

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. This act may be cited as the "Compassionate  
6 Medical Cannabis Act of 2014."

7 Section 2. Section 381.986, Florida Statutes, is created  
8 to read:

9 381.986 Compassionate use of low-THC cannabis.-

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

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

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14 (b) "Low-THC cannabis" means a plant of the genus  
15 Cannabis, the dried flowers of which contain 0.8 percent or less  
16 of tetrahydrocannabinol and more than 10 percent of cannabidiol  
17 weight for weight; the seeds thereof; the resin extracted from  
18 any part of such plant; or any compound, manufacture, salt,  
19 derivative, mixture, or preparation of such plant or its seeds  
20 or resin that is dispensed only from a dispensing organization.

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

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

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

35 (2) PHYSICIAN ORDERING.—Effective January 1, 2015, a  
36 physician licensed under chapter 458 or chapter 459 who has  
37 examined and is treating a patient suffering from cancer or a  
38 physical medical condition that chronically produces symptoms of  
39 seizures or severe and persistent muscle spasms may order for

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40 the patient's medical use low-THC cannabis to treat such  
41 disease, disorder, or condition or to alleviate symptoms of such  
42 disease, disorder, or condition, if no other satisfactory  
43 alternative treatment options exist for that patient and all of  
44 the following conditions apply:

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

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

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

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

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

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65       (f) The physician obtains the voluntary informed consent  
66 of the patient or the patient's legal guardian to treatment with  
67 low-THC cannabis after sufficiently explaining the current state  
68 of knowledge in the medical community of the effectiveness of  
69 treatment of the patient's condition with low-THC cannabis, the  
70 medically acceptable alternatives, and the potential risks and  
71 side effects.

72       (3) PENALTIES.—

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

77       1. Cancer or a physical medical condition that chronically  
78 produces symptoms of seizures or severe and persistent muscle  
79 spasms that can be treated with low-THC cannabis; or

80       2. Symptoms of cancer or a physical medical condition that  
81 chronically produces symptoms of seizures or severe and  
82 persistent muscle spasms that can be alleviated with low-THC  
83 cannabis.

84       (b) Any person who fraudulently represents that he or she  
85 has cancer or a physical medical condition that chronically  
86 produces symptoms of seizures or severe and persistent muscle  
87 spasms to a physician for the purpose of being ordered low-THC  
88 cannabis by such physician commits a misdemeanor of the first  
89 degree, punishable as provided in s. 775.082 or s. 775.083.

90       (4) PHYSICIAN EDUCATION.—

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91 (a) Before ordering low-THC cannabis for use by a patient  
92 in this state, the appropriate board shall require the ordering  
93 physician licensed under chapter 458 or chapter 459 to  
94 successfully complete an 8-hour course and subsequent  
95 examination offered by the Florida Medical Association or the  
96 Florida Osteopathic Medical Association that encompasses the  
97 clinical indications for the appropriate use of low-THC  
98 cannabis, the appropriate delivery mechanisms, the  
99 contraindications for such use, as well as the relevant state  
100 and federal laws governing the ordering, dispensing, and  
101 possessing of this substance. The first course and examination  
102 shall be presented by October 1, 2014, and shall be administered  
103 at least annually thereafter. Successful completion of the  
104 course may be used by a physician to satisfy 8 hours of the  
105 continuing medical education requirements required by his or her  
106 respective board for licensure renewal. This course may be  
107 offered in a distance learning format.

108 (b) The appropriate board shall require the medical  
109 director of each dispensing organization approved under  
110 subsection (5) to successfully complete a 2-hour course and  
111 subsequent examination offered by the Florida Medical  
112 Association or the Florida Osteopathic Medical Association that  
113 encompasses appropriate safety procedures and knowledge of low-  
114 THC cannabis.

115 (c) Successful completion of the course and examination  
116 specified in paragraph (a) is required for every physician who

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117 orders low-THC cannabis each time such physician renews his or  
118 her license. In addition, successful completion of the course  
119 and examination specified in paragraph (b) is required for the  
120 medical director of each dispensing organization each time such  
121 physician renews his or her license.

122 (d) A physician who fails to comply with this subsection  
123 and who orders low-THC cannabis may be subject to disciplinary  
124 action under the applicable practice act and under s.  
125 456.072(1)(k).

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

128 (a) Create a secure, electronic, and online compassionate  
129 use registry for the registration of physicians and patients as  
130 provided under this section. The registry must be accessible to  
131 law enforcement agencies and to a dispensing organization in  
132 order to verify patient authorization for low-THC cannabis and  
133 record the low-THC cannabis dispensed. The registry must prevent  
134 an active registration of a patient by multiple physicians.

135 (b) Authorize the establishment of five dispensing  
136 organizations to ensure reasonable statewide accessibility and  
137 availability as necessary for patients registered in the  
138 compassionate use registry and who are ordered low-THC cannabis  
139 under this section, one in each of the following regions:  
140 northwest Florida, northeast Florida, central Florida, southeast  
141 Florida, and southwest Florida. The department shall develop an  
142 application form and impose an initial application and biennial

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143 renewal fee that is sufficient to cover the costs of  
144 administering this section. An applicant for approval as a  
145 dispensing organization must be able to demonstrate:

146 1. The technical and technological ability to cultivate  
147 and produce low-THC cannabis. The applicant must possess a valid  
148 certificate of registration issued by the Department of  
149 Agriculture and Consumer Services pursuant to s. 581.131 that is  
150 issued for the cultivation of more than 400,000 plants, be  
151 operated by a nurseryman as defined in s. 581.011, and have been  
152 operated as a registered nursery in this state for at least 30  
153 continuous years.

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

156 3. The ability to maintain accountability of all raw  
157 materials, finished products, and any byproducts to prevent  
158 diversion or unlawful access to or possession of these  
159 substances.

160 4. An infrastructure reasonably located to dispense low-  
161 THC cannabis to registered patients statewide or regionally as  
162 determined by the department.

163 5. The financial ability to maintain operations for the  
164 duration of the 2-year approval cycle, including the provision  
165 of certified financials to the department. Upon approval, the  
166 applicant must post a \$5 million performance bond.

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167 6. That all owners and managers have been fingerprinted  
168 and have successfully passed a level 2 background screening  
169 pursuant to s. 435.04.

170 7. The employment of a medical director who is a physician  
171 licensed under chapter 458 or chapter 459 to supervise the  
172 activities of the dispensing organization.

173 (c) Monitor physician registration and ordering of low-THC  
174 cannabis for ordering practices that could facilitate unlawful  
175 diversion or misuse of low-THC cannabis and take disciplinary  
176 action as indicated.

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

178 (6) DISPENSING ORGANIZATION.—An approved dispensing  
179 organization shall maintain compliance with the criteria  
180 demonstrated for selection and approval as a dispensing  
181 organization under subsection (5) at all times. Before  
182 dispensing low-THC cannabis to a qualified patient, the  
183 dispensing organization shall verify that the patient has an  
184 active registration in the compassionate use registry, the order  
185 presented matches the order contents as recorded in the  
186 registry, and the order has not already been filled. Upon  
187 dispensing the low-THC cannabis, the dispensing organization  
188 shall record in the registry the date, time, quantity, and form  
189 of low-THC cannabis dispensed.

190 (7) EXCEPTIONS TO OTHER LAWS.—

191 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
192 any other provision of law, but subject to the requirements of

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193 this section, a qualified patient and the qualified patient's  
194 legal representative may purchase and possess for the patient's  
195 medical use up to the amount of low-THC cannabis ordered for the  
196 patient.

197 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
198 any other provision of law, but subject to the requirements of  
199 this section, an approved dispensing organization and its  
200 owners, managers, and employees may manufacture, possess, sell,  
201 deliver, distribute, dispense, and lawfully dispose of  
202 reasonable quantities, as established by department rule, of  
203 low-THC cannabis. For purposes of this subsection, the terms  
204 "manufacture," "possession," "deliver," "distribute," and  
205 "dispense" have the same meanings as provided in s. 893.02.

206 (c) An approved dispensing organization and its owners,  
207 managers, and employees are not subject to licensure or  
208 regulation under chapter 465 for manufacturing, possessing,  
209 selling, delivering, distributing, dispensing, or lawfully  
210 disposing of reasonable quantities, as established by department  
211 rule, of low-THC cannabis.

212 Section 3. Section 385.211, Florida Statutes, is created  
213 to read:

214 385.211 Refractory and intractable epilepsy treatment and  
215 research at recognized medical centers.—

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

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218 dispensed only from a dispensing organization as defined in s.  
219 381.986.

220 (2) Notwithstanding chapter 893, medical centers  
221 recognized pursuant to s. 381.925 may conduct research on  
222 cannabidiol and low-THC cannabis. This research may include, but  
223 is not limited to, the agricultural development, production,  
224 clinical research, and use of liquid medical derivatives of  
225 cannabidiol and low-THC cannabis for the treatment for  
226 refractory or intractable epilepsy. The authority for recognized  
227 medical centers to conduct this research is derived from 21  
228 C.F.R. parts 312 and 316. Current state or privately obtained  
229 research funds may be used to support the activities described  
230 in this section.

231 Section 4. Section 385.212, Florida Statutes, is created  
232 to read:

233 385.212 Powers and duties of the Department of Health;  
234 Office of Compassionate Use.—

235 (1) The Department of Health shall establish an Office of  
236 Compassionate Use under the direction of the Deputy State Health  
237 Officer.

238 (2) The Office of Compassionate Use may enhance access to  
239 investigational new drugs for Florida patients through approved  
240 clinical treatment plans or studies. The Office of Compassionate  
241 Use may:

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

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244 (b) Make any necessary application to the United States  
245 Food and Drug Administration or a pharmaceutical manufacturer to  
246 facilitate enhanced access to compassionate use for Florida  
247 patients.

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

250 (3) The department may adopt rules necessary to implement  
251 this section.

252 Section 5. Subsection (3) of section 893.02, Florida  
253 Statutes, is amended to read:

254 893.02 Definitions.—The following words and phrases as  
255 used in this chapter shall have the following meanings, unless  
256 the context otherwise requires:

257 (3) "Cannabis" means all parts of any plant of the genus  
258 Cannabis, whether growing or not; the seeds thereof; the resin  
259 extracted from any part of the plant; and every compound,  
260 manufacture, salt, derivative, mixture, or preparation of the  
261 plant or its seeds or resin. The term does not include "low-THC  
262 cannabis," as defined in s. 381.986, if manufactured, possessed,  
263 sold, purchased, delivered, distributed, or dispensed, in  
264 conformance with s. 381.986.

265 Section 6. Section 1004.441, Florida Statutes, is created  
266 to read:

267 1004.441 Refractory and intractable epilepsy treatment and  
268 research.—

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269 (1) As used in this section, the term "low-THC cannabis"  
270 means "low-THC cannabis" as defined in s. 381.986 that is  
271 dispensed only from a dispensing organization as defined in s.  
272 381.986.

273 (2) Notwithstanding chapter 893, state universities with  
274 both medical and agricultural research programs, including those  
275 that have satellite campuses or research agreements with other  
276 similar institutions, may conduct research on cannabidiol and  
277 low-THC cannabis. This research may include, but is not limited  
278 to, the agricultural development, production, clinical research,  
279 and use of liquid medical derivatives of cannabidiol and low-THC  
280 cannabis for the treatment for refractory or intractable  
281 epilepsy. The authority for state universities to conduct this  
282 research is derived from 21 C.F.R. parts 312 and 316. Current  
283 state or privately obtained research funds may be used to  
284 support the activities authorized by this section.

285 Section 7. (1) As used in this section, the term  
286 "cannabidiol" means an extract from the cannabis plant that has  
287 less than 0.8 percent tetrahydrocannabinol and the chemical  
288 signature 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-  
289 5-pentylbenzene-1,3-diol, or a derivative thereof, as determined  
290 by the International Union of Pure and Applied Chemistry.

291 (2) For the 2014-2015 fiscal year, \$1 million in  
292 nonrecurring general revenue is appropriated to the Department  
293 of Health for the James and Esther King Biomedical Research  
294 Program and shall be deposited into the Biomedical Research

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295 Trust Fund. These funds shall be reserved for research of  
296 cannabidiol and its effect on intractable childhood epilepsy.

297 (3) Biomedical research funding for research of  
298 cannabidiol and its effect on intractable childhood epilepsy  
299 shall be awarded pursuant to s. 215.5602, Florida Statutes. An  
300 application for such funding may be submitted by any research  
301 university in the state that has obtained approval from the  
302 United States Food and Drug Administration for an exploratory  
303 investigational new drug study of cannabidiol and its effect on  
304 intractable childhood epilepsy. For purposes of this section,  
305 the Biomedical Research Advisory Council created under s.  
306 215.5602, Florida Statutes, shall advise the State Surgeon  
307 General as to the direction and scope of research of cannabidiol  
308 and its effect on intractable childhood epilepsy and the award  
309 of research funding.

310 Section 8. This act shall take effect upon becoming a law.

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

314 Remove everything before the enacting clause and insert:

315 A bill to be entitled

316 An act relating to cannabis; providing a short title;  
317 creating s. 381.986, F.S.; defining terms; authorizing  
318 specified physicians to order low-THC cannabis for use  
319 by specified patients; providing conditions;  
320 prohibiting specified acts by physicians or persons

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321 seeking low-THC cannabis; providing criminal  
322 penalties; requiring physician education; providing  
323 duties of the Department of Health; requiring the  
324 department to create a compassionate use registry;  
325 providing requirements for the registry; requiring the  
326 department to authorize a specified number of  
327 dispensing organizations; authorizing rulemaking;  
328 providing requirements and duties for a dispensing  
329 organization; providing exceptions to specified laws;  
330 creating s. 385.211, F.S.; defining the term "low-THC  
331 cannabis"; authorizing certain medical centers to  
332 conduct research on cannabidiol and low-THC cannabis;  
333 authorizing state or privately obtained research funds  
334 to be used to support such research; creating s.  
335 385.212, F.S.; requiring the department to establish  
336 an Office of Compassionate Use; authorizing the office  
337 to engage in specified activities; authorizing  
338 rulemaking; amending s. 893.02, F.S.; revising the  
339 term "cannabis" as used in the Florida Comprehensive  
340 Drug Abuse Prevention and Control Act and as  
341 applicable to certain criminal offenses proscribing  
342 the sale, manufacture, delivery, possession,  
343 dispensing, distribution, or purchase of cannabis, to  
344 which penalties apply; creating s. 1004.441, F.S.;  
345 defining the term "low-THC cannabis"; authorizing  
346 state universities with both medical and agricultural

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347 research programs to conduct specified research on  
348 cannabidiol and low-THC cannabis; authorizing state or  
349 privately obtained research funds to be used to  
350 support such research; providing an appropriation to  
351 the department for research of cannabidiol and its  
352 effect on intractable childhood epilepsy; specifying  
353 how biomedical research funding for research of  
354 cannabidiol and its effect on intractable childhood  
355 epilepsy shall be awarded; specifying who may apply  
356 for such funding; providing an effective date.

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