

1 A bill to be entitled

2 An act relating to cannabis; creating s. 381.986,
3 F.S.; defining terms; authorizing specified physicians
4 to order low-THC cannabis for use by specified
5 patients; providing conditions; prohibiting specified
6 acts by physicians or persons seeking low-THC
7 cannabis; providing criminal penalties; requiring
8 physician education; providing duties of the
9 Department of Health; requiring the department to
10 create a compassionate use registry; providing
11 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
 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. Section 381.986, Florida Statutes, is created
 47 to read:

48 381.986 Compassionate use of low-THC cannabis.-

49 (1) DEFINITIONS.—As used in this section, the term:

50 (a) "Dispensing organization" means an organization

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

52 low-THC cannabis pursuant to this section.

53 (b) "Low-THC cannabis" means a plant of the genus
54 Cannabis, the dried flowers of which contain 0.8 percent or less
55 of tetrahydrocannabinol and more than 10 percent of cannabidiol
56 weight for weight; the seeds thereof; the resin extracted from
57 any part of such plant; or any compound, manufacture, salt,
58 derivative, mixture, or preparation of such plant or its seeds
59 or resin that is dispensed only from a dispensing organization.

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

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

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

74 (2) PHYSICIAN ORDERING.—A physician licensed under chapter
75 458 or chapter 459 who has examined and is treating a patient
76 suffering from a serious medical condition, including, but not
77 limited to, treatment for cancer or neurological conditions, may
78 order for the patient's medical use low-THC cannabis to treat

79 such condition or alleviate symptoms of such condition, such as
80 seizures or severe and persistent muscle spasms, if no other
81 satisfactory alternative treatment options exist for that
82 patient and all of the following conditions apply:

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

84 (b) The physician determines that the risks of ordering
85 low-THC cannabis are reasonable in light of the potential
86 benefit for that patient. If a patient is younger than 18 years
87 of age, a second physician must concur with this determination,
88 and such determination must be documented in the patient's
89 medical record.

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

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

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

103 (f) The physician obtains the voluntary informed consent
104 of the patient or the patient's legal guardian to treatment with

105 low-THC cannabis after sufficiently explaining the current state
106 of knowledge in the medical community of the effectiveness of
107 treatment of the patient's condition with low-THC cannabis, the
108 medically acceptable alternatives, and the potential risks and
109 side effects.

110 (3) PENALTIES.—

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

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

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

119 (b) Any person who fraudulently represents a medical
120 condition to a physician for the purpose of being ordered low-
121 THC cannabis by such physician commits a misdemeanor of the
122 first degree, punishable as provided in s. 775.082 or s.
123 775.083.

124 (4) PHYSICIAN EDUCATION.—

125 (a) Before ordering low-THC cannabis for use by a patient
126 in this state, the appropriate board shall require the ordering
127 physician licensed under chapter 458 or chapter 459 to
128 successfully complete an 8-hour course and subsequent
129 examination offered by the Florida Medical Association that
130 encompasses the clinical indications for the appropriate use of

131 low-THC cannabis, the appropriate delivery mechanisms, the
132 contraindications for such use, as well as the relevant state
133 and federal laws governing the ordering, dispensing, and
134 possessing of this substance. The first course and examination
135 shall be presented by October 1, 2014, and shall be administered
136 at least annually thereafter. Successful completion of the
137 course may be used by a physician to satisfy 8 hours of the
138 continuing medical education requirements required by his or her
139 respective board for licensure renewal. This course may be
140 offered in a distance learning format.

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

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

148 (d) A physician who fails to comply with this subsection
149 and who orders low-THC cannabis may be subject to disciplinary
150 action under the applicable practice act and under s.
151 456.072(1)(k).

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

154 (a) Create a secure, electronic, and online compassionate
155 use registry for the registration of physicians and patients as
156 provided under this section. The registry must be accessible to

157 law enforcement agencies and to a dispensing organization in
158 order to verify patient authorization for low-THC cannabis and
159 record the low-THC cannabis dispensed. The registry must prevent
160 an active registration of a patient by multiple physicians.

161 (b) Authorize the establishment of four dispensing
162 organizations, one in each of the following regions: northwest
163 Florida, northeast Florida, central Florida, and south Florida,
164 to ensure reasonable statewide accessibility and availability as
165 necessary for patients registered in the compassionate use
166 registry and who are ordered low-THC cannabis under this
167 section. The department shall develop an application form and
168 impose an initial application and biennial renewal fee that is
169 sufficient to cover the costs of administering this section. An
170 applicant for approval as a dispensing organization must be able
171 to demonstrate:

172 1. The technical and technological ability to cultivate
173 and produce low-THC cannabis.

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

176 3. The ability to maintain accountability of all raw
177 materials, finished products, and any byproducts to prevent
178 diversion or unlawful access to or possession of these
179 substances.

180 4. An infrastructure reasonably located to dispense low-
181 THC cannabis to registered patients statewide or regionally as
182 determined by the department.

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

185 6. That all owners, managers, and employees have been
 186 fingerprinted and have successfully passed a level 2 background
 187 screening pursuant to s. 435.04.

188 (c) Monitor physician registration and ordering of low-THC
 189 cannabis for ordering practices that could facilitate unlawful
 190 diversion or misuse of low-THC cannabis and take disciplinary
 191 action as indicated.

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

193 (6) DISPENSING ORGANIZATION.—An approved dispensing
 194 organization shall maintain compliance with the criteria
 195 demonstrated for selection and approval as a dispensing
 196 organization under subsection (5) at all times. Before
 197 dispensing low-THC cannabis to a qualified patient, the
 198 dispensing organization shall verify that the patient has an
 199 active registration in the compassionate use registry, the order
 200 presented matches the order contents as recorded in the
 201 registry, and the order has not already been filled. Upon
 202 dispensing the low-THC cannabis, the dispensing organization
 203 shall record in the registry the date, time, quantity, and form
 204 of low-THC cannabis dispensed.

205 (7) EXCEPTIONS TO OTHER LAWS.—

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

209 legal representative may purchase and possess for the patient's
 210 medical use up to the amount of low-THC cannabis ordered for the
 211 patient.

212 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
 213 any other provision of law, but subject to the requirements of
 214 this section, an approved dispensing organization and its
 215 owners, managers, and employees may manufacture, possess, sell,
 216 deliver, distribute, dispense, and lawfully dispose of
 217 reasonable quantities, as established by department rule, of
 218 low-THC cannabis. For purposes of this subsection, the terms
 219 "manufacture," "possession," "deliver," "distribute," and
 220 "dispense" have the same meanings as provided in s. 893.02.

221 (c) An approved dispensing organization and its owners,
 222 managers, and employees are not subject to licensure or
 223 regulation under chapter 465 for manufacturing, possessing,
 224 selling, delivering, distributing, dispensing, or lawfully
 225 disposing of reasonable quantities, as established by department
 226 rule, of low-THC cannabis.

227 Section 2. Section 385.211, Florida Statutes, is created
 228 to read:

229 385.211 Refractory and intractable epilepsy treatment and
 230 research at recognized medical centers.—

231 (1) As used in this section, the term "low-THC cannabis"
 232 means "low-THC cannabis" as defined in s. 381.986 that is
 233 dispensed only from a dispensing organization as defined in s.
 234 381.986.

235 (2) Notwithstanding chapter 893, medical centers
 236 recognized pursuant to s. 381.925 may conduct research on
 237 cannabidiol and low-THC cannabis. This research may include, but
 238 is not limited to, the agricultural development, production,
 239 clinical research, and use of liquid medical derivatives of
 240 cannabidiol and low-THC cannabis for the treatment for
 241 refractory or intractable epilepsy. The authority for recognized
 242 medical centers to conduct this research is derived from 21
 243 C.F.R. parts 312 and 316. Current state or privately obtained
 244 research funds may be used to support the activities described
 245 in this section.

246 Section 3. Section 385.212, Florida Statutes, is created
 247 to read:

248 385.212 Powers and duties of the Department of Health;
 249 Office of Compassionate Use.—

250 (1) The Department of Health shall establish an Office of
 251 Compassionate Use under the direction of the Deputy State Health
 252 Officer.

253 (2) The Office of Compassionate Use may enhance access to
 254 investigational new drugs for Florida patients through approved
 255 clinical treatment plans or studies. The Office of Compassionate
 256 Use may:

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

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

261 facilitate enhanced access to compassionate use for Florida
 262 patients.

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

265 (3) The department may adopt rules necessary to implement
 266 this section.

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

269 893.02 Definitions.—The following words and phrases as
 270 used in this chapter shall have the following meanings, unless
 271 the context otherwise requires:

272 (3) "Cannabis" means all parts of any plant of the genus
 273 Cannabis, whether growing or not; the seeds thereof; the resin
 274 extracted from any part of the plant; and every compound,
 275 manufacture, salt, derivative, mixture, or preparation of the
 276 plant or its seeds or resin. The term does not include "low-THC
 277 cannabis," as defined in s. 381.986, if manufactured, possessed,
 278 sold, purchased, delivered, distributed, or dispensed, in
 279 conformance with s. 381.986.

280 Section 5. Section 1004.441, Florida Statutes, is created
 281 to read:

282 1004.441 Refractory and intractable epilepsy treatment and
 283 research.—

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

286 dispensed only from a dispensing organization as defined in s.
287 381.986.

288 (2) Notwithstanding chapter 893, state universities with
289 both medical and agricultural research programs, including those
290 that have satellite campuses or research agreements with other
291 similar institutions, may conduct research on cannabidiol and
292 low-THC cannabis. This research may include, but is not limited
293 to, the agricultural development, production, clinical research,
294 and use of liquid medical derivatives of cannabidiol and low-THC
295 cannabis for the treatment for refractory or intractable
296 epilepsy. The authority for state universities to conduct this
297 research is derived from 21 C.F.R. parts 312 and 316. Current
298 state or privately obtained research funds may be used to
299 support the activities authorized by this section.

300 Section 6. (1) As used in this section, the term
301 "cannabidiol" means an extract from the cannabis plant that has
302 less than 0.8 percent tetrahydrocannabinol and the chemical
303 signature 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-
304 5-pentylbenzene-1,3-diol, or a derivative thereof, as determined
305 by the International Union of Pure and Applied Chemistry.

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

312 (3) Biomedical research funding for research of
313 cannabidiol and its effect on intractable childhood epilepsy
314 shall be awarded pursuant to s. 215.5602, Florida Statutes. An
315 application for such funding may be submitted by any research
316 university in the state that has obtained approval from the
317 United States Food and Drug Administration for an exploratory
318 investigational new drug study of cannabidiol and its effect on
319 intractable childhood epilepsy. For purposes of this section,
320 the Biomedical Research Advisory Council created under s.
321 215.5602, Florida Statutes, shall advise the State Surgeon
322 General as to the direction and scope of research of cannabidiol
323 and its effect on intractable childhood epilepsy and the award
324 of research funding.

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