



617332

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/23/2014	.	
	.	
	.	
	.	

---

The Committee on Appropriations (Bradley) recommended the following:

**Senate Amendment (with title amendment)**

Delete everything after the enacting clause  
and insert:

Section 1. Section 456.60, Florida Statutes, is created to  
read:

456.60 Compassionate use of low-THC cannabis.—

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

(a) "Dispensing organization" means an organization  
approved by the department to cultivate, process, and dispense



617332

11 low-THC cannabis pursuant to this section.

12 (b) "Low-THC cannabis" means a substance that contains no  
13 more than 0.8 percent of any tetrahydrocannabinol and at least  
14 10 percent cannabidiol and that is dispensed only from a  
15 dispensing organization.

16 (c) "Medical use" means administration of the ordered  
17 amount of low-THC cannabis. The term does not include the  
18 possession, use, or administration by smoking. The term also  
19 does not include the transfer of low-THC cannabis to a person  
20 other than the qualified patient for whom it was ordered or the  
21 qualified patient's legal representative on behalf of the  
22 qualified patient.

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

27 (e) "Smoking" means burning or igniting a substance and  
28 inhaling the smoke. Smoking does not include the use of a  
29 vaporizer.

30 (2) PHYSICIAN ORDERING.—Effective January 1, 2015, a  
31 physician licensed under chapter 458 or chapter 459 who has  
32 examined and treated a patient suffering from a physical medical  
33 condition, or from treatment for a medical condition, which  
34 chronically produces symptoms of seizures or severe and  
35 persistent muscle spasms may order for the patient's medical use  
36 low-THC cannabis to treat or alleviate such symptoms if all of  
37 the following conditions apply:

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

39 (b) The physician has treated the patient for his or her



617332

40 symptoms or a medical condition in which his or her symptoms  
41 were present for at least 2 months.

42 (c) The physician determines the risks of ordering low-THC  
43 cannabis are reasonable in light of the potential benefit for  
44 that patient. If a patient is younger than 18 years of age, a  
45 second physician must concur with this determination, and such  
46 determination must be documented in the patient's medical  
47 record.

48 (d) The physician registers as the orderer of low-THC  
49 cannabis for the named patient on the compassionate use registry  
50 maintained by the department and updates the registry to reflect  
51 the contents of the order. The physician shall inactivate the  
52 patient's registration when treatment is discontinued.

53 (e) The physician maintains a patient treatment plan that  
54 includes the dose, route of administration, planned duration,  
55 and monitoring of the patient's symptoms and other indicators of  
56 tolerance or reaction to the low-THC cannabis.

57 (f) The physician submits the patient treatment plan  
58 quarterly to the University of Florida College of Pharmacy for  
59 research on the safety and efficacy of low-THC cannabis on  
60 patients with such symptoms.

61 (3) PHYSICIAN EDUCATION.—Before ordering low-THC cannabis  
62 for use by a patient in this state, the appropriate board shall  
63 require the ordering physician licensed under chapter 458 or  
64 chapter 459 to successfully complete an 8-hour course and  
65 subsequent examination offered by the Florida Medical  
66 Association which must encompass the clinical indications for  
67 the appropriate use of low-THC cannabis, the appropriate  
68 delivery mechanisms, the contraindications for such use, as well



617332

69 as the relevant state and federal laws governing the ordering,  
70 dispensing, and possessing of such substance. The first course  
71 and examination shall be presented by October 1, 2014, and shall  
72 be administered at least annually thereafter. Successful  
73 completion of the course may be used by a physician to satisfy 8  
74 hours of the continuing medical education requirements required  
75 by his or her respective board for licensure renewal. The course  
76 may be offered in a distance learning format.

77 (4) DUTIES OF THE DEPARTMENT.—

78 (a) By January 1, 2015, the department shall:

79 1. Create a secure, electronic, and online compassionate  
80 use registry for the registration of physicians and patients as  
81 provided under this section. The registry must be accessible to  
82 law enforcement agencies and to a dispensing organization in  
83 order to verify patient authorization for low-THC cannabis and  
84 record the low-THC cannabis dispensed. The registry must prevent  
85 an active registration of a patient by multiple physicians.

86 2. Authorize at least one, but no more than four,  
87 dispensing organizations, to ensure reasonable statewide  
88 accessibility and availability as necessary for patients  
89 registered in the compassionate use registry and who are ordered  
90 low-THC cannabis under this section. The department shall  
91 develop an application form and impose an initial application  
92 and biennial renewal fee that is sufficient to cover the costs  
93 of administering this section. An applicant for approval as a  
94 dispensing organization must be able to demonstrate:

95 a. The technical and technological ability to cultivate and  
96 produce low-THC cannabis.

97 b. The ability to secure the premises, resources, and



617332

98 personnel necessary to operate as a dispensing organization.

99 c. The ability to maintain accountability of all raw  
100 materials, finished product, and any byproducts to prevent  
101 diversion or unlawful access to or possession of these  
102 substances.

103 d. An infrastructure reasonably located to dispense low-THC  
104 cannabis to registered patients statewide or regionally as  
105 determined by the department.

106 e. The financial ability to maintain operations for the  
107 duration of the 2-year approval cycle.

108 f. That all owners, managers, and employees have been  
109 fingerprinted and successfully passed background screening  
110 pursuant to s. 435.04.

111 3. Implement a process for timely issuing identification  
112 cards to patients registered in the compassionate use registry.  
113 The identification card expires 1 year after the date issued. A  
114 new identification card may be issued to a patient for whom a  
115 physician continues registration and treatment with low-THC  
116 cannabis.

117 (b) The department shall monitor physician registration and  
118 the ordering of low-THC cannabis for ordering practices that  
119 could facilitate unlawful diversion or misuse of low-THC  
120 cannabis, and take disciplinary action as indicated.

121 (c) The department shall monitor and inspect the activities  
122 of each approved dispensing organization for compliance with  
123 this section.

124 (d) The department may adopt rules pertaining to:

125 1. The submission of relevant information to the  
126 compassionate use registry in order to issue patient



617332

127 identification cards; and  
128 2. Recordkeeping requirements to demonstrate compliance  
129 with this section, including maintaining records for the  
130 production and finished product testing of low-THC cannabis.  
131 (e) The department shall establish the Office of  
132 Compassionate Use under the direction of the Deputy State Health  
133 Officer to administer this section, including access to the  
134 compassionate use registry under ss. 385.30 and 456.61.  
135 (5) DISPENSING ORGANIZATION.—  
136 (a) An approved dispensing organization shall:  
137 1. Maintain compliance with the criteria demonstrated for  
138 selection and approval under subparagraph (4) (a)2. as a  
139 dispensing organization at all times;  
140 2. Maintain and make records available for inspection and  
141 desk review by the department and law enforcement agencies; and  
142 3. Make all premises, resources, raw materials, finished  
143 product, byproducts, and vehicles available for inspection by  
144 the department and law enforcement agencies.  
145 (b) Before dispensing low-THC cannabis to a qualified  
146 patient, the dispensing organization shall verify that the  
147 patient has an active registration in the compassionate use  
148 registry, the order presented matches the order contents as  
149 recorded in the registry, and the order has not already been  
150 filled. Upon dispensing the low-THC cannabis, the dispensing  
151 organization shall record in the registry the date, time,  
152 quantity, and form of low-THC cannabis dispensed.  
153 (6) EXCEPTIONS TO OTHER SECTIONS OF LAW.—  
154 (a) Notwithstanding any other section of law, but subject  
155 to the requirements of this section, a qualified patient and the



617332

156 qualified patient's legal representative may purchase, acquire,  
157 and possess for the patient's medical use up to the amount of  
158 low-THC cannabis ordered to the patient.

159 (b) Notwithstanding any other section of law, but subject  
160 to the requirements of this section, an approved dispensing  
161 organization and its owners, managers, and employees may  
162 acquire, possess, cultivate, and lawfully dispose of excess  
163 product in reasonable quantities to produce low-THC cannabis and  
164 possess, process, and dispense low-THC cannabis.

165 (c) An approved dispensing organization is not subject to  
166 licensure and regulation under chapter 465, and the owners,  
167 managers, and employees of a dispensing organization are not  
168 subject to licensure and regulation for the practice of pharmacy  
169 under chapter 465.

170 Section 2. Section 385.30, Florida Statutes, is created to  
171 read:

172 385.30 State university participation in approved studies  
173 and clinical treatment plans.—

174 (1) All state universities with both medical and  
175 agricultural research programs, including those that have  
176 satellite campuses or research agreements with other similar  
177 institutions, are encouraged to develop or participate in  
178 Federal Drug Administration-approved studies and clinical  
179 research treatment plans using low-THC cannabis as defined in s.  
180 456.60 which are directed toward refractory or intractable  
181 epilepsy relief in pediatric patients as authorized by s.  
182 1004.441.

183 (2) Each state university that is selected to participate  
184 in a Federal Drug Administration-approved study or clinical



617332

185 treatment plan described in subsection (1) may request from the  
186 Department of Health a grant of up to \$100,000 annually.

187 (3) To be eligible for the annual grant, the participating  
188 medical college or medical school must submit a report to the  
189 Department of Health by January 1 of each year which contains,  
190 at a minimum:

191 (a) The gender and age of each patient participating in the  
192 study or clinical treatment plan during the calendar year;

193 (b) The names of participating physicians; and

194 (c) The level of seizure reduction in each participating  
195 patient during the calendar year.

196 (4) The grant award decisions of the Department of Health  
197 pursuant to this section are not subject to chapter 120.

198 Section 3. Section 1004.441, Florida Statutes, is created  
199 to read:

200 1004.441 Refractory and intractable epilepsy treatment and  
201 research.—Notwithstanding chapter 893, state universities with  
202 both medical and agricultural research programs, including those  
203 that have satellite campuses or research agreements with other  
204 similar institutions, may conduct research on low-THC cannabis  
205 as defined in s. 456.60. This research may include, but is not  
206 limited to, the agricultural development, production, clinical  
207 research, and use of liquid medical derivatives of low-THC  
208 cannabis for the treatment for refractory or intractable  
209 epilepsy. Current state or privately obtained research funds may  
210 be used to support the activities authorized by this section.

211 Section 4. The Department of Health may submit a budget  
212 amendment request using excess funds from the Biomedical  
213 Research Trust Fund to implement this act during the 2014-2015





617332

214 state fiscal year.

215 Section 5. This act shall take effect July 1, 2014.

216

217 ===== T I T L E A M E N D M E N T =====

218 And the title is amended as follows:

219 Delete everything before the enacting clause  
220 and insert:

221 A bill to be entitled  
222 An act relating to low-THC cannabis; creating s.  
223 456.60, F.S.; defining terms; authorizing specified  
224 physicians to order low-THC cannabis for use by  
225 specified patients; providing conditions; providing  
226 education requirements for physicians; providing  
227 duties of the Department of Health; requiring the  
228 department to create a compassionate use registry;  
229 providing requirements for the registry; requiring the  
230 department to authorize a specified number of  
231 dispensing organizations; authorizing the department  
232 to adopt specified rules; requiring the department to  
233 establish the Office of Compassionate Use; providing  
234 for inspections of dispensing organizations by the  
235 department and law enforcement agencies; providing  
236 requirements and duties for a dispensing organization;  
237 providing exceptions to specified laws; creating s.  
238 385.30, F.S.; encouraging state universities with both  
239 medical and agricultural programs to participate in  
240 specified Federal Drug Administration-approved  
241 research directed toward refractory or intractable  
242 epilepsy relief in pediatric patients; authorizing



617332

243 participating state universities to annually request a  
244 grant from the department; requiring a state  
245 university that requests a grant to submit a specified  
246 report to the department; providing applicability;  
247 creating s. 1004.441, F.S.; authorizing state  
248 universities with both medical and agricultural  
249 programs to conduct specified research on low-THC  
250 cannabis; authorizing the use of current state or  
251 privately obtained research funds to support such  
252 research; authorizing the department to submit a  
253 budget amendment request to use excess funds in the  
254 Biomedical Research Trust Fund to implement this act;  
255 providing an effective date.