

**By** the Committees on Appropriations; and Health Policy; and Senators Bradley, Bean, Brandes, Galvano, Sobel, Soto, Gardiner, Stargel, and Simpson

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1                                   A bill to be entitled  
2       An act relating to low-THC cannabis; creating s.  
3       456.60, F.S.; defining terms; authorizing specified  
4       physicians to order low-THC cannabis for use by  
5       specified patients; providing conditions; providing  
6       education requirements for physicians; providing  
7       duties of the Department of Health; requiring the  
8       department to create a compassionate use registry;  
9       providing requirements for the registry; requiring the  
10      department to authorize a specified number of  
11      dispensing organizations; authorizing the department  
12      to adopt specified rules; requiring the department to  
13      establish the Office of Compassionate Use; providing  
14      for inspections of dispensing organizations by the  
15      department and law enforcement agencies; providing  
16      requirements and duties for a dispensing organization;  
17      providing exceptions to specified laws; creating s.  
18      385.30, F.S.; encouraging state universities with both  
19      medical and agricultural programs to participate in  
20      specified Federal Food and Drug Administration-  
21      approved research directed toward refractory or  
22      intractable epilepsy relief in pediatric patients;  
23      authorizing participating state universities to  
24      annually request a grant from the department;  
25      requiring a state university that requests a grant to  
26      submit a specified report to the department; providing  
27      applicability; creating s. 1004.441, F.S.; authorizing  
28      state universities with both medical and agricultural  
29      programs to conduct specified research on low-THC

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30 cannabis; authorizing the use of current state or  
31 privately obtained research funds to support such  
32 research; authorizing the department to submit a  
33 budget amendment request to use excess funds in the  
34 Biomedical Research Trust Fund to implement this act;  
35 providing an effective date.  
36

37 Be It Enacted by the Legislature of the State of Florida:  
38

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

41 456.60 Compassionate use of low-THC cannabis.—

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

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

46 (b) "Low-THC cannabis" means a substance that contains no  
47 more than 0.8 percent of any tetrahydrocannabinol and at least  
48 10 percent cannabidiol and that is dispensed only from a  
49 dispensing organization.

50 (c) "Medical use" means administration of the ordered  
51 amount of low-THC cannabis. The term does not include the  
52 possession, use, or administration by smoking. The term also  
53 does not include the transfer of low-THC cannabis to a person  
54 other than the qualified patient for whom it was ordered or the  
55 qualified patient's legal representative on behalf of the  
56 qualified patient.

57 (d) "Qualified patient" means a resident of this state who  
58 has been added to the compassionate use registry by a physician

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59 licensed under chapter 458 or chapter 459 to receive low-THC  
60 cannabis from a dispensing organization.

61 (e) "Smoking" means burning or igniting a substance and  
62 inhaling the smoke. Smoking does not include the use of a  
63 vaporizer.

64 (2) PHYSICIAN ORDERING.—Effective January 1, 2015, a  
65 physician licensed under chapter 458 or chapter 459 who has  
66 examined and treated a patient suffering from a physical medical  
67 condition, or from treatment for a medical condition, which  
68 chronically produces symptoms of seizures or severe and  
69 persistent muscle spasms may order for the patient's medical use  
70 low-THC cannabis to treat or alleviate such symptoms if all of  
71 the following conditions apply:

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

73 (b) The physician has treated the patient for his or her  
74 symptoms or a medical condition in which his or her symptoms  
75 were present for at least 2 months.

76 (c) The physician determines the risks of ordering low-THC  
77 cannabis are reasonable in light of the potential benefit for  
78 that patient. If a patient is younger than 18 years of age, a  
79 second physician must concur with this determination, and such  
80 determination must be documented in the patient's medical  
81 record.

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

87 (e) The physician maintains a patient treatment plan that

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88 includes the dose, route of administration, planned duration,  
89 and monitoring of the patient's symptoms and other indicators of  
90 tolerance or reaction to the low-THC cannabis.

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

95 (3) PHYSICIAN EDUCATION.—Before ordering low-THC cannabis  
96 for use by a patient in this state, the appropriate board shall  
97 require the ordering physician licensed under chapter 458 or  
98 chapter 459 to successfully complete an 8-hour course and  
99 subsequent examination offered by the Florida Medical  
100 Association which must encompass the clinical indications for  
101 the appropriate use of low-THC cannabis, the appropriate  
102 delivery mechanisms, the contraindications for such use, as well  
103 as the relevant state and federal laws governing the ordering,  
104 dispensing, and possessing of such substance. The first course  
105 and examination shall be presented by October 1, 2014, and shall  
106 be administered at least annually thereafter. Successful  
107 completion of the course may be used by a physician to satisfy 8  
108 hours of the continuing medical education requirements required  
109 by his or her respective board for licensure renewal. The course  
110 may be offered in a distance learning format.

111 (4) DUTIES OF THE DEPARTMENT.—

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

113 1. Create a secure, electronic, and online compassionate  
114 use registry for the registration of physicians and patients as  
115 provided under this section. The registry must be accessible to  
116 law enforcement agencies and to a dispensing organization in

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117 order to verify patient authorization for low-THC cannabis and  
118 record the low-THC cannabis dispensed. The registry must prevent  
119 an active registration of a patient by multiple physicians.

120 2. Authorize at least one, but no more than four,  
121 dispensing organizations, to ensure reasonable statewide  
122 accessibility and availability as necessary for patients  
123 registered in the compassionate use registry and who are ordered  
124 low-THC cannabis under this section. The department shall  
125 develop an application form and impose an initial application  
126 and biennial renewal fee that is sufficient to cover the costs  
127 of administering this section. An applicant for approval as a  
128 dispensing organization must be able to demonstrate:

129 a. The technical and technological ability to cultivate and  
130 produce low-THC cannabis.

131 b. The ability to secure the premises, resources, and  
132 personnel necessary to operate as a dispensing organization.

133 c. The ability to maintain accountability of all raw  
134 materials, finished product, and any byproducts to prevent  
135 diversion or unlawful access to or possession of these  
136 substances.

137 d. An infrastructure reasonably located to dispense low-THC  
138 cannabis to registered patients statewide or regionally as  
139 determined by the department.

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

142 f. That all owners, managers, and employees have been  
143 fingerprinted and successfully passed background screening  
144 pursuant to s. 435.04.

145 3. Implement a process for timely issuing identification

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146 cards to patients registered in the compassionate use registry.  
147 The identification card expires 1 year after the date issued. A  
148 new identification card may be issued to a patient for whom a  
149 physician continues registration and treatment with low-THC  
150 cannabis.

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

155 (c) The department shall monitor and inspect the activities  
156 of each approved dispensing organization for compliance with  
157 this section.

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

159 1. The submission of relevant information to the  
160 compassionate use registry in order to issue patient  
161 identification cards; and

162 2. Recordkeeping requirements to demonstrate compliance  
163 with this section, including maintaining records for the  
164 production and finished product testing of low-THC cannabis.

165 (e) The department shall establish the Office of  
166 Compassionate Use under the direction of the Deputy State Health  
167 Officer to administer this section, including access to the  
168 compassionate use registry under s. 456.61, and s. 385.30.

169 (5) DISPENSING ORGANIZATION.—

170 (a) An approved dispensing organization shall:

171 1. Maintain compliance with the criteria demonstrated for  
172 selection and approval under subparagraph (4) (a)2. as a  
173 dispensing organization at all times;

174 2. Maintain and make records available for inspection and

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175 desk review by the department and law enforcement agencies; and

176 3. Make all premises, resources, raw materials, finished  
177 product, byproducts, and vehicles available for inspection by  
178 the department and law enforcement agencies.

179 (b) Before dispensing low-THC cannabis to a qualified  
180 patient, the dispensing organization shall verify that the  
181 patient has an active registration in the compassionate use  
182 registry, the order presented matches the order contents as  
183 recorded in the registry, and the order has not already been  
184 filled. Upon dispensing the low-THC cannabis, the dispensing  
185 organization shall record in the registry the date, time,  
186 quantity, and form of low-THC cannabis dispensed.

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

188 (a) Notwithstanding any other section of law, but subject  
189 to the requirements of this section, a qualified patient and the  
190 qualified patient's legal representative may purchase, acquire,  
191 and possess for the patient's medical use up to the amount of  
192 low-THC cannabis ordered to the patient.

193 (b) Notwithstanding any other section of law, but subject  
194 to the requirements of this section, an approved dispensing  
195 organization and its owners, managers, and employees may  
196 acquire, possess, cultivate, and lawfully dispose of excess  
197 product in reasonable quantities to produce low-THC cannabis and  
198 possess, process, and dispense low-THC cannabis.

199 (c) An approved dispensing organization is not subject to  
200 licensure and regulation under chapter 465, and the owners,  
201 managers, and employees of a dispensing organization are not  
202 subject to licensure and regulation for the practice of pharmacy  
203 under chapter 465.

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204 Section 2. Section 385.30, Florida Statutes, is created to  
205 read:

206 385.30 State university participation in approved studies  
207 and clinical treatment plans.-

208 (1) All state universities with both medical and  
209 agricultural research programs, including those that have  
210 satellite campuses or research agreements with other similar  
211 institutions, are encouraged to develop or participate in  
212 Federal Food and Drug Administration-approved studies and  
213 clinical research treatment plans using low-THC cannabis as  
214 defined in s. 456.60 which are directed toward refractory or  
215 intractable epilepsy relief in pediatric patients as authorized  
216 by s. 1004.441.

217 (2) Each state university that is selected to participate  
218 in a Federal Food and Drug Administration-approved study or  
219 clinical treatment plan described in subsection (1) may request  
220 from the Department of Health a grant of up to \$100,000  
221 annually.

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

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

228 (b) The names of participating physicians; and

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

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



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233 Section 3. Section 1004.441, Florida Statutes, is created  
234 to read:

235 1004.441 Refractory and intractable epilepsy treatment and  
236 research.—Notwithstanding chapter 893, state universities with  
237 both medical and agricultural research programs, including those  
238 that have satellite campuses or research agreements with other  
239 similar institutions, may conduct research on low-THC cannabis  
240 as defined in s. 456.60. This research may include, but is not  
241 limited to, the agricultural development, production, clinical  
242 research, and use of liquid medical derivatives of low-THC  
243 cannabis for the treatment for refractory or intractable  
244 epilepsy. Current state or privately obtained research funds may  
245 be used to support the activities authorized by this section.

246 Section 4. The Department of Health may submit a budget  
247 amendment request using excess funds from the Biomedical  
248 Research Trust Fund to implement this act during the 2014-2015  
249 state fiscal year.

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