

20141030er

1  
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

20141030er

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

20141030er

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

20141030er

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

20141030er

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

20141030er

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

20141030er

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.

20141030er

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



20141030er

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

20141030er

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

20141030er

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

20141030er

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

20141030er

349 of research funding.

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