

Amendment No. 6

COMMITTEE/SUBCOMMITTEE ACTION

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WITHDRAWN	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

1 Committee/Subcommittee hearing bill: Professions & Public  
 2 Health Subcommittee  
 3 Representative Smith, C. offered the following:

**Amendment to Amendment (901715) by Representative Smith, C.**

Remove lines 48-347 of the amendment and insert:

8 35,000 milligrams of tetrahydrocannabinol ~~The department shall~~  
 9 ~~use the daily dose amount to calculate a 70-day supply.~~

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

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

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

20 c. A description of how the patient will benefit from an  
21 increased amount.

22 d. The minimum daily dose amount of marijuana that would  
23 be sufficient for the treatment of the qualified patient's  
24 qualifying medical condition.

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

27 3. The department shall approve or disapprove the request  
28 within 14 days after receipt of the complete documentation  
29 required by this paragraph. The request shall be deemed approved  
30 if the department fails to act within this time period.

31 (8) MEDICAL MARIJUANA TREATMENT CENTERS.—

32 (e) A licensed medical marijuana treatment center shall  
33 cultivate, process, transport, and dispense marijuana for  
34 medical use. A licensed medical marijuana treatment center may  
35 not contract for services directly related to the cultivation,  
36 processing, and dispensing of marijuana or marijuana delivery  
37 devices, except that a medical marijuana treatment center  
38 licensed pursuant to subparagraph (a)1. may contract with a  
39 single entity for the cultivation, processing, transporting, and  
40 dispensing of marijuana and marijuana delivery devices. A  
41 licensed medical marijuana treatment center must, at all times,

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42 maintain compliance with the criteria demonstrated and  
43 representations made in the initial application and the criteria  
44 established in this subsection. Upon request, the department may  
45 grant a medical marijuana treatment center a variance from the  
46 representations made in the initial application. Consideration  
47 of such a request shall be based upon the individual facts and  
48 circumstances surrounding the request. A variance may not be  
49 granted unless the requesting medical marijuana treatment center  
50 can demonstrate to the department that it has a proposed  
51 alternative to the specific representation made in its  
52 application which fulfills the same or a similar purpose as the  
53 specific representation in a way that the department can  
54 reasonably determine will not be a lower standard than the  
55 specific representation in the application. A variance may not  
56 be granted from the requirements in subparagraph 2. and  
57 subparagraphs (b)1. and 2.

58 1. A licensed medical marijuana treatment center may  
59 transfer ownership to an individual or entity who meets the  
60 requirements of this section. A publicly traded corporation or  
61 publicly traded company that meets the requirements of this  
62 section is not precluded from ownership of a medical marijuana  
63 treatment center. To accommodate a change in ownership:

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

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

71           c. Upon receipt of an application for a license, the  
72 department shall examine the application and, within 30 days  
73 after receipt, notify the applicant in writing of any apparent  
74 errors or omissions and request any additional information  
75 required.

76           d. Requested information omitted from an application for  
77 licensure must be filed with the department within 21 days after  
78 the department's request for omitted information or the  
79 application shall be deemed incomplete and shall be withdrawn  
80 from further consideration and the fees shall be forfeited.

81  
82 Within 30 days after the receipt of a complete application, the  
83 department shall approve or deny the application.

84           2. A medical marijuana treatment center, and any  
85 individual or entity who directly or indirectly owns, controls,  
86 or holds with power to vote 5 percent or more of the voting  
87 shares of a medical marijuana treatment center, may not acquire  
88 direct or indirect ownership or control of any voting shares or  
89 other form of ownership of any other medical marijuana treatment  
90 center.

91           3. A medical marijuana treatment center and any individual

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92 or entity that directly or indirectly owns, controls, or holds  
93 with power to vote 5 percent or more of the voting shares of a  
94 medical marijuana treatment center may not employ a qualified  
95 physician or have any direct or indirect economic interest in a  
96 qualified physician's practice or a marijuana testing  
97 laboratory.

98 4. A medical marijuana treatment center may not enter into  
99 any form of profit-sharing arrangement with the property owner  
100 or lessor of any of its facilities where cultivation,  
101 processing, storing, or dispensing of marijuana and marijuana  
102 delivery devices occurs.

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

106 6. Each medical marijuana treatment center must adopt and  
107 enforce policies and procedures to ensure employees and  
108 volunteers receive training on the legal requirements to  
109 dispense marijuana to qualified patients.

110 7. When growing marijuana, a medical marijuana treatment  
111 center:

112 a. May use pesticides determined by the department, after  
113 consultation with the Department of Agriculture and Consumer  
114 Services, to be safely applied to plants intended for human  
115 consumption, but may not use pesticides designated as  
116 restricted-use pesticides pursuant to s. 487.042.

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

119 c. Must inspect seeds and growing plants for plant pests  
120 that endanger or threaten the horticultural and agricultural  
121 interests of the state in accordance with chapter 581 and any  
122 rules adopted thereunder.

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

126 8. Each medical marijuana treatment center must produce  
127 and make available for purchase at least one low-THC cannabis  
128 product.

129 9. A medical marijuana treatment center that produces  
130 edibles must hold a permit to operate as a food establishment  
131 pursuant to chapter 500, the Florida Food Safety Act, and must  
132 comply with all the requirements for food establishments  
133 pursuant to chapter 500 and any rules adopted thereunder.  
134 Edibles may not contain more than 200 milligrams of  
135 tetrahydrocannabinol, and a single serving portion of an edible  
136 may not exceed 10 milligrams of tetrahydrocannabinol. Edibles  
137 may have a potency variance of no greater than 15 percent of the  
138 10 milligrams of tetrahydrocannabinol per single serving limit  
139 or 15 percent of the 200 milligrams of tetrahydrocannabinol per  
140 product limit. Edibles may not be attractive to children; be  
141 manufactured in the shape of humans, cartoons, or animals; be

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142 manufactured in a form that bears any reasonable resemblance to  
143 products available for consumption as commercially available  
144 candy; or contain any color additives. To discourage consumption  
145 of edibles by children, the department shall determine by rule  
146 any shapes, forms, and ingredients allowed and prohibited for  
147 edibles. Medical marijuana treatment centers may not begin  
148 processing or dispensing edibles until after the effective date  
149 of the rule. The department shall also adopt sanitation rules  
150 providing the standards and requirements for the storage,  
151 display, or dispensing of edibles.

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

161 11. A medical marijuana treatment center that produces  
162 prerolled marijuana cigarettes may not use wrapping paper made  
163 with tobacco or hemp.

164 12. When processing marijuana, a medical marijuana  
165 treatment center must:

166 a. Process the marijuana within an enclosed structure and

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167 in a room separate from other plants or products.

168 b. Comply with department rules when processing marijuana  
169 with hydrocarbon solvents or other solvents or gases exhibiting  
170 potential toxicity to humans. The department shall determine by  
171 rule the requirements for medical marijuana treatment centers to  
172 use such solvents or gases exhibiting potential toxicity to  
173 humans.

174 c. Comply with federal and state laws and regulations and  
175 department rules for solid and liquid wastes. The department  
176 shall determine by rule procedures for the storage, handling,  
177 transportation, management, and disposal of solid and liquid  
178 waste generated during marijuana production and processing. The  
179 Department of Environmental Protection shall assist the  
180 department in developing such rules.

181 13. A medical marijuana treatment center must test  
182 marijuana using a medical marijuana testing laboratory before it  
183 is dispensed. Results must be verified and signed by two medical  
184 marijuana treatment center employees. Before dispensing, the  
185 medical marijuana treatment center must determine that the test  
186 results indicate that low-THC cannabis meets the definition of  
187 low-THC cannabis, the concentration of tetrahydrocannabinol  
188 meets the potency requirements of this section, the labeling of  
189 the concentration of tetrahydrocannabinol and cannabidiol is  
190 accurate, and all marijuana is safe for human consumption and  
191 free from contaminants that are unsafe for human consumption.

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192 The department shall determine by rule which contaminants must  
193 be tested for and the maximum levels of each contaminant which  
194 are safe for human consumption. The Department of Agriculture  
195 and Consumer Services shall assist the department in developing  
196 the testing requirements for contaminants that are unsafe for  
197 human consumption in edibles. The department shall also  
198 determine by rule the procedures for the treatment of marijuana  
199 that fails to meet the testing requirements of this section, s.  
200 381.988, or department rule. The department may select samples  
201 of marijuana available in a cultivation facility, processing  
202 facility, or for purchase in a dispensing facility which shall  
203 be tested by the department to determine that the marijuana  
204 meets the potency requirements of this section, is safe for  
205 human consumption, and the labeling of the tetrahydrocannabinol  
206 and cannabidiol concentration is accurate or to verify medical  
207 marijuana testing laboratory results. The department may also  
208 sample marijuana delivery devices from a dispensing facility to  
209 determine that the marijuana delivery device is safe for use by  
210 qualified patients. A medical marijuana treatment center may not  
211 require payment from the department for the sample. A medical  
212 marijuana treatment center must recall all marijuana which fails  
213 to meet the potency requirements of this section, which is  
214 unsafe for human consumption, or for which the labeling of the  
215 tetrahydrocannabinol and cannabidiol concentration is  
216 inaccurate. The medical marijuana treatment center must retain

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

232 14. When packaging marijuana, a medical marijuana  
233 treatment center must:

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

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

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

241 (II) The name of the medical marijuana treatment center

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242 from which the marijuana originates.

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

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

247 (V) The name of the patient.

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

252 (VII) The recommended dose.

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

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

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

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

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267           16. In addition to the packaging and labeling requirements  
268 specified in subparagraphs 14. and 15., marijuana in a form for  
269 smoking must be packaged in a sealed receptacle with a legible  
270 and prominent warning to keep away from children and a warning  
271 that states marijuana smoke contains carcinogens and may  
272 negatively affect health. Such receptacles for marijuana in a  
273 form for smoking must be plain, opaque, and white without  
274 depictions of the product or images other than the medical  
275 marijuana treatment center's department-approved logo and the  
276 marijuana universal symbol.

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

282           18. Each edible shall be individually sealed in plain,  
283 opaque wrapping marked only with the marijuana universal symbol.  
284 Where practical, each edible shall be marked with the marijuana  
285 universal symbol. In addition to the packaging and labeling  
286 requirements in subparagraphs 14. and 15., edible receptacles  
287 must be plain, opaque, and white without depictions of the  
288 product or images other than the medical marijuana treatment  
289 center's department-approved logo and the marijuana universal  
290 symbol. The receptacle must also include a list of all the  
291 edible's ingredients, storage instructions, an expiration date,

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292 a legible and prominent warning to keep away from children and  
293 pets, and a warning that the edible has not been produced or  
294 inspected pursuant to federal food safety laws.

295 19. When dispensing marijuana or a marijuana delivery  
296 device, a medical marijuana treatment center:

297 a. May dispense any active, valid order for low-THC  
298 cannabis, medical cannabis and cannabis delivery devices issued  
299 pursuant to former s. 381.986, Florida Statutes 2016, which was  
300 entered into the medical marijuana use registry before July 1,  
301 2017.

302 b. May not dispense more than two 35-day supplies ~~a 70-day~~  
303 ~~supply~~ of marijuana within any 70-day period to a qualified  
304 patient or caregiver. ~~May not dispense more than one 35-day~~  
305 ~~supply of marijuana in a form for smoking within any 35-day~~  
306 ~~period to a qualified patient or caregiver.~~ A 35-day supply of  
307 marijuana ~~in a form for smoking~~ may not exceed 35,000 milligrams