CHAMBER ACTION

Senate House

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Representative Harrell offered the following:

Substitute Amendment for Amendment (252453) (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. This act may be cited as the "Refractory and Intractable Epilepsy Relief Act."

Section 2. Findings and intent.—

(1) Patients, especially those with critical medical conditions, should have lawful access to participation in studies and clinical treatment plans approved by the United States Food and Drug Administration.

(2) In the case of purported medications claiming relief properties from extreme medical conditions, the use of expanded

access referred to as "compassionate use," a process which is outlined by the United States Food and Drug Administration, should be encouraged.

(3) Compassionate use is often the only available treatment for patients with a serious disease or condition who have found no satisfactory alternative.

(4) Patients 18 years of age or younger who are diagnosed with refractory or intractable epilepsy are candidates for compassionate use.

(5) Participation in studies and clinical treatment plans approved by the United States Food and Drug Administration for the treatment of refractory or intractable epilepsy in pediatric patients by state universities with medical and agricultural research programs would enhance access to compassionate use for patients in this state and should be encouraged.

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

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

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

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

(a) Create a network of state universities and medical centers recognized pursuant to s. 381.925.

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

(c) Enter into any agreements necessary to facilitate enhanced access to compassionate use for Florida patients.

(3) The department may adopt rules necessary to implement this section.

Section 4. Section 385.30, Florida Statutes, is created to read:

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

(1) All state universities with both medical and agricultural research programs, including those that have satellite campuses or research agreements with other similar institutions, are encouraged to develop or participate in United States Food and Drug Administration-approved studies and clinical research treatment plans directed toward refractory or intractable epilepsy relief in pediatric patients as authorized by s. 1004.441.

(2) Each state university that is selected to participate in a United States Food and Drug Administration-approved study or clinical treatment plan described in subsection (1) may request from the Department of Health, notwithstanding any other

related grants or appropriations, a grant of up to $100,000 annually.

(3) Each university must ensure that all physicians associated with the study or treatment plan participate in the refractory epilepsy relief registry described in s. 358.32.

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

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

(b) The names of participating physicians; and

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

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

Section 5. Section 385.31, Florida Statutes, is created to read:

385.31 Refractory epilepsy patient relief and eligibility.—Notwithstanding any provision of chapter 893, a patient deemed eligible for participation in an investigational new drug study or treatment plan that has been approved by the United States Food and Drug Administration may be prescribed all medications, including canabidiol, approved as part of such a study or treatment plan.

Section 6. Section 385.32, Florida Statutes, is created to read:

385.32 Refractory epilepsy relief registry.—

(1) The Department of Health shall create a refractory epilepsy relief registry for the registration of physicians and patients as provided under this section. The registry must prevent an active registration of a patient by multiple physicians.

(2) Each physician participating in an investigational new drug study or treatment plan approved by the United States Food and Drug Administration must submit the patient's name, age, and 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:

456.601 Use of cannabidiol for refractory or intractable epilepsy; documentation.—A medical doctor licensed under chapter 458 or a doctor of osteopathic medicine licensed under chapter 459 who prescribes cannabidiol to a patient 18 years of age or younger for refractory or intractable epilepsy must provide written documentation affirming that the patient has been diagnosed with refractory or intractable epilepsy and may benefit from the medical use of cannabidiol.

Section 8. Section 1004.441, Florida Statutes, is created to read:

1004.441 Refractory and intractable epilepsy treatment and research.—

(1) Notwithstanding chapter 893, state universities with both medical and agricultural research programs, including those that have satellite campuses or research agreements with other similar institutions, may conduct research on cannabidiol. This research may include, but is not limited to, the agricultural development, production, manufacture, dispensing, clinical research, and use of liquid medical derivatives of cannabidiol for the treatment of refractory or intractable epilepsy.

(2) A state university that meets the criteria in s. 385.30 or s. 1004.441 that cultivates or delivers cannabidiol and any derivatives of cannabidiol shall adhere to rules adopted to assure the identity, strength, quality and purity of products and must be prepared according to applicable current good

manufacturing practices in accordance with chapter 499 and 21 C.F.R. part 211.

(3) The authority for state universities to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities authorized by this section.

(4) The department of health shall adopt rules to implement this section.

(5) This section expires June 30, 2016, unless reenacted by the Legislature before that date.

Section 9. This act shall take effect July 1, 2014.

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

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to refractory and intractable epilepsy treatment and research; providing a short title; 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 and clinical research treatment plans directed toward refractory or intractable epilepsy relief; authorizing

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