

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

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

115 (d) A physician who fails to comply with this subsection
116 and who orders low-THC cannabis may be subject to disciplinary

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117 action under the applicable practice act and under s.

118 456.072(1)(k).

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

121 (a) Create a secure, electronic, and online compassionate
122 use registry for the registration of physicians and patients as
123 provided under this section. The registry must be accessible to
124 law enforcement agencies and to a dispensing organization in
125 order to verify patient authorization for low-THC cannabis and
126 record the low-THC cannabis dispensed. The registry must prevent
127 an active registration of a patient by multiple physicians.

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

139 1. The technical and technological ability to cultivate
140 and produce low-THC cannabis.

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

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143 3. The ability to maintain accountability of all raw
144 materials, finished products, and any byproducts to prevent
145 diversion or unlawful access to or possession of these
146 substances.

147 4. An infrastructure reasonably located to dispense low-
148 THC cannabis to registered patients statewide or regionally as
149 determined by the department.

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

152 6. That all owners, managers, and employees have been
153 fingerprinted and have successfully passed a level 2 background
154 screening pursuant to s. 435.04.

155 (c) Monitor physician registration and ordering of low-THC
156 cannabis for ordering practices that could facilitate unlawful
157 diversion or misuse of low-THC cannabis and take disciplinary
158 action as indicated.

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

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

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169 dispensing the low-THC cannabis, the dispensing organization
170 shall record in the registry the date, time, quantity, and form
171 of low-THC cannabis dispensed.

172 (7) EXCEPTIONS TO OTHER LAWS.—

173 (a) 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, a qualified patient and the qualified patient's
176 legal representative may purchase and possess for the patient's
177 medical use up to the amount of low-THC cannabis ordered for the
178 patient.

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

188 (c) An approved dispensing organization and its owners,
189 managers, and employees are not subject to licensure or
190 regulation under chapter 465 for manufacturing, possessing,
191 selling, delivering, distributing, dispensing, or lawfully
192 disposing of reasonable quantities, as established by department
193 rule, of low-THC cannabis.

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194 Section 3. Section 385.211, Florida Statutes, is created
195 to read:

196 385.211 Refractory and intractable epilepsy treatment and
197 research at recognized medical centers.—

198 (1) As used in this section, the term "low-THC cannabis"
199 means "low-THC cannabis" as defined in s. 381.986 that is
200 dispensed only from a dispensing organization as defined in s.
201 381.986.

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

213 Section 4. Section 385.212, Florida Statutes, is created
214 to read:

215 385.212 Powers and duties of the Department of Health;
216 Office of Compassionate Use.—

217 (1) The Department of Health shall establish an Office of
218 Compassionate Use under the direction of the Deputy State Health
219 Officer.

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220 (2) The Office of Compassionate Use may enhance access to
221 investigational new drugs for Florida patients through approved
222 clinical treatment plans or studies. The Office of Compassionate
223 Use may:

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

226 (b) Make any necessary application to the United States
227 Food and Drug Administration or a pharmaceutical manufacturer to
228 facilitate enhanced access to compassionate use for Florida
229 patients.

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

232 (3) The department may adopt rules necessary to implement
233 this section.

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

236 893.02 Definitions.—The following words and phrases as
237 used in this chapter shall have the following meanings, unless
238 the context otherwise requires:

239 (3) "Cannabis" means all parts of any plant of the genus
240 Cannabis, whether growing or not; the seeds thereof; the resin
241 extracted from any part of the plant; and every compound,
242 manufacture, salt, derivative, mixture, or preparation of the
243 plant or its seeds or resin. The term does not include "low-THC
244 cannabis," as defined in s. 381.986, if manufactured, possessed,

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245 sold, purchased, delivered, distributed, or dispensed, in
246 conformance with s. 381.986.

247 Section 6. Section 1004.441, Florida Statutes, is created
248 to read:

249 1004.441 Refractory and intractable epilepsy treatment and
250 research.—

251 (1) As used in this section, the term "low-THC cannabis"
252 means "low-THC cannabis" as defined in s. 381.986 that is
253 dispensed only from a dispensing organization as defined in s.
254 381.986.

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

267 Section 7. (1) As used in this section, the term
268 "cannabidiol" means an extract from the cannabis plant that has
269 less than 0.8 percent tetrahydrocannabinol and the chemical
270 signature 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-

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271 5-pentylbenzene-1,3-diol, or a derivative thereof, as determined
272 by the International Union of Pure and Applied Chemistry.

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

279 (3) Biomedical research funding for research of
280 cannabidiol and its effect on intractable childhood epilepsy
281 shall be awarded pursuant to s. 215.5602, Florida Statutes. An
282 application for such funding may be submitted by any research
283 university in the state that has obtained approval from the
284 United States Food and Drug Administration for an exploratory
285 investigational new drug study of cannabidiol and its effect on
286 intractable childhood epilepsy. For purposes of this section,
287 the Biomedical Research Advisory Council created under s.
288 215.5602, Florida Statutes, shall advise the State Surgeon
289 General as to the direction and scope of research of cannabidiol
290 and its effect on intractable childhood epilepsy and the award
291 of research funding.

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

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

295 Remove everything before the enacting clause and insert:
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297 A bill to be entitled
298 An act relating to cannabis; providing a short title;
299 creating s. 381.986, F.S.; defining terms; authorizing
300 specified physicians to order low-THC cannabis for use
301 by specified patients; providing conditions;
302 prohibiting specified acts by physicians or persons
303 seeking low-THC cannabis; providing criminal
304 penalties; requiring physician education; providing
305 duties of the Department of Health; requiring the
306 department to create a compassionate use registry;
307 providing requirements for the registry; requiring the
308 department to authorize a specified number of
309 dispensing organizations; authorizing rulemaking;
310 providing requirements and duties for a dispensing
311 organization; providing exceptions to specified laws;
312 creating s. 385.211, F.S.; defining the term "low-THC
313 cannabis"; authorizing certain medical centers to
314 conduct research on cannabidiol and low-THC cannabis;
315 authorizing state or privately obtained research funds
316 to be used to support such research; creating s.
317 385.212, F.S.; requiring the department to establish
318 an Office of Compassionate Use; authorizing the office
319 to engage in specified activities; authorizing
320 rulemaking; amending s. 893.02, F.S.; revising the
321 term "cannabis" as used in the Florida Comprehensive
322 Drug Abuse Prevention and Control Act and as

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323 applicable to certain criminal offenses proscribing
324 the sale, manufacture, delivery, possession,
325 dispensing, distribution, or purchase of cannabis, to
326 which penalties apply; creating s. 1004.441, F.S.;
327 defining the term "low-THC cannabis"; authorizing
328 state universities with both medical and agricultural
329 research programs to conduct specified research on
330 cannabidiol and low-THC cannabis; authorizing state or
331 privately obtained research funds to be used to
332 support such research; providing an appropriation to
333 the department for research of cannabidiol and its
334 effect on intractable childhood epilepsy; specifying
335 how biomedical research funding for research of
336 cannabidiol and its effect on intractable childhood
337 epilepsy shall be awarded; specifying who may apply
338 for such funding; providing an effective date.

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