

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; requiring physician  
6 education; providing duties of the Department of  
7 Health; requiring the department to create a  
8 compassionate use registry; providing requirements for  
9 the registry; requiring the department to authorize a  
10 specified number of dispensing organizations;  
11 providing requirements and duties for a dispensing  
12 organization; providing exceptions to specified laws;  
13 creating s. 385.211, F.S.; defining "low-THC  
14 cannabis;" authorizing certain medical centers to  
15 conduct research on cannabidiol and low-THC cannabis;  
16 citing authority for such research; authorizing state  
17 or privately obtained research funds to be used to  
18 support such research; creating s. 385.212, F.S.;  
19 requiring the Department of Health to establish an  
20 Office of Compassionate Use; authorizing the Office of  
21 Compassionate Use to engage in specified activities;  
22 amending s. 893.02, F.S.; revising the definition of  
23 the term "cannabis" for purposes of the Florida  
24 Comprehensive Drug Abuse Prevention and Control Act  
25 and as applicable to certain criminal offenses  
26 proscribing the sale, manufacture, delivery,

27 possession, dispensing, distribution, or purchase of  
 28 cannabis, to which penalties apply; creating s.  
 29 1004.441, F.S.; authorizing state universities with  
 30 both medical and agricultural programs to conduct  
 31 specified research on cannabidiol and low-THC  
 32 cannabis; citing authority for such research;  
 33 authorizing state or privately obtained research funds  
 34 to be used to support such research; providing an  
 35 appropriation to the Department of Health for research  
 36 of cannabidiol and its effect on intractable childhood  
 37 epilepsy; specifying how biomedical research funding  
 38 for research of cannabidiol and its effect on  
 39 intractable childhood epilepsy shall be awarded;  
 40 specifying who may apply for such funding; providing  
 41 effective dates.

42  
 43 Be It Enacted by the Legislature of the State of Florida:

44  
 45 Section 1. Section 381.986, Florida Statutes, is created  
 46 to read:

47 381.986 Compassionate use of low-THC cannabis.-

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

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

52 (b) "Low-THC cannabis" means a plant of the genus

53 Cannabis, the dried flowers of which contain .8 percent or less  
 54 of tetrahydrocannabinol and more than 10 percent of cannabidiol  
 55 weight for weight; the seeds thereof; the resin extracted from  
 56 any part of such plant; or any compound, manufacture, salt,  
 57 derivative, mixture, or preparation of such plant or its seeds  
 58 or resin and that is dispensed only from a dispensing  
 59 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 who is treating a  
 76 patient suffering from a serious medical condition, including  
 77 but not limited to, treatment for cancer or neurological  
 78 conditions, may order for the patient's medical use low-THC

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

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

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

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

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

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

104 (f) The physician obtains the voluntary informed consent

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

111 (3) PHYSICIAN EDUCATION.—

112 (a) Prior to ordering low-THC cannabis for use by a  
 113 patient in this state, the appropriate board shall require the  
 114 ordering physician licensed under chapter 458 or chapter 459 to  
 115 successfully complete an 8 hour course and subsequent  
 116 examination offered by the Florida Medical Association that will  
 117 encompass the clinical indications for the appropriate use of  
 118 low-THC cannabis, the appropriate delivery mechanisms, the  
 119 contraindications for such use, as well as the relevant state  
 120 and federal laws governing the ordering, dispensing, and  
 121 possessing of this substance. The first course and examination  
 122 shall be presented by October 1, 2014, and shall be administered  
 123 at least annually thereafter. Successful completion of the  
 124 course may be used by a physician to satisfy 8 hours of the  
 125 continuing medical education requirements required by their  
 126 respective board for licensure renewal. This course may be  
 127 offered in a distance learning format.

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

131 (c) Each licensee to whom this section applies shall  
 132 submit confirmation of having completed such course and  
 133 examination on a form provided by the board, when submitting  
 134 fees for every licensure renewal.

135 (d) A physician who fails to comply with this subsection  
 136 and who orders low-THC cannabis may be subject to disciplinary  
 137 action under each respective practice act and under s.  
 138 456.072 (1) (k) .

139 (4) DUTIES OF THE DEPARTMENT.— By January 1, 2015, the  
 140 department shall:

141 (a) Create a secure, electronic, and online compassionate  
 142 use registry for the registration of physicians and patients as  
 143 provided under this section. The registry must be accessible to  
 144 law enforcement agencies and to a dispensing organization in  
 145 order to verify patient authorization for low-THC cannabis and  
 146 record the low-THC cannabis dispensed. The registry must prevent  
 147 an active registration of a patient by multiple physicians.

148 (b) Authorize the establishment of a dispensing  
 149 organization in northwest Florida, northeast Florida, central  
 150 Florida, and south Florida, to ensure reasonable statewide  
 151 accessibility and availability as necessary for patients  
 152 registered in the compassionate use registry and who are ordered  
 153 low-THC cannabis under this section. The department shall  
 154 develop an application form and impose an initial application  
 155 and biennial renewal fee that is sufficient to cover the costs  
 156 of administering this section. An applicant for approval as a

157 dispensing organization must be able to demonstrate:

158 1. The technical and technological ability to cultivate  
 159 and produce low-THC cannabis.

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

162 3. The ability to maintain accountability of all raw  
 163 materials, finished product, and any byproducts to prevent  
 164 diversion or unlawful access to or possession of these  
 165 substances.

166 4. An infrastructure reasonably located to dispense low-  
 167 THC cannabis to registered patients statewide or regionally as  
 168 determined by the department.

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

171 6. That all owners, managers, and employees have been  
 172 fingerprinted and have successfully passed a Level 2 background  
 173 screening pursuant to s. 435.04.

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

178 (d) Adopt rules pursuant to ss. 120.536 and 120.54  
 179 necessary to implement the provisions of this section.

180 (5) DISPENSING ORGANIZATION.—An approved dispensing  
 181 organization shall maintain compliance with the criteria  
 182 demonstrated for selection and approval as a dispensing

183 organization under subsection (4) at all times. Before  
 184 dispensing low-THC cannabis to a qualified patient, the  
 185 dispensing organization shall verify that the patient has an  
 186 active registration in the compassionate use registry, the order  
 187 presented matches the order contents as recorded in the  
 188 registry, and the order has not already been filled. Upon  
 189 dispensing the low-THC cannabis, the dispensing organization  
 190 shall record in the registry the date, time, quantity, and form  
 191 of low-THC cannabis dispensed.

192 (6) EXCEPTIONS TO OTHER SECTIONS OF LAW.—

193 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
 194 any other section of law, but subject to the requirements of  
 195 this section, a qualified patient and the qualified patient's  
 196 legal representative may purchase and possess for the patient's  
 197 medical use up to the amount of low-THC cannabis ordered to the  
 198 patient.

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

208 (c) An approved dispensing organization and its owners,

209 managers, and employees are not subject to licensure or  
 210 regulation under ch. 465 for manufacturing, possessing, selling,  
 211 delivering, distributing, dispensing, or lawfully disposing of  
 212 reasonable quantities, as established by department rule, of  
 213 low-THC cannabis.

214 Section 2. Section 385.211, Florida Statutes, is created  
 215 to read:

216 385.211 Refractory and intractable epilepsy treatment and  
 217 research at recognized medical centers.-

218 (1) For purposes of this section, "low-THC cannabis" means  
 219 a plant of the genus Cannabis, the dried flowers of which  
 220 contain .8 percent or less of tetrahydrocannabinol and more than  
 221 10 percent of cannabidiol weight for weight; the seeds thereof;  
 222 the resin extracted from any part of such plant; or any  
 223 compound, manufacture, salt, derivative, mixture, or preparation  
 224 of such plant or its seeds or resin and that is dispensed only  
 225 from a dispensing organization, as defined in s. 381.986.

226 (2) Notwithstanding chapter 893, medical centers recognized  
 227 pursuant to s. 381.925 may conduct research on cannabidiol and  
 228 low-THC cannabis. This research may include, but is not limited  
 229 to, the agricultural development, production, clinical research,  
 230 and use of liquid medical derivatives of cannabidiol and low-THC  
 231 cannabis for the treatment for refractory or intractable  
 232 epilepsy. The authority for recognized medical centers to  
 233 conduct this research is derived from 21 C.F.R. 312 and 316.

234 Current state or privately obtained research funds may be used  
 235 to support the activities described in this section.

236 Section 3. Section 385.212, Florida Statutes, is created  
 237 to read:

238 385.212 Powers and duties of the Department of Health;  
 239 Office of Compassionate Use.—

240 (1) The Department of Health shall establish an Office of  
 241 Compassionate Use under the direction of the Deputy State Health  
 242 Officer.

243 (2) The Office of Compassionate Use is authorized to  
 244 enhance access to investigational new drugs for Florida patients  
 245 through approved clinical treatment plans or studies. The  
 246 Office of Compassionate Use may:

247 (a) Create a network of State Universities and medical  
 248 centers recognized pursuant to s. 381.925;

249 (b) Make any necessary application to the United States  
 250 Food and Drug Administration or a pharmaceutical manufacturer to  
 251 facilitate enhanced access to compassionate use for Florida  
 252 patients;

253 (c) Enter into any agreements necessary to facilitate  
 254 enhanced access to compassionate use for Florida patients; and

255 (3) The department may adopt rules pursuant to ss. 120.536  
 256 and 120.54 necessary to implement the provisions of this  
 257 section.

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

260 893.02 Definitions.—The following words and phrases as  
 261 used in this chapter shall have the following meanings, unless  
 262 the context otherwise requires:

263 (3) "Cannabis" means all parts of any plant of the genus  
 264 Cannabis, whether growing or not; the seeds thereof; the resin  
 265 extracted from any part of the plant; and every compound,  
 266 manufacture, salt, derivative, mixture, or preparation of the  
 267 plant or its seeds or resin. The term does not include any plant  
 268 of the genus Cannabis, the dried flowers of which contain .8  
 269 percent or less of tetrahydrocannabinol and more than 10 percent  
 270 of cannabidiol weight for weight; the seeds thereof; the resin  
 271 extracted from any part of such plant; or any compound,  
 272 manufacture, salt, derivative, mixture, or preparation of such  
 273 plant or its seeds or resin, if manufactured, possessed, sold,  
 274 purchased, delivered, distributed, or dispensed, in conformance  
 275 with s. 381.986.

276 Section 5. Section 1004.441, Florida Statutes, is created  
 277 to read:

278 1004.441 Refractory and intractable epilepsy treatment and  
 279 research.—

280 (1) For purposes of this section, "low-THC cannabis" means  
 281 a plant of the genus Cannabis, the dried flowers of which  
 282 contain .8 percent or less of tetrahydrocannabinol and more than  
 283 10 percent of cannabidiol weight for weight; the seeds thereof;  
 284 the resin extracted from any part of such plant; or any  
 285 compound, manufacture, salt, derivative, mixture, or preparation

286 of such plant or its seeds or resin and that is dispensed only  
 287 from a dispensing organization, as defined in s. 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. 312 and 316. Current state or  
 298 privately obtained research funds may be used to support the  
 299 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 cannabidiol  
313 and its effect on intractable childhood epilepsy shall be  
314 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 the purposes of this  
320 section, the Biomedical Research Advisory Council created under  
321 s. 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.