

Amendment No. 3

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	_____	(Y/N)
ADOPTED AS AMENDED	_____	(Y/N)
ADOPTED W/O OBJECTION	_____	(Y/N)
FAILED TO ADOPT	_____	(Y/N)
WITHDRAWN	_____	(Y/N)
OTHER		

1 Committee/Subcommittee hearing bill: Professions & Public
 2 Health Subcommittee

3 Representative Smith, C. offered the following:

4
 5 **Amendment (with directory and title amendments)**

6 Remove lines 528-908 and insert:
 7 use registry may be used for research purposes. The Office of
 8 Program Policy Analysis and Government Accountability shall
 9 research the use of high concentrate THC, including any adverse
 10 patient outcomes recorded as a result of the use of THC using
 11 existing data from the medical marijuana use registry and
 12 patients' de-identified health information. The office shall
 13 report its findings to the Governor, the President of the
 14 Senate, and the Speaker of the House of Representatives by
 15 October 1, 2021.

16 (d) A qualified physician may not issue a physician

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17 certification to a patient under 18 years of age for marijuana,
18 except for low-THC cannabis, unless the qualified physician
19 determines that marijuana other than low-THC cannabis is the
20 most effective treatment for the patient and a second physician
21 who is a board-certified pediatrician concurs with such
22 determination. A qualified physician may not issue a physician
23 certification for marijuana in a form for smoking to a patient
24 under 18 years of age unless the patient is diagnosed with a
25 terminal condition, the qualified physician determines that
26 smoking is the most effective route of administration for the
27 patient, and a second physician who is a board-certified
28 pediatrician concurs with such determination. Such
29 determinations ~~determination~~ and concurrences ~~concurrence~~ must
30 be documented in the patient's medical record and in the medical
31 marijuana use registry. The certifying physician must obtain the
32 written informed consent of such patient's parent or legal
33 guardian before issuing a physician certification to the patient
34 for marijuana or marijuana in a form for smoking. The qualified
35 physician must use a standardized informed consent form adopted
36 in rule by the Board of Medicine and the Board of Osteopathic
37 Medicine which must include information concerning the negative
38 health effects of marijuana and smoking marijuana on persons
39 under 18 years of age and an acknowledgment that the qualified
40 physician has sufficiently explained the contents of the form.

41 (f) A qualified physician may not issue a physician

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42 certification for ~~more than three 70-day supply limits of~~
43 ~~marijuana or~~ more than six 35-day supply limits of marijuana ~~in~~
44 ~~a form for smoking~~. The department ~~may~~ shall quantify by rule a
45 daily dose amount with equivalent dose amounts for each
46 allowable form of marijuana dispensed by a medical marijuana
47 treatment center. A 35-day supply of marijuana may not exceed
48 54,250 milligrams of tetrahydrocannabinol ~~The department shall~~
49 ~~use the daily dose amount to calculate a 70-day supply.~~

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

- 57 a. The qualified patient's qualifying medical condition.
58 b. The dosage and route of administration that was
59 insufficient to provide relief to the qualified patient.
60 c. A description of how the patient will benefit from an
61 increased amount.
62 d. The minimum daily dose amount of marijuana that would
63 be sufficient for the treatment of the qualified patient's
64 qualifying medical condition.

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

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

71 (8) MEDICAL MARIJUANA TREATMENT CENTERS.—

72 (e) A licensed medical marijuana treatment center shall
73 cultivate, process, transport, and dispense marijuana for
74 medical use. A licensed medical marijuana treatment center may
75 not contract for services directly related to the cultivation,
76 processing, and dispensing of marijuana or marijuana delivery
77 devices, except that a medical marijuana treatment center
78 licensed pursuant to subparagraph (a)1. may contract with a
79 single entity for the cultivation, processing, transporting, and
80 dispensing of marijuana and marijuana delivery devices. A
81 licensed medical marijuana treatment center must, at all times,
82 maintain compliance with the criteria demonstrated and
83 representations made in the initial application and the criteria
84 established in this subsection. Upon request, the department may
85 grant a medical marijuana treatment center a variance from the
86 representations made in the initial application. Consideration
87 of such a request shall be based upon the individual facts and
88 circumstances surrounding the request. A variance may not be
89 granted unless the requesting medical marijuana treatment center
90 can demonstrate to the department that it has a proposed
91 alternative to the specific representation made in its

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92 application which fulfills the same or a similar purpose as the
93 specific representation in a way that the department can
94 reasonably determine will not be a lower standard than the
95 specific representation in the application. A variance may not
96 be granted from the requirements in subparagraph 2. and
97 subparagraphs (b)1. and 2.

98 1. A licensed medical marijuana treatment center may
99 transfer ownership to an individual or entity who meets the
100 requirements of this section. A publicly traded corporation or
101 publicly traded company that meets the requirements of this
102 section is not precluded from ownership of a medical marijuana
103 treatment center. To accommodate a change in ownership:

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

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

111 c. Upon receipt of an application for a license, the
112 department shall examine the application and, within 30 days
113 after receipt, notify the applicant in writing of any apparent
114 errors or omissions and request any additional information
115 required.

116 d. Requested information omitted from an application for

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117 licensure must be filed with the department within 21 days after
118 the department's request for omitted information or the
119 application shall be deemed incomplete and shall be withdrawn
120 from further consideration and the fees shall be forfeited.

121
122 Within 30 days after the receipt of a complete application, the
123 department shall approve or deny the application.

124 2. A medical marijuana treatment center, and any
125 individual or entity who directly or indirectly owns, controls,
126 or holds with power to vote 5 percent or more of the voting
127 shares of a medical marijuana treatment center, may not acquire
128 direct or indirect ownership or control of any voting shares or
129 other form of ownership of any other medical marijuana treatment
130 center.

131 3. A medical marijuana treatment center and any individual
132 or entity that directly or indirectly owns, controls, or holds
133 with power to vote 5 percent or more of the voting shares of a
134 medical marijuana treatment center may not employ a qualified
135 physician or have any direct or indirect economic interest in a
136 qualified physician's practice or a marijuana testing
137 laboratory.

138 4. A medical marijuana treatment center may not enter into
139 any form of profit-sharing arrangement with the property owner
140 or lessor of any of its facilities where cultivation,
141 processing, storing, or dispensing of marijuana and marijuana

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142 delivery devices occurs.

143 5. All employees of a medical marijuana treatment center
144 must be 21 years of age or older and have passed a background
145 screening pursuant to subsection (9).

146 6. Each medical marijuana treatment center must adopt and
147 enforce policies and procedures to ensure employees and
148 volunteers receive training on the legal requirements to
149 dispense marijuana to qualified patients.

150 7. When growing marijuana, a medical marijuana treatment
151 center:

152 a. May use pesticides determined by the department, after
153 consultation with the Department of Agriculture and Consumer
154 Services, to be safely applied to plants intended for human
155 consumption, but may not use pesticides designated as
156 restricted-use pesticides pursuant to s. 487.042.

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

159 c. Must inspect seeds and growing plants for plant pests
160 that endanger or threaten the horticultural and agricultural
161 interests of the state in accordance with chapter 581 and any
162 rules adopted thereunder.

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

166 8. Each medical marijuana treatment center must produce

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167 and make available for purchase at least one low-THC cannabis
168 product.

169 9. A medical marijuana treatment center that produces
170 edibles must hold a permit to operate as a food establishment
171 pursuant to chapter 500, the Florida Food Safety Act, and must
172 comply with all the requirements for food establishments
173 pursuant to chapter 500 and any rules adopted thereunder.
174 Edibles may not contain more than 200 milligrams of
175 tetrahydrocannabinol, and a single serving portion of an edible
176 may not exceed 10 milligrams of tetrahydrocannabinol. Edibles
177 may have a potency variance of no greater than 15 percent of the
178 10 milligrams of tetrahydrocannabinol per single serving limit
179 or 15 percent of the 200 milligrams of tetrahydrocannabinol per
180 product limit. Edibles may not be attractive to children; be
181 manufactured in the shape of humans, cartoons, or animals; be
182 manufactured in a form that bears any reasonable resemblance to
183 products available for consumption as commercially available
184 candy; or contain any color additives. To discourage consumption
185 of edibles by children, the department shall determine by rule
186 any shapes, forms, and ingredients allowed and prohibited for
187 edibles. Medical marijuana treatment centers may not begin
188 processing or dispensing edibles until after the effective date
189 of the rule. The department shall also adopt sanitation rules
190 providing the standards and requirements for the storage,
191 display, or dispensing of edibles.

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192 10. Within 12 months after licensure, a medical marijuana
193 treatment center must demonstrate to the department that all of
194 its processing facilities have passed a Food Safety Good
195 Manufacturing Practices, such as Global Food Safety Initiative
196 or equivalent, inspection by a nationally accredited certifying
197 body. A medical marijuana treatment center must immediately stop
198 processing at any facility which fails to pass this inspection
199 until it demonstrates to the department that such facility has
200 met this requirement.

201 11. A medical marijuana treatment center that produces
202 prerolled marijuana cigarettes may not use wrapping paper made
203 with tobacco or hemp.

204 12. When processing marijuana, a medical marijuana
205 treatment center must:

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

208 b. Comply with department rules when processing marijuana
209 with hydrocarbon solvents or other solvents or gases exhibiting
210 potential toxicity to humans. The department shall determine by
211 rule the requirements for medical marijuana treatment centers to
212 use such solvents or gases exhibiting potential toxicity to
213 humans.

214 c. Comply with federal and state laws and regulations and
215 department rules for solid and liquid wastes. The department
216 shall determine by rule procedures for the storage, handling,

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217 transportation, management, and disposal of solid and liquid
218 waste generated during marijuana production and processing. The
219 Department of Environmental Protection shall assist the
220 department in developing such rules.

221 13. A medical marijuana treatment center must test
222 marijuana using a medical marijuana testing laboratory before it
223 is dispensed. Results must be verified and signed by two medical
224 marijuana treatment center employees. Before dispensing, the
225 medical marijuana treatment center must determine that the test
226 results indicate that low-THC cannabis meets the definition of
227 low-THC cannabis, the concentration of tetrahydrocannabinol
228 meets the potency requirements of this section, the labeling of
229 the concentration of tetrahydrocannabinol and cannabidiol is
230 accurate, and all marijuana is safe for human consumption and
231 free from contaminants that are unsafe for human consumption.
232 The department shall determine by rule which contaminants must
233 be tested for and the maximum levels of each contaminant which
234 are safe for human consumption. The Department of Agriculture
235 and Consumer Services shall assist the department in developing
236 the testing requirements for contaminants that are unsafe for
237 human consumption in edibles. The department shall also
238 determine by rule the procedures for the treatment of marijuana
239 that fails to meet the testing requirements of this section, s.
240 381.988, or department rule. The department may select samples
241 of marijuana available in a cultivation facility, processing

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242 facility, or for purchase in a dispensing facility which shall
243 be tested by the department to determine that the marijuana
244 meets the potency requirements of this section, is safe for
245 human consumption, and the labeling of the tetrahydrocannabinol
246 and cannabidiol concentration is accurate or to verify medical
247 marijuana testing laboratory results. The department may also
248 sample marijuana delivery devices from a dispensing facility to
249 determine that the marijuana delivery device is safe for use by
250 qualified patients. A medical marijuana treatment center may not
251 require payment from the department for the sample. A medical
252 marijuana treatment center must recall all marijuana which fails
253 to meet the potency requirements of this section, which is
254 unsafe for human consumption, or for which the labeling of the
255 tetrahydrocannabinol and cannabidiol concentration is
256 inaccurate. The medical marijuana treatment center must retain
257 records of all testing and samples of each homogenous batch of
258 marijuana for at least 9 months. The medical marijuana treatment
259 center must contract with a marijuana testing laboratory to
260 perform audits on the medical marijuana treatment center's
261 standard operating procedures, testing records, and samples and
262 provide the results to the department to confirm that the
263 marijuana or low-THC cannabis meets the requirements of this
264 section and that the marijuana or low-THC cannabis is safe for
265 human consumption. A medical marijuana treatment center shall
266 reserve two processed samples from each batch and retain such

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267 samples for at least 9 months for the purpose of such audits. A
268 medical marijuana treatment center may use a laboratory that has
269 not been certified by the department under s. 381.988 until such
270 time as at least one laboratory holds the required
271 certification, but in no event later than July 1, 2018.

272 14. When packaging marijuana, a medical marijuana
273 treatment center must:

274 a. Package the marijuana in compliance with the United
275 States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.
276 1471 et seq.

277 b. Package the marijuana in a receptacle that has a firmly
278 affixed and legible label stating the following information:

279 (I) The marijuana or low-THC cannabis meets the
280 requirements of subparagraph 13.

281 (II) The name of the medical marijuana treatment center
282 from which the marijuana originates.

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

285 (IV) The name of the physician who issued the physician
286 certification.

287 (V) The name of the patient.

288 (VI) The product name, if applicable, and dosage form,
289 including concentration of tetrahydrocannabinol and cannabidiol.
290 The product name may not contain wording commonly associated
291 with products marketed by or to children.

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292 (VII) The recommended dose.

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

295 (IX) A marijuana universal symbol developed by the
296 department.

297 15. The medical marijuana treatment center shall include
298 in each package a patient package insert with information on the
299 specific product dispensed related to:

- 300 a. Clinical pharmacology.
- 301 b. Indications and use.
- 302 c. Dosage and administration.
- 303 d. Dosage forms and strengths.
- 304 e. Contraindications.
- 305 f. Warnings and precautions.
- 306 g. Adverse reactions.

307 16. In addition to the packaging and labeling requirements
308 specified in subparagraphs 14. and 15., marijuana in a form for
309 smoking must be packaged in a sealed receptacle with a legible
310 and prominent warning to keep away from children and a warning
311 that states marijuana smoke contains carcinogens and may
312 negatively affect health. Such receptacles for marijuana in a
313 form for smoking must be plain, opaque, and white without
314 depictions of the product or images other than the medical
315 marijuana treatment center's department-approved logo and the
316 marijuana universal symbol.

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317 17. The department shall adopt rules to regulate the
318 types, appearance, and labeling of marijuana delivery devices
319 dispensed from a medical marijuana treatment center. The rules
320 must require marijuana delivery devices to have an appearance
321 consistent with medical use.

322 18. Each edible shall be individually sealed in plain,
323 opaque wrapping marked only with the marijuana universal symbol.
324 Where practical, each edible shall be marked with the marijuana
325 universal symbol. In addition to the packaging and labeling
326 requirements in subparagraphs 14. and 15., edible receptacles
327 must be plain, opaque, and white without depictions of the
328 product or images other than the medical marijuana treatment
329 center's department-approved logo and the marijuana universal
330 symbol. The receptacle must also include a list of all the
331 edible's ingredients, storage instructions, an expiration date,
332 a legible and prominent warning to keep away from children and
333 pets, and a warning that the edible has not been produced or
334 inspected pursuant to federal food safety laws.

335 19. When dispensing marijuana or a marijuana delivery
336 device, a medical marijuana treatment center:

337 a. May dispense any active, valid order for low-THC
338 cannabis, medical cannabis and cannabis delivery devices issued
339 pursuant to former s. 381.986, Florida Statutes 2016, which was
340 entered into the medical marijuana use registry before July 1,
341 2017.

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342 b. May not dispense more than two 35-day supplies ~~a 70-day~~
343 ~~supply~~ of marijuana within any 70-day period to a qualified
344 patient or caregiver. ~~May not dispense more than one 35-day~~
345 ~~supply of marijuana in a form for smoking within any 35-day~~
346 ~~period to a qualified patient or caregiver.~~ A 35-day supply of
347 marijuana ~~in a form for smoking~~ may not exceed 54,250 milligrams
348 of tetrahydrocannabinol ~~2.5 ounces~~ unless an exception to this
349 amount is approved by the department pursuant to paragraph
350 (4) (f).

351 c. Must have the medical marijuana treatment center's
352 employee who dispenses the marijuana or a marijuana delivery
353 device enter into the medical marijuana use registry his or her
354 name or unique employee identifier.

355 d. Must verify that the qualified patient and the
356 caregiver, if applicable, each have an active registration in
357 the medical marijuana use registry and an active and valid
358 medical marijuana use registry identification card, the amount
359 and type of marijuana dispensed matches the physician
360 certification in the medical marijuana use registry for that
361 qualified patient, and the physician certification has not
362 already been filled.

363 e. May not dispense marijuana to a qualified patient who
364 is younger than 18 years of age. If the qualified patient is
365 younger than 18 years of age, marijuana may only be dispensed to
366 the qualified patient's caregiver.

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

372 g. Must, upon dispensing the marijuana or marijuana
373 delivery device, record in the registry the date, time,
374 quantity, and form of marijuana dispensed; the type of marijuana
375 delivery device dispensed; and the name and medical marijuana
376 use registry identification number of the qualified patient or
377 caregiver to whom the marijuana delivery device was dispensed.

378 h. Must ensure that patient records are not visible to
379

380 -----

381 **D I R E C T O R Y A M E N D M E N T**

382 Remove lines 450-456 and insert:

383 Section 2. Effective July 1, 2022, paragraphs (a), (d),
384 and (f) of subsection (4), paragraph (e) of subsection (8), and
385 paragraph (a) of subsection (14) of s. 381.986, Florida
386 Statutes, are amended to read:

387

388 -----

389 **T I T L E A M E N D M E N T**

390 Remove lines 26-41 and insert:

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391 dispose of marijuana; requiring the Office of Program
392 Policy Analysis and Government Accountability to
393 research the use of high concentrate THC and report
394 its findings to the Governor and Legislature by a
395 specified date; prohibiting a qualified physician from
396 issuing a physician certification to a minor patient
397 for marijuana, except for low-THC cannabis; providing
398 an exception; revising the supply limits of marijuana
399 for which a physician certification may be issued;
400 limiting the potency of tetrahydrocannabinol in such
401 supply; prohibiting a medical marijuana treatment
402 center from dispensing a certain daily supply within a
403 specified period to conform to changes made by the
404 act; amending s. 381.988, F.S.; prohibiting a