

20141030e1

1 A bill to be entitled
2 An act relating to cannabis; providing a short title;
3 creating s. 381.986, F.S.; defining terms; authorizing
4 specified physicians to order low-THC cannabis for use
5 by specified patients; providing conditions;
6 prohibiting specified acts by physicians or persons
7 seeking low-THC cannabis; providing criminal
8 penalties; requiring physician education; providing
9 duties of the Department of Health; requiring the
10 department to create a compassionate use registry;
11 providing requirements for the registry; requiring the
12 department to authorize a specified number of
13 dispensing organizations; authorizing rulemaking;
14 providing requirements and duties for a dispensing
15 organization; providing exceptions to specified laws;
16 creating s. 385.211, F.S.; defining the term "low-THC
17 cannabis"; authorizing certain medical centers to
18 conduct research on cannabidiol and low-THC cannabis;
19 authorizing state or privately obtained research funds
20 to be used to support such research; creating s.
21 385.212, F.S.; requiring the department to establish
22 an Office of Compassionate Use; authorizing the office
23 to engage in specified activities; authorizing
24 rulemaking; amending s. 893.02, F.S.; revising the
25 term "cannabis" as used in the Florida Comprehensive
26 Drug Abuse Prevention and Control Act and as
27 applicable to certain criminal offenses proscribing
28 the sale, manufacture, delivery, possession,
29 dispensing, distribution, or purchase of cannabis, to

20141030e1

30 which penalties apply; creating s. 1004.441, F.S.;

31 defining the term "low-THC cannabis"; authorizing

32 state universities with both medical and agricultural

33 research programs to conduct specified research on

34 cannabidiol and low-THC cannabis; authorizing state or

35 privately obtained research funds to be used to

36 support such research; providing an appropriation to

37 the department for research of cannabidiol and its

38 effect on intractable childhood epilepsy; specifying

39 how biomedical research funding for research of

40 cannabidiol and its effect on intractable childhood

41 epilepsy shall be awarded; specifying who may apply

42 for such funding; providing an effective date.

43

44 Be It Enacted by the Legislature of the State of Florida:

45

46 Section 1. This act may be cited as the "Compassionate

47 Medical Cannabis Act of 2014."

48 Section 2. Section 381.986, Florida Statutes, is created to

49 read:

50 381.986 Compassionate use of low-THC cannabis.-

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

52 (a) "Dispensing organization" means an organization

53 approved by the department to cultivate, process, and dispense

54 low-THC cannabis pursuant to this section.

55 (b) "Low-THC cannabis" means a plant of the genus *Cannabis*,

56 the dried flowers of which contain 0.8 percent or less of

57 tetrahydrocannabinol and more than 10 percent of cannabidiol

58 weight for weight; the seeds thereof; the resin extracted from

20141030e1

59 any part of such plant; or any compound, manufacture, salt,
60 derivative, mixture, or preparation of such plant or its seeds
61 or resin that is dispensed only from a dispensing organization.

62 (c) "Medical use" means administration of the ordered
63 amount of low-THC cannabis. The term does not include the
64 possession, use, or administration by smoking. The term also
65 does not include the transfer of low-THC cannabis to a person
66 other than the qualified patient for whom it was ordered or the
67 qualified patient's legal representative on behalf of the
68 qualified patient.

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

73 (e) "Smoking" means burning or igniting a substance and
74 inhaling the smoke. Smoking does not include the use of a
75 vaporizer.

76 (2) PHYSICIAN ORDERING.—Effective January 1, 2015, a
77 physician licensed under chapter 458 or chapter 459 who has
78 examined and is treating a patient suffering from cancer or a
79 physical medical condition that chronically produces symptoms of
80 seizures or severe and persistent muscle spasms may order for
81 the patient's medical use low-THC cannabis to treat such
82 disease, disorder, or condition or to alleviate symptoms of such
83 disease, disorder, or condition, if no other satisfactory
84 alternative treatment options exist for that patient and all of
85 the following conditions apply:

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

87 (b) The physician determines that the risks of ordering

20141030e1

88 low-THC cannabis are reasonable in light of the potential
89 benefit for that patient. If a patient is younger than 18 years
90 of age, a second physician must concur with this determination,
91 and such determination must be documented in the patient's
92 medical record.

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

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

102 (e) The physician submits the patient treatment plan
103 quarterly to the University of Florida College of Pharmacy for
104 research on the safety and efficacy of low-THC cannabis on
105 patients.

106 (f) The physician obtains the voluntary informed consent of
107 the patient or the patient's legal guardian to treatment with
108 low-THC cannabis after sufficiently explaining the current state
109 of knowledge in the medical community of the effectiveness of
110 treatment of the patient's condition with low-THC cannabis, the
111 medically acceptable alternatives, and the potential risks and
112 side effects.

113 (3) PENALTIES.—

114 (a) A physician commits a misdemeanor of the first degree,
115 punishable as provided in s. 775.082 or s. 775.083, if the
116 physician orders low-THC cannabis for a patient without a

20141030e1

117 reasonable belief that the patient is suffering from:

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

121 2. Symptoms of cancer or a physical medical condition that
122 chronically produces symptoms of seizures or severe and
123 persistent muscle spasms that can be alleviated with low-THC
124 cannabis.

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

131 (4) PHYSICIAN EDUCATION.—

132 (a) Before ordering low-THC cannabis for use by a patient
133 in this state, the appropriate board shall require the ordering
134 physician licensed under chapter 458 or chapter 459 to
135 successfully complete an 8-hour course and subsequent
136 examination offered by the Florida Medical Association or the
137 Florida Osteopathic Medical Association that encompasses the
138 clinical indications for the appropriate use of low-THC
139 cannabis, the appropriate delivery mechanisms, the
140 contraindications for such use, as well as the relevant state
141 and federal laws governing the ordering, dispensing, and
142 possessing of this substance. The first course and examination
143 shall be presented by October 1, 2014, and shall be administered
144 at least annually thereafter. Successful completion of the
145 course may be used by a physician to satisfy 8 hours of the

20141030e1

146 continuing medical education requirements required by his or her
147 respective board for licensure renewal. This course may be
148 offered in a distance learning format.

149 (b) The appropriate board shall require the medical
150 director of each dispensing organization approved under
151 subsection (5) to successfully complete a 2-hour course and
152 subsequent examination offered by the Florida Medical
153 Association or the Florida Osteopathic Medical Association that
154 encompasses appropriate safety procedures and knowledge of low-
155 THC cannabis.

156 (c) Successful completion of the course and examination
157 specified in paragraph (a) is required for every physician who
158 orders low-THC cannabis each time such physician renews his or
159 her license. In addition, successful completion of the course
160 and examination specified in paragraph (b) is required for the
161 medical director of each dispensing organization each time such
162 physician renews his or her license.

163 (d) A physician who fails to comply with this subsection
164 and who orders low-THC cannabis may be subject to disciplinary
165 action under the applicable practice act and under s.
166 456.072(1)(k).

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

169 (a) Create a secure, electronic, and online compassionate
170 use registry for the registration of physicians and patients as
171 provided under this section. The registry must be accessible to
172 law enforcement agencies and to a dispensing organization in
173 order to verify patient authorization for low-THC cannabis and
174 record the low-THC cannabis dispensed. The registry must prevent

20141030e1

175 an active registration of a patient by multiple physicians.

176 (b) Authorize the establishment of five dispensing
177 organizations to ensure reasonable statewide accessibility and
178 availability as necessary for patients registered in the
179 compassionate use registry and who are ordered low-THC cannabis
180 under this section, one in each of the following regions:
181 northwest Florida, northeast Florida, central Florida, southeast
182 Florida, and southwest Florida. The department shall develop an
183 application form and impose an initial application and biennial
184 renewal fee that is sufficient to cover the costs of
185 administering this section. An applicant for approval as a
186 dispensing organization must be able to demonstrate:

187 1. The technical and technological ability to cultivate and
188 produce low-THC cannabis. The applicant must possess a valid
189 certificate of registration issued by the Department of
190 Agriculture and Consumer Services pursuant to s. 581.131 that is
191 issued for the cultivation of more than 400,000 plants, be
192 operated by a nurseryman as defined in s. 581.011, and have been
193 operated as a registered nursery in this state for at least 30
194 continuous years.

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

197 3. The ability to maintain accountability of all raw
198 materials, finished products, and any byproducts to prevent
199 diversion or unlawful access to or possession of these
200 substances.

201 4. An infrastructure reasonably located to dispense low-THC
202 cannabis to registered patients statewide or regionally as
203 determined by the department.

20141030e1

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

208 6. That all owners and managers have been fingerprinted and
209 have successfully passed a level 2 background screening pursuant
210 to s. 435.04.

211 7. The employment of a medical director who is a physician
212 licensed under chapter 458 or chapter 459 to supervise the
213 activities of the dispensing organization.

214 (c) Monitor physician registration and ordering of low-THC
215 cannabis for ordering practices that could facilitate unlawful
216 diversion or misuse of low-THC cannabis and take disciplinary
217 action as indicated.

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

219 (6) DISPENSING ORGANIZATION.—An approved dispensing
220 organization shall maintain compliance with the criteria
221 demonstrated for selection and approval as a dispensing
222 organization under subsection (5) at all times. Before
223 dispensing low-THC cannabis to a qualified patient, the
224 dispensing organization shall verify that the patient has an
225 active registration in the compassionate use registry, the order
226 presented matches the order contents as recorded in the
227 registry, and the order has not already been filled. Upon
228 dispensing the low-THC cannabis, the dispensing organization
229 shall record in the registry the date, time, quantity, and form
230 of low-THC cannabis dispensed.

231 (7) EXCEPTIONS TO OTHER LAWS.—

232 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or

20141030e1

233 any other provision of law, but subject to the requirements of
234 this section, a qualified patient and the qualified patient's
235 legal representative may purchase and possess for the patient's
236 medical use up to the amount of low-THC cannabis ordered for the
237 patient.

238 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
239 any other provision of law, but subject to the requirements of
240 this section, an approved dispensing organization and its
241 owners, managers, and employees may manufacture, possess, sell,
242 deliver, distribute, dispense, and lawfully dispose of
243 reasonable quantities, as established by department rule, of
244 low-THC cannabis. For purposes of this subsection, the terms
245 "manufacture," "possession," "deliver," "distribute," and
246 "dispense" have the same meanings as provided in s. 893.02.

247 (c) An approved dispensing organization and its owners,
248 managers, and employees are not subject to licensure or
249 regulation under chapter 465 for manufacturing, possessing,
250 selling, delivering, distributing, dispensing, or lawfully
251 disposing of reasonable quantities, as established by department
252 rule, of low-THC cannabis.

253 Section 3. Section 385.211, Florida Statutes, is created to
254 read:

255 385.211 Refractory and intractable epilepsy treatment and
256 research at recognized medical centers.—

257 (1) As used in this section, the term "low-THC cannabis"
258 means "low-THC cannabis" as defined in s. 381.986 that is
259 dispensed only from a dispensing organization as defined in s.
260 381.986.

261 (2) Notwithstanding chapter 893, medical centers recognized

20141030e1

262 pursuant to s. 381.925 may conduct research on cannabidiol and
263 low-THC cannabis. This research may include, but is not limited
264 to, the agricultural development, production, clinical research,
265 and use of liquid medical derivatives of cannabidiol and low-THC
266 cannabis for the treatment for refractory or intractable
267 epilepsy. The authority for recognized medical centers to
268 conduct this research is derived from 21 C.F.R. parts 312 and
269 316. Current state or privately obtained research funds may be
270 used to support the activities described in this section.

271 Section 4. Section 385.212, Florida Statutes, is created to
272 read:

273 385.212 Powers and duties of the Department of Health;
274 Office of Compassionate Use.—

275 (1) The Department of Health shall establish an Office of
276 Compassionate Use under the direction of the Deputy State Health
277 Officer.

278 (2) The Office of Compassionate Use may enhance access to
279 investigational new drugs for Florida patients through approved
280 clinical treatment plans or studies. The Office of Compassionate
281 Use may:

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

284 (b) Make any necessary application to the United States
285 Food and Drug Administration or a pharmaceutical manufacturer to
286 facilitate enhanced access to compassionate use for Florida
287 patients.

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

290 (3) The department may adopt rules necessary to implement

20141030e1

291 this section.

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

294 893.02 Definitions.—The following words and phrases as used
295 in this chapter shall have the following meanings, unless the
296 context otherwise requires:

297 (3) "Cannabis" means all parts of any plant of the genus
298 *Cannabis*, whether growing or not; the seeds thereof; the resin
299 extracted from any part of the plant; and every compound,
300 manufacture, salt, derivative, mixture, or preparation of the
301 plant or its seeds or resin. The term does not include "low-THC
302 cannabis," as defined in s. 381.986, if manufactured, possessed,
303 sold, purchased, delivered, distributed, or dispensed, in
304 conformance with s. 381.986.

305 Section 6. Section 1004.441, Florida Statutes, is created
306 to read:

307 1004.441 Refractory and intractable epilepsy treatment and
308 research.—

309 (1) As used in this section, the term "low-THC cannabis"
310 means "low-THC cannabis" as defined in s. 381.986 that is
311 dispensed only from a dispensing organization as defined in s.
312 381.986.

313 (2) Notwithstanding chapter 893, state universities with
314 both medical and agricultural research programs, including those
315 that have satellite campuses or research agreements with other
316 similar institutions, may conduct research on cannabidiol and
317 low-THC cannabis. This research may include, but is not limited
318 to, the agricultural development, production, clinical research,
319 and use of liquid medical derivatives of cannabidiol and low-THC

20141030e1

320 cannabis for the treatment for refractory or intractable
321 epilepsy. The authority for state universities to conduct this
322 research is derived from 21 C.F.R. parts 312 and 316. Current
323 state or privately obtained research funds may be used to
324 support the activities authorized by this section.

325 Section 7. (1) As used in this section, the term
326 "cannabidiol" means an extract from the cannabis plant that has
327 less than 0.8 percent tetrahydrocannabinol and the chemical
328 signature 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-
329 5-pentylbenzene-1,3-diol, or a derivative thereof, as determined
330 by the International Union of Pure and Applied Chemistry.

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

337 (3) Biomedical research funding for research of cannabidiol
338 and its effect on intractable childhood epilepsy shall be
339 awarded pursuant to s. 215.5602, Florida Statutes. An
340 application for such funding may be submitted by any research
341 university in the state that has obtained approval from the
342 United States Food and Drug Administration for an exploratory
343 investigational new drug study of cannabidiol and its effect on
344 intractable childhood epilepsy. For purposes of this section,
345 the Biomedical Research Advisory Council created under s.
346 215.5602, Florida Statutes, shall advise the State Surgeon
347 General as to the direction and scope of research of cannabidiol
348 and its effect on intractable childhood epilepsy and the award

20141030e1

349 of research funding.

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