limit
222 | or the 200 milligrams of tetrahydrocannabinol per product limit.

223 | Edibles may not be attractive to children; be manufactured in
224 | the shape of humans, cartoons, or animals; be manufactured in a
225 | form that bears any reasonable resemblance to products available
226 | for consumption as commercially available candy; or contain any
227 | color additives. To discourage consumption of edibles by
228 | children, the department shall determine by rule any shapes,
229 | forms, and ingredients allowed and prohibited for edibles.

230 | Medical marijuana treatment centers may not begin processing or
231 | dispensing edibles until after the effective date of the rule.
232 | The department shall also adopt sanitation rules providing the
233 | standards and requirements for the storage, display, or
234 | dispensing of edibles.

235 | 9. Within 12 months after licensure, a medical marijuana
236 | treatment center must demonstrate to the department that all of
237 | its processing facilities have passed a Food Safety Good
238 | Manufacturing Practices, such as Global Food Safety Initiative
239 | or equivalent, inspection by a nationally accredited certifying
240 | body. A medical marijuana treatment center must immediately stop
241 | processing at any facility which fails to pass this inspection
242 | until it demonstrates to the department that such facility has
243 | met this requirement.



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

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

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

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

257 c. Comply with federal and state laws and regulations and
258 department rules for solid and liquid wastes. The department
259 shall determine by rule procedures for the storage, handling,
260 transportation, management, and disposal of solid and liquid
261 waste generated during marijuana production and processing. The
262 Department of Environmental Protection shall assist the
263 department in developing such rules.

264 12.d. A medical marijuana treatment center must test the
265 ~~processed~~ marijuana using a medical marijuana testing laboratory
266 before it is dispensed. Results must be verified and signed by
267 two medical marijuana treatment center employees. Before
268 dispensing, the medical marijuana treatment center must
269 determine that the test results indicate that low-THC cannabis
270 meets the definition of low-THC cannabis, the concentration of
271 tetrahydrocannabinol meets the potency requirements of this
272 section, the labeling of the concentration of



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273 tetrahydrocannabinol and cannabidiol is accurate, and all
274 marijuana is safe for human consumption and free from
275 contaminants that are unsafe for human consumption. The
276 department shall determine by rule which contaminants must be
277 tested for and the maximum levels of each contaminant which are
278 safe for human consumption. The Department of Agriculture and
279 Consumer Services shall assist the department in developing the
280 testing requirements for contaminants that are unsafe for human
281 consumption in edibles. The department shall also determine by
282 rule the procedures for the treatment of marijuana that fails to
283 meet the testing requirements of this section, s. 381.988, or
284 department rule. The department may select ~~a~~ random samples of
285 marijuana, sample from edibles available in a cultivation
286 facility, processing facility, or for purchase in a dispensing
287 facility which shall be tested by the department to determine
288 that the marijuana edible meets the potency requirements of this
289 section, is safe for human consumption, and the labeling of the
290 tetrahydrocannabinol and cannabidiol concentration is accurate.
291 A medical marijuana treatment center may not require payment
292 from the department for the sample. A medical marijuana
293 treatment center must recall edibles, including all edibles made
294 from the same batch of marijuana, which fail to meet the potency
295 requirements of this section, which are unsafe for human
296 consumption, or for which the labeling of the
297 tetrahydrocannabinol and cannabidiol concentration is
298 inaccurate. The medical marijuana treatment center must retain
299 records of all testing and samples of each homogenous batch of
300 marijuana for at least 9 months. The medical marijuana treatment
301 center must contract with a marijuana testing laboratory to



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302 perform audits on the medical marijuana treatment center's
303 standard operating procedures, testing records, and samples and
304 provide the results to the department to confirm that the
305 marijuana or low-THC cannabis meets the requirements of this
306 section and that the marijuana or low-THC cannabis is safe for
307 human consumption. A medical marijuana treatment center shall
308 reserve two processed samples from each batch and retain such
309 samples for at least 9 months for the purpose of such audits. A
310 medical marijuana treatment center may use a laboratory that has
311 not been certified by the department under s. 381.988 until such
312 time as at least one laboratory holds the required
313 certification, but in no event later than July 1, 2021 ~~2018~~.

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

316 a.e. Package the marijuana in compliance with the United
317 States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.
318 1471 et seq.

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

322 (I) The marijuana or low-THC cannabis meets the
323 requirements of subparagraph 12 ~~sub-subparagraph d~~.

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

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

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

330 (V) The name of the patient.



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331 (VI) The product name, if applicable, and dosage form,
332 including concentration of tetrahydrocannabinol and cannabidiol.
333 The product name may not contain wording commonly associated
334 with products marketed by or to children.

335 (VII) The recommended dose.

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

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

340 14.12. The medical marijuana treatment center shall include
341 in each package a patient package insert with information on the
342 specific product dispensed related to:

- 343 a. Clinical pharmacology.
- 344 b. Indications and use.
- 345 c. Dosage and administration.
- 346 d. Dosage forms and strengths.
- 347 e. Contraindications.
- 348 f. Warnings and precautions.
- 349 g. Adverse reactions.

350 15.13. In addition to the packaging and labeling
351 requirements specified in subparagraphs 11. and 14. 12.,
352 marijuana in a form for smoking must be packaged in a sealed
353 receptacle with a legible and prominent warning to keep away
354 from children and a warning that states marijuana smoke contains
355 carcinogens and may negatively affect health. Such receptacles
356 for marijuana in a form for smoking must be plain, opaque, and
357 white without depictions of the product or images other than the
358 medical marijuana treatment center's department-approved logo
359 and the marijuana universal symbol.



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360 ~~16.14.~~ The department shall adopt rules to regulate the
361 types, appearance, and labeling of marijuana delivery devices
362 dispensed from a medical marijuana treatment center. The rules
363 must require marijuana delivery devices to have an appearance
364 consistent with medical use.

365 ~~17.15.~~ Each edible shall be individually sealed in plain,
366 opaque wrapping marked only with the marijuana universal symbol.
367 Where practical, each edible shall be marked with the marijuana
368 universal symbol. In addition to the packaging and labeling
369 requirements in subparagraphs 11. and ~~14. 12.~~, edible
370 receptacles must be plain, opaque, and white without depictions
371 of the product or images other than the medical marijuana
372 treatment center's department-approved logo and the marijuana
373 universal symbol. The receptacle must also include a list of all
374 the edible's ingredients, storage instructions, an expiration
375 date, a legible and prominent warning to keep away from children
376 and pets, and a warning that the edible has not been produced or
377 inspected pursuant to federal food safety laws.

378 ~~18.16.~~ When dispensing marijuana or a marijuana delivery
379 device, a medical marijuana treatment center:

380 a. May dispense any active, valid order for low-THC
381 cannabis, medical cannabis and cannabis delivery devices issued
382 pursuant to former s. 381.986, Florida Statutes 2016, which was
383 entered into the medical marijuana use registry before July 1,
384 2017.

385 b. May not dispense more than a 70-day supply of marijuana
386 within any 70-day period to a qualified patient or caregiver.
387 May not dispense more than one 35-day supply of marijuana in a
388 form for smoking within any 35-day period to a qualified patient



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389 or caregiver. A 35-day supply of marijuana in a form for smoking
390 may not exceed 2.5 ounces unless an exception to this amount is
391 approved by the department pursuant to paragraph (4) (f).

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

396 d. Must verify that the qualified patient and the
397 caregiver, if applicable, each have an active registration in
398 the medical marijuana use registry and an active and valid
399 medical marijuana use registry identification card, the amount
400 and type of marijuana dispensed matches the physician
401 certification in the medical marijuana use registry for that
402 qualified patient, and the physician certification has not
403 already been filled.

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

408 f. May not dispense marijuana with a concentration of
409 tetrahydrocannabinol which exceeds 10 percent to a qualified
410 patient 18 to 21 years of age, to his or her caregiver, or to
411 the caregiver of a qualified patient under 18 years of age for
412 the qualified patient's medical use. However, if a qualified
413 patient younger than 21 years of age has an exception approved
414 by the department under paragraph (4) (f) relating to the
415 concentration of tetrahydrocannabinol or the qualified patient's
416 certification indicates that he or she is diagnosed with a
417 terminal condition, marijuana with a concentration of



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418 tetrahydrocannabinol which exceeds 10 percent may be dispensed
419 to such a qualified patient who is 18 years of age or older or
420 to his or her caregiver or to such a qualified patient's
421 caregiver if the patient is younger than 18 years of age, for
422 the qualified patient's medical use.

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

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

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

437 (14) EXCEPTIONS TO OTHER LAWS.—

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

444 Section 6. Present subsection (11) of section 381.988,
445 Florida Statutes, is redesignated as subsection (12), and a new
446 subsection (11) is added to that section, to read:



447 381.988 Medical marijuana testing laboratories; marijuana
448 tests conducted by a certified laboratory.-

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

456
457 ===== T I T L E A M E N D M E N T =====

458 And the title is amended as follows:

459 Delete line 19

460 and insert:

461 Program; amending s. 381.986, F.S.; revising
462 requirements for qualified physicians who issue
463 physician certifications for the medical use of
464 marijuana; prohibiting qualified physicians from
465 certifying for certain qualified patients marijuana
466 with concentration of tetrahydrocannabinol exceeding a
467 specified amount; providing exceptions; revising a
468 provision related to the tetrahydrocannabinol limits
469 for edibles; revising provisions related to the
470 testing, processing, and packaging of marijuana for
471 medical use; prohibiting medical marijuana treatment
472 centers from dispensing for certain qualified patients
473 marijuana with a concentration of tetrahydrocannabinol
474 exceeding a certain amount; providing exceptions;
475 authorizing the department and its employees to



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476 acquire, possess, test, transport, and lawfully
477 dispose of marijuana under certain circumstances;
478 amending s. 381.988, F.S.; prohibiting certified
479 medical marijuana testing laboratories and their
480 officers, directors, and employees from having an
481 economic interest in, or a financial relationship
482 with, a medical marijuana treatment center; providing
483 construction; amending s. 401.35, F.S.; clarifying