



617332

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/22/2014	.	
	.	
	.	
	.	

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.