Bill No. CS/CS/SB 1030 (2014)

	Amendment No.
	CHAMBER ACTION
	Senate House
	·
1	Representative Harrell offered the following:
2	
3	Substitute Amendment for Amendment (252453) (with title
4	amendment)
5	Remove everything after the enacting clause and insert:
6	Section 1. This act may be cited as the "Refractory and
7	Intractable Epilepsy Relief Act."
8	Section 2. Findings and intent
9	(1) Patients, especially those with critical medical
10	conditions, should have lawful access to participation in
11	studies and clinical treatment plans approved by the United
12	States Food and Drug Administration.
13	(2) In the case of purported medications claiming relief
14	properties from extreme medical conditions, the use of expanded
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15	access referred to as "compassionate use," a process which is
16	outlined by the United States Food and Drug Administration,
17	should be encouraged.
18	(3) Compassionate use is often the only available
19	treatment for patients with a serious disease or condition who
20	have found no satisfactory alternative.
21	(4) Patients 18 years of age or younger who are diagnosed
22	with refractory or intractable epilepsy are candidates for
23	compassionate use.
24	(5) Participation in studies and clinical treatment plans
25	approved by the United States Food and Drug Administration for
26	the treatment of refractory or intractable epilepsy in pediatric
27	patients by state universities with medical and agricultural
28	research programs would enhance access to compassionate use for
29	patients in this state and should be encouraged.
30	Section 3. Section 385.212, Florida Statutes, is created
31	to read:
32	385.212 Powers and duties of the Department of Health;
33	Office of Compassionate Use
34	(1) The Department of Health shall establish an Office of
35	Compassionate Use under the direction of the Deputy State Health
36	Officer.
37	(2) The Office of Compassionate Use may enhance access to
38	investigational new drugs for Florida patients through approved
39	clinical treatment plans or studies. The Office of Compassionate
40	Use may:
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41	(a) Create a network of state universities and medical
42	centers recognized pursuant to s. 381.925.
43	(b) Make any necessary application to the United States
44	Food and Drug Administration or a pharmaceutical manufacturer to
45	facilitate enhanced access to compassionate use for Florida
46	patients.
47	(c) Enter into any agreements necessary to facilitate
48	enhanced access to compassionate use for Florida patients.
49	(3) The department may adopt rules necessary to implement
50	this section.
51	Section 4. Section 385.30, Florida Statutes, is created to
52	read:
53	385.30 State university participation in approved studies
54	and clinical treatment plans
55	(1) All state universities with both medical and
56	agricultural research programs, including those that have
57	satellite campuses or research agreements with other similar
58	institutions, are encouraged to develop or participate in United
59	States Food and Drug Administration-approved studies and
60	clinical research treatment plans directed toward refractory or
61	intractable epilepsy relief in pediatric patients as authorized
62	by s. 1004.441.
63	(2) Each state university that is selected to participate
64	in a United States Food and Drug Administration-approved study
65	or clinical treatment plan described in subsection (1) may
66	request from the Department of Health, notwithstanding any other
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67	related grants or appropriations, a grant of up to \$100,000
68	annually.
69	(3) Each university must ensure that all physicians
70	associated with the study or treatment plan participate in the
71	refractory epilepsy relief registry described in s. 358.32.
72	(4) To be eligible for the annual grant, the participating
73	medical college or medical school must submit a report to the
74	Department of Health by January 1 of each year which contains,
75	at a minimum:
76	(a) The gender and age of each patient participating in
77	the study or clinical treatment plan during the calendar year;
78	(b) The names of participating physicians; and
79	(c) The level of seizure reduction in each participating
80	patient during the calendar year.
81	(5) The grant award decisions of the Department of Health
82	pursuant to this section are not subject to chapter 120.
83	Section 5. Section 385.31, Florida Statutes, is created to
84	read:
85	385.31 Refractory epilepsy patient relief and
86	eligibility.—Notwithstanding any provision of chapter 893, a
87	patient deemed eligible for participation in an investigational
88	new drug study or treatment plan that has been approved by the
89	United States Food and Drug Administration may be prescribed all
90	medications, including canabidiol, approved as part of such a
91	study or treatment plan.

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93read:94385.32 Refractory epilepsy relief registry95(1) The Department of Health shall create a refractory96epilepsy relief registry for the registration of physicians and97patients as provided under this section. The registry must98prevent an active registration of a patient by multiple99physicians.100(2) Each physician participating in an investigational new101drug study or treatment plan approved by the United States Food102and Drug Administration must submit the patient's name, age, and103gender; specific indication for each prescription; date of104diagnosis; treatment dosage; and date of prescription to the105registry each month that the patient participates in a study or106treatment plan for which he or she receives a medication that he107or she would not have been eligible to receive but for s.118385.31.119(3) The department shall protect the confidentiality of111all patients listed in the registry to the extent permitted by112law. All records containing the identity of patients shall be113shall keep such records from public disclosure, other than for114valid medical or law enforcement purposes, to the extent115permitted by law.116Section 7. Section 456.601, Florida Statutes, is created117to read:401099	92	Section 6. Section 385.32, Florida Statutes, is created to
95 (1) The Department of Health shall create a refractory 96 epilepsy relief registry for the registration of physicians and 97 patients as provided under this section. The registry must 98 prevent an active registration of a patient by multiple 99 physicians. 100 (2) Each physician participating in an investigational new 101 drug study or treatment plan approved by the United States Food 102 and Drug Administration must submit the patient's name, age, and 103 gender; specific indication for each prescription; date of 104 diagnosis; treatment dosage; and date of prescription to the 105 registry each month that the patient participates in a study or 106 treatment plan for which he or she receives a medication that he 107 or she would not have been eligible to receive but for s. 108 385.31. 109 (3) The department shall protect the confidentiality of 110 all patients listed in the registry to the extent permitted by 111 law. All records containing the identity of patients shall be 112 confidential to the extent permitted by law and the department 113 shall keep such records from public disclosure, other than for 114 valid medical or law enforcement purposes, to the extent 115 permitted by law. 116 Section 7. Section 456.601, Florida Statutes, is created 117 to read:	93	read:
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<pre>gender; specific indication for each prescription; date of diagnosis; treatment dosage; and date of prescription to the registry each month that the patient participates in a study or treatment plan for which he or she receives a medication that he or she would not have been eligible to receive but for s. 385.31. (3) The department shall protect the confidentiality of all patients listed in the registry to the extent permitted by law. All records containing the identity of patients shall be confidential to the extent permitted by law and the department shall keep such records from public disclosure, other than for valid medical or law enforcement purposes, to the extent permitted by law. Section 7. Section 456.601, Florida Statutes, is created to read:</pre>	101	drug study or treatment plan approved by the United States Food
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108 <u>385.31.</u> (3) The department shall protect the confidentiality of all patients listed in the registry to the extent permitted by law. All records containing the identity of patients shall be confidential to the extent permitted by law and the department shall keep such records from public disclosure, other than for valid medical or law enforcement purposes, to the extent permitted by law. Section 7. Section 456.601, Florida Statutes, is created to read:	106	treatment plan for which he or she receives a medication that he
109 (3) The department shall protect the confidentiality of all patients listed in the registry to the extent permitted by law. All records containing the identity of patients shall be confidential to the extent permitted by law and the department shall keep such records from public disclosure, other than for valid medical or law enforcement purposes, to the extent permitted by law. Section 7. Section 456.601, Florida Statutes, is created to read:	107	or she would not have been eligible to receive but for s.
110 all patients listed in the registry to the extent permitted by 111 law. All records containing the identity of patients shall be 112 confidential to the extent permitted by law and the department 113 shall keep such records from public disclosure, other than for 114 valid medical or law enforcement purposes, to the extent 115 permitted by law. 116 Section 7. Section 456.601, Florida Statutes, is created 117 to read:	108	<u>385.31.</u>
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113 <u>shall keep such records from public disclosure, other than for</u> 114 <u>valid medical or law enforcement purposes, to the extent</u> 115 <u>permitted by law.</u> 116 Section 7. Section 456.601, Florida Statutes, is created 117 to read:	111	law. All records containing the identity of patients shall be
<pre>114 valid medical or law enforcement purposes, to the extent 115 permitted by law. 116 Section 7. Section 456.601, Florida Statutes, is created 117 to read:</pre>	112	confidential to the extent permitted by law and the department
<pre>115 permitted by law. 116 Section 7. Section 456.601, Florida Statutes, is created 117 to read:</pre>	113	shall keep such records from public disclosure, other than for
116 Section 7. Section 456.601, Florida Statutes, is created 117 to read:	114	valid medical or law enforcement purposes, to the extent
117 to read:	115	permitted by law.
	116	Section 7. Section 456.601, Florida Statutes, is created
401099	117	to read:
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Amendment No.

	Amendment No.
118	456.601 Use of cannabidiol for refractory or intractable
119	epilepsy; documentationA medical doctor licensed under chapter
120	458 or a doctor of osteopathic medicine licensed under chapter
121	459 who prescribes cannabidiol to a patient 18 years of age or
122	younger for refractory or intractable epilepsy must provide
123	written documentation affirming that the patient has been
124	diagnosed with refractory or intractable epilepsy and may
125	benefit from the medical use of cannabidiol.
126	Section 8. Section 1004.441, Florida Statutes, is created
127	to read:
128	1004.441 Refractory and intractable epilepsy treatment and
129	research
130	(1) Notwithstanding chapter 893, state universities with
131	both medical and agricultural research programs, including those
132	that have satellite campuses or research agreements with other
133	similar institutions, may conduct research on cannabidiol. This
134	research may include, but is not limited to, the agricultural
135	development, production, manufacture, dispensing, clinical
136	research, and use of liquid medical derivatives of cannabidiol
137	for the treatment of refractory or intractable epilepsy.
138	(2) A state university that meets the criteria in s.
139	385.30 or s. 1004.441 that cultivates or delivers cannabidiol
140	and any derivatives of cannabidiol shall adhere to rules adopted
141	to assure the identity, strength, quality and purity of products
142	and must be prepared according to applicable current good

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143	manufacturing practices in accordance with chapter 499 and 21
144	<u>C.F.R. part 211.</u>
145	(3) The authority for state universities to conduct this
146	research is derived from 21 C.F.R. parts 312 and 316. Current
147	state or privately obtained research funds may be used to
148	support the activities authorized by this section.
149	(4) The department of health shall adopt rules to
150	implement this section.
151	(5) This section expires June 30, 2016, unless reenacted
152	by the Legislature before that date.
153	Section 9. This act shall take effect July 1, 2014.
154	
155	
156	TITLE AMENDMENT
157	Remove everything before the enacting clause and insert:
158	A bill to be entitled
159	An act relating to refractory and intractable epilepsy
160	treatment and research; providing a short title;
160 161	treatment and research; providing a short title; providing findings and intent; creating s. 385.212,
161	providing findings and intent; creating s. 385.212,
161 162	providing findings and intent; creating s. 385.212, F.S.; requiring the Department of Health to establish
161 162 163	providing findings and intent; creating s. 385.212, F.S.; requiring the Department of Health to establish an Office of Compassionate Use; authorizing the office
161 162 163 164	providing findings and intent; creating s. 385.212, F.S.; requiring the Department of Health to establish an Office of Compassionate Use; authorizing the office to engage in specified activities; authorizing
161 162 163 164 165	providing findings and intent; creating s. 385.212, F.S.; requiring the Department of Health to establish an Office of Compassionate Use; authorizing the office to engage in specified activities; authorizing rulemaking; creating s. 385.30, F.S.; authorizing
161 162 163 164 165 166	providing findings and intent; creating s. 385.212, F.S.; requiring the Department of Health to establish an Office of Compassionate Use; authorizing the office to engage in specified activities; authorizing rulemaking; creating s. 385.30, F.S.; authorizing certain medical centers to conduct research studies

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169	state or privately obtained research funds to be used
170	to support such research; creating s. 385.31, F.S.;
171	providing that, notwithstanding chapter 893, F.S.,
172	patients deemed eligible for participation in United
173	States Food and Drug Administration-approved
174	investigational new drug studies or treatment plans
175	may be prescribed all approved medications; creating
176	s. 385.32, F.S.; requiring the department to create
177	the refractory epilepsy relief registry; providing
178	requirements for the registry; providing for
179	confidentiality to the extent permitted by law;
180	creating s. 456.601, F.S.; requiring physicians
181	prescribing cannabidiol to certain patients to provide
182	certain documentation; creating s. 1004.441, F.S.;
183	authorizing state universities with both medical and
184	agricultural research programs to conduct specified
185	research on cannabidiol; requiring universities that
186	cultivate or deliver cannabidiol to meet specified
187	standards; authorizing state or privately obtained
188	research funds to be used to support such research;
189	providing for rulemaking; providing an effective date.

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