

Amendment No.

CHAMBER ACTION

Senate

House

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1 Representative Gaetz offered the following:

2  
3 **Amendment (with title amendment)**

4 Remove everything after the enacting clause and insert:

5 Section 1. Section 381.986, Florida Statutes, is created  
6 to read:

7 381.986 Compassionate use of low-THC cannabis.-

8 (1) DEFINITIONS.-As used in this section, the term:

9 (a) "Dispensing organization" means an organization  
10 approved by the department to cultivate, process, and dispense  
11 low-THC cannabis pursuant to this section.

12 (b) "Low-THC cannabis" means a plant of the genus  
13 Cannabis, the dried flowers of which contain 0.8 percent or less  
14 of tetrahydrocannabinol and more than 10 percent of cannabidiol

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15 weight for weight; the seeds thereof; the resin extracted from  
16 any part of such plant; or any compound, manufacture, salt,  
17 derivative, mixture, or preparation of such plant or its seeds  
18 or resin that is dispensed only from a dispensing organization.

19 (c) "Medical use" means administration of the ordered  
20 amount of low-THC cannabis. The term does not include the  
21 possession, use, or administration by smoking. The term also  
22 does not include the transfer of low-THC cannabis to a person  
23 other than the qualified patient for whom it was ordered or the  
24 qualified patient's legal representative on behalf of the  
25 qualified patient.

26 (d) "Qualified patient" means a resident of this state who  
27 has been added to the compassionate use registry by a physician  
28 licensed under chapter 458 or chapter 459 to receive low-THC  
29 cannabis from a dispensing organization.

30 (e) "Smoking" means burning or igniting a substance and  
31 inhaling the smoke. Smoking does not include the use of a  
32 vaporizer.

33 (2) PHYSICIAN ORDERING.—Effective January 1, 2015, a  
34 physician licensed under chapter 458 or chapter 459 who has  
35 examined and is treating a patient suffering from cancer, a  
36 neurological disease or disorder, or a physical medical  
37 condition that chronically produces symptoms of seizures or  
38 severe and persistent muscle spasms may order for the patient's  
39 medical use low-THC cannabis to treat such disease, disorder, or  
40 condition or to alleviate symptoms of such disease, disorder, or

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41 condition, if no other satisfactory alternative treatment  
42 options exist for that patient and all of the following  
43 conditions apply:

44 (a) The patient is a permanent resident of this state.

45 (b) The physician determines that the risks of ordering  
46 low-THC cannabis are reasonable in light of the potential  
47 benefit for that patient. If a patient is younger than 18 years  
48 of age, a second physician must concur with this determination,  
49 and such determination must be documented in the patient's  
50 medical record.

51 (c) The physician registers as the orderer of low-THC  
52 cannabis for the named patient on the compassionate use registry  
53 maintained by the department and updates the registry to reflect  
54 the contents of the order. The physician shall deactivate the  
55 patient's registration when treatment is discontinued.

56 (d) The physician maintains a patient treatment plan that  
57 includes the dose, route of administration, planned duration,  
58 and monitoring of the patient's symptoms and other indicators of  
59 tolerance or reaction to the low-THC cannabis.

60 (e) The physician submits the patient treatment plan  
61 quarterly to the University of Florida College of Pharmacy for  
62 research on the safety and efficacy of low-THC cannabis on  
63 patients.

64 (f) The physician obtains the voluntary informed consent  
65 of the patient or the patient's legal guardian to treatment with  
66 low-THC cannabis after sufficiently explaining the current state

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67 of knowledge in the medical community of the effectiveness of  
68 treatment of the patient's condition with low-THC cannabis, the  
69 medically acceptable alternatives, and the potential risks and  
70 side effects.

71 (3) PENALTIES.—

72 (a) A physician commits a misdemeanor of the first degree,  
73 punishable as provided in s. 775.082 or s. 775.083, if the  
74 physician orders low-THC cannabis for a patient without a  
75 reasonable belief that the patient is suffering from:

76 1. A serious medical condition that can be treated with  
77 low-THC cannabis; or

78 2. Symptoms of a serious medical condition that can be  
79 alleviated with low-THC cannabis.

80 (b) Any person who fraudulently represents a medical  
81 condition to a physician for the purpose of being ordered low-  
82 THC cannabis by such physician commits a misdemeanor of the  
83 first degree, punishable as provided in s. 775.082 or s.  
84 775.083.

85 (4) PHYSICIAN EDUCATION.—

86 (a) Before ordering low-THC cannabis for use by a patient  
87 in this state, the appropriate board shall require the ordering  
88 physician licensed under chapter 458 or chapter 459 to  
89 successfully complete an 8-hour course and subsequent  
90 examination offered by the Florida Medical Association that  
91 encompasses the clinical indications for the appropriate use of  
92 low-THC cannabis, the appropriate delivery mechanisms, the

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93 contraindications for such use, as well as the relevant state  
94 and federal laws governing the ordering, dispensing, and  
95 possessing of this substance. The first course and examination  
96 shall be presented by October 1, 2014, and shall be administered  
97 at least annually thereafter. Successful completion of the  
98 course may be used by a physician to satisfy 8 hours of the  
99 continuing medical education requirements required by his or her  
100 respective board for licensure renewal. This course may be  
101 offered in a distance learning format.

102 (b) Successful completion of this course and examination  
103 is required for every physician who orders low-THC cannabis each  
104 time such physician renews his or her license.

105 (c) Each licensee to whom this section applies shall  
106 submit confirmation of having completed such course and  
107 examination on a form provided by the board when submitting fees  
108 for every licensure renewal.

109 (d) A physician who fails to comply with this subsection  
110 and who orders low-THC cannabis may be subject to disciplinary  
111 action under the applicable practice act and under s.  
112 456.072 (1) (k).

113 (5) DUTIES OF THE DEPARTMENT.—By January 1, 2015, the  
114 department shall:

115 (a) Create a secure, electronic, and online compassionate  
116 use registry for the registration of physicians and patients as  
117 provided under this section. The registry must be accessible to  
118 law enforcement agencies and to a dispensing organization in

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119 order to verify patient authorization for low-THC cannabis and  
120 record the low-THC cannabis dispensed. The registry must prevent  
121 an active registration of a patient by multiple physicians.

122 (b) Authorize the establishment of four dispensing  
123 organizations, one in each of the following regions: northwest  
124 Florida, northeast Florida, central Florida, and south Florida,  
125 to ensure reasonable statewide accessibility and availability as  
126 necessary for patients registered in the compassionate use  
127 registry and who are ordered low-THC cannabis under this  
128 section. The department shall develop an application form and  
129 impose an initial application and biennial renewal fee that is  
130 sufficient to cover the costs of administering this section. An  
131 applicant for approval as a dispensing organization must be able  
132 to demonstrate:

133 1. The technical and technological ability to cultivate  
134 and produce low-THC cannabis.

135 2. The ability to secure the premises, resources, and  
136 personnel necessary to operate as a dispensing organization.

137 3. The ability to maintain accountability of all raw  
138 materials, finished products, and any byproducts to prevent  
139 diversion or unlawful access to or possession of these  
140 substances.

141 4. An infrastructure reasonably located to dispense low-  
142 THC cannabis to registered patients statewide or regionally as  
143 determined by the department.

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144 5. The financial ability to maintain operations for the  
145 duration of the 2-year approval cycle.

146 6. That all owners, managers, and employees have been  
147 fingerprinted and have successfully passed a level 2 background  
148 screening pursuant to s. 435.04.

149 (c) Monitor physician registration and ordering of low-THC  
150 cannabis for ordering practices that could facilitate unlawful  
151 diversion or misuse of low-THC cannabis and take disciplinary  
152 action as indicated.

153 (d) Adopt rules necessary to implement this section.

154 (6) DISPENSING ORGANIZATION.—An approved dispensing  
155 organization shall maintain compliance with the criteria  
156 demonstrated for selection and approval as a dispensing  
157 organization under subsection (5) at all times. Before  
158 dispensing low-THC cannabis to a qualified patient, the  
159 dispensing organization shall verify that the patient has an  
160 active registration in the compassionate use registry, the order  
161 presented matches the order contents as recorded in the  
162 registry, and the order has not already been filled. Upon  
163 dispensing the low-THC cannabis, the dispensing organization  
164 shall record in the registry the date, time, quantity, and form  
165 of low-THC cannabis dispensed.

166 (7) EXCEPTIONS TO OTHER LAWS.—

167 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
168 any other provision of law, but subject to the requirements of  
169 this section, a qualified patient and the qualified patient's

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170 legal representative may purchase and possess for the patient's  
171 medical use up to the amount of low-THC cannabis ordered for the  
172 patient.

173 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
174 any other provision of law, but subject to the requirements of  
175 this section, an approved dispensing organization and its  
176 owners, managers, and employees may manufacture, possess, sell,  
177 deliver, distribute, dispense, and lawfully dispose of  
178 reasonable quantities, as established by department rule, of  
179 low-THC cannabis. For purposes of this subsection, the terms  
180 "manufacture," "possession," "deliver," "distribute," and  
181 "dispense" have the same meanings as provided in s. 893.02.

182 (c) An approved dispensing organization and its owners,  
183 managers, and employees are not subject to licensure or  
184 regulation under chapter 465 for manufacturing, possessing,  
185 selling, delivering, distributing, dispensing, or lawfully  
186 disposing of reasonable quantities, as established by department  
187 rule, of low-THC cannabis.

188 Section 2. Section 385.211, Florida Statutes, is created  
189 to read:

190 385.211 Refractory and intractable epilepsy treatment and  
191 research at recognized medical centers.—

192 (1) As used in this section, the term "low-THC cannabis"  
193 means "low-THC cannabis" as defined in s. 381.986 that is  
194 dispensed only from a dispensing organization as defined in s.  
195 381.986.

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196 (2) Notwithstanding chapter 893, medical centers  
197 recognized pursuant to s. 381.925 may conduct research on  
198 cannabidiol and low-THC cannabis. This research may include, but  
199 is not limited to, the agricultural development, production,  
200 clinical research, and use of liquid medical derivatives of  
201 cannabidiol and low-THC cannabis for the treatment for  
202 refractory or intractable epilepsy. The authority for recognized  
203 medical centers to conduct this research is derived from 21  
204 C.F.R. parts 312 and 316. Current state or privately obtained  
205 research funds may be used to support the activities described  
206 in this section.

207 Section 3. Section 385.212, Florida Statutes, is created  
208 to read:

209 385.212 Powers and duties of the Department of Health;  
210 Office of Compassionate Use.—

211 (1) The Department of Health shall establish an Office of  
212 Compassionate Use under the direction of the Deputy State Health  
213 Officer.

214 (2) The Office of Compassionate Use may enhance access to  
215 investigational new drugs for Florida patients through approved  
216 clinical treatment plans or studies. The Office of Compassionate  
217 Use may:

218 (a) Create a network of state universities and medical  
219 centers recognized pursuant to s. 381.925.

220 (b) Make any necessary application to the United States  
221 Food and Drug Administration or a pharmaceutical manufacturer to

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222 facilitate enhanced access to compassionate use for Florida  
223 patients.

224 (c) Enter into any agreements necessary to facilitate  
225 enhanced access to compassionate use for Florida patients.

226 (3) The department may adopt rules necessary to implement  
227 this section.

228 Section 4. Subsection (3) of section 893.02, Florida  
229 Statutes, is amended to read:

230 893.02 Definitions.—The following words and phrases as  
231 used in this chapter shall have the following meanings, unless  
232 the context otherwise requires:

233 (3) "Cannabis" means all parts of any plant of the genus  
234 Cannabis, whether growing or not; the seeds thereof; the resin  
235 extracted from any part of the plant; and every compound,  
236 manufacture, salt, derivative, mixture, or preparation of the  
237 plant or its seeds or resin. The term does not include "low-THC  
238 cannabis," as defined in s. 381.986, if manufactured, possessed,  
239 sold, purchased, delivered, distributed, or dispensed, in  
240 conformance with s. 381.986.

241 Section 5. Section 1004.441, Florida Statutes, is created  
242 to read:

243 1004.441 Refractory and intractable epilepsy treatment and  
244 research.—

245 (1) As used in this section, the term "low-THC cannabis"  
246 means "low-THC cannabis" as defined in s. 381.986 that is

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247 dispensed only from a dispensing organization as defined in s.  
248 381.986.

249 (2) Notwithstanding chapter 893, state universities with  
250 both medical and agricultural research programs, including those  
251 that have satellite campuses or research agreements with other  
252 similar institutions, may conduct research on cannabidiol and  
253 low-THC cannabis. This research may include, but is not limited  
254 to, the agricultural development, production, clinical research,  
255 and use of liquid medical derivatives of cannabidiol and low-THC  
256 cannabis for the treatment for refractory or intractable  
257 epilepsy. The authority for state universities to conduct this  
258 research is derived from 21 C.F.R. parts 312 and 316. Current  
259 state or privately obtained research funds may be used to  
260 support the activities authorized by this section.

261 Section 6. (1) As used in this section, the term  
262 "cannabidiol" means an extract from the cannabis plant that has  
263 less than 0.8 percent tetrahydrocannabinol and the chemical  
264 signature 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-  
265 5-pentylbenzene-1,3-diol, or a derivative thereof, as determined  
266 by the International Union of Pure and Applied Chemistry.

267 (2) For the 2014-2015 fiscal year, \$1 million in  
268 nonrecurring general revenue is appropriated to the Department  
269 of Health for the James and Esther King Biomedical Research  
270 Program and shall be deposited into the Biomedical Research  
271 Trust Fund. These funds shall be reserved for research of  
272 cannabidiol and its effect on intractable childhood epilepsy.

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273 (3) Biomedical research funding for research of  
 274 cannabidiol and its effect on intractable childhood epilepsy  
 275 shall be awarded pursuant to s. 215.5602, Florida Statutes. An  
 276 application for such funding may be submitted by any research  
 277 university in the state that has obtained approval from the  
 278 United States Food and Drug Administration for an exploratory  
 279 investigational new drug study of cannabidiol and its effect on  
 280 intractable childhood epilepsy. For purposes of this section,  
 281 the Biomedical Research Advisory Council created under s.  
 282 215.5602, Florida Statutes, shall advise the State Surgeon  
 283 General as to the direction and scope of research of cannabidiol  
 284 and its effect on intractable childhood epilepsy and the award  
 285 of research funding.

286 Section 7. This act shall take effect upon becoming a law.

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 288  
 289 **T I T L E A M E N D M E N T**

290 Remove everything before the enacting clause and insert:

291 A bill to be entitled

292 An act relating to cannabis; creating s. 381.986,  
 293 F.S.; defining terms; authorizing specified physicians  
 294 to order low-THC cannabis for use by specified  
 295 patients; providing conditions; prohibiting specified  
 296 acts by physicians or persons seeking low-THC  
 297 cannabis; providing criminal penalties; requiring  
 298 physician education; providing duties of the

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299 Department of Health; requiring the department to  
300 create a compassionate use registry; providing  
301 requirements for the registry; requiring the  
302 department to authorize a specified number of  
303 dispensing organizations; authorizing rulemaking;  
304 providing requirements and duties for a dispensing  
305 organization; providing exceptions to specified laws;  
306 creating s. 385.211, F.S.; defining the term "low-THC  
307 cannabis"; authorizing certain medical centers to  
308 conduct research on cannabidiol and low-THC cannabis;  
309 authorizing state or privately obtained research funds  
310 to be used to support such research; creating s.  
311 385.212, F.S.; requiring the department to establish  
312 an Office of Compassionate Use; authorizing the office  
313 to engage in specified activities; authorizing  
314 rulemaking; amending s. 893.02, F.S.; revising the  
315 term "cannabis" as used in the Florida Comprehensive  
316 Drug Abuse Prevention and Control Act and as  
317 applicable to certain criminal offenses proscribing  
318 the sale, manufacture, delivery, possession,  
319 dispensing, distribution, or purchase of cannabis, to  
320 which penalties apply; creating s. 1004.441, F.S.;  
321 defining the term "low-THC cannabis"; authorizing  
322 state universities with both medical and agricultural  
323 research programs to conduct specified research on  
324 cannabidiol and low-THC cannabis; authorizing state or

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325 | privately obtained research funds to be used to  
326 | support such research; providing an appropriation to  
327 | the department for research of cannabidiol and its  
328 | effect on intractable childhood epilepsy; specifying  
329 | how biomedical research funding for research of  
330 | cannabidiol and its effect on intractable childhood  
331 | epilepsy shall be awarded; specifying who may apply  
332 | for such funding; providing an effective date.

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