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Indicates New Matter

AMENDED

April 2, 2014

**H. 4803**

Introduced by Reps. Horne, Erickson, Gilliard, Whipper, D.C. Moss, McCoy, K.R. Crawford, Weeks, Cobb‑Hunter and Knight

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Read the first time February 27, 2014.

**A** **BILL**

TO AMEND ARTICLE 4, CHAPTER 53, TITLE 44, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO THE CONTROLLED SUBSTANCES THERAPEUTIC RESEARCH ACT OF 1980, SO AS TO ENACT THE “MEDICAL CANNABIS THERAPEUTIC TREATMENT RESEARCH ACT”, TO ESTABLISH THE MEDICAL CANNABIS THERAPEUTIC TREATMENT RESEARCH PROGRAM AT THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, TO PROVIDE FOR PATIENTS ELIGIBLE TO PARTICIPATE IN THE PROGRAM, TO PROVIDE WHO AND UNDER WHAT CIRCUMSTANCES MEDICAL CANNABIS CAN BE ADMINISTERED TO A PATIENT, TO PROVIDE FOR NOTICE TO A PARTICIPATING PATIENT THAT THE PATIENT WILL BE PARTICIPATING IN A RESEARCH STUDY AND OF THE EXPERIMENTAL NATURE OF THE MEDICAL CANNABIS PROGRAM, TO PROVIDE FOR THE PROTECTION OF A PARTICIPATING PATIENT’S PERSONAL INFORMATION, TO PROVIDE FOR THE OPERATION OF THE PROGRAM BY THE DIRECTOR OF THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, TO PROVIDE REPORTING REQUIREMENTS BY ACADEMIC MEDICAL CENTERS THAT SUPERVISE OR ADMINISTER MEDICAL CANNABIS TREATMENTS, TO PROVIDE CRIMINAL AND CIVIL IMMUNITY FROM STATE ACTIONS OR SUITS ARISING FROM THE PROPER IMPLEMENTATION OF THIS ACT, TO PROVIDE THAT THE STATE SHALL DEFEND STATE EMPLOYEES WHO, IN GOOD FAITH, CARRY OUT THE PROVISIONS OF THIS ACT, AND TO REQUIRE THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL TO COLLABORATE WITH ACADEMIC MEDICAL CENTERS TO ASSIST INTERESTED PATIENTS WITH THE APPLICATION PROCESS TO PARTICIPATE IN EXISTING UNITED STATES FOOD AND DRUG ADMINISTRATION-APPROVED INVESTIGATIONAL NEW DRUG STUDIES CONCERNING MEDICAL CANNABIS.

Amend Title To Conform

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Paragraph 27 of Section 44‑53‑110 of the 1976 Code is amended to read:

“‘Marijuana’ means:

(1) all species or variety of the marijuana plant and all parts thereof whether growing or not;

(2) the seeds of the marijuana plant;

(3) the resin extracted from any part of the marijuana plant;

(4) every compound, manufacture, salt, derivative, mixture, or preparation of the marijuana plant, marijuana seeds, or marijuana resin.

‘Marijuana’ does not mean:

(1) the mature stalks of the marijuana plant or fibers produced from these stalks;

(2) oil or cake made from the seeds of the marijuana plant, including cannabidiol derived from the seeds of the marijuana plant;

(3) any other compound, manufacture, salt, derivatives, mixture, or preparation of the mature stalks (except the resin extracted therefrom), including cannabidiol derived from mature stalks ;

(4) the sterilized seed of the marijuana plant which is incapable of germination;

(5) for persons participating in a clinical trial or in an expanded access program related to administering cannabidiol for the treatment of severe forms of epilepsy pursuant to Article 18, Chapter 53, Title 44, a drug or substance approved for the use of those participants by the federal Food and Drug Administration;

(6) for persons, or the persons’ parents, legal guardians, or other caretakers, who have received a written certification from a physician licensed in this State that the person has been diagnosed by a physician as having Lennox Gastaut Syndrome, Dravet Syndrome, also known as ‘severe myoclonic epilepsy of infancy’, or any other severe form of epilepsy that is not adequately treated by traditional medical therapies, the substance cannabidiol, a nonpsychoactive cannabinoid, or any compound, manufacture, salt, derivative, mixture, or preparation of any plant of the genus cannabis that contains three‑tenths of one percent or less of tetrahydrocannabinol and more than fifteen percent of cannabidiol.

(a) For purposes of this item, written certification means a document dated and signed by a physician stating that the patient has been diagnosed with Lennox Gastaut Syndrome, Dravet Syndrome, also known as ‘severe myoclonic epilepsy of infancy’, or any other severe form of epilepsy that is not adequately treated by traditional medical therapies and the physician’s conclusion that the patient might benefit from the medical use of cannabidiol.

(b) A physician is not subject to detrimental action, including arrest, prosecution, penalty, denial of a right or privilege, civil penalty, or disciplinary action by a professional licensing board for providing written certification for the medical use of cannabidiol to a patient in accordance with this section.”

SECTION 2. Chapter 53, Title 44 of the 1976 Code is amended by adding:

“Article 18

Julian’s Law

Section 44‑53‑1810. As used in this article:

(1) ‘Academic Medical Center’ means a research hospital that operates a medical residency program for physicians and conducts research that involves human subjects.

(2) ‘Approved source’ means a provider approved by the federal Food and Drug Administration which produces cannabidiol that:

(a) has been manufactured and tested in a facility approved or certified by the federal Food and Drug Administration or similar national regulatory agency in another country, which has been approved by the federal Food and Drug Administration; and

(b) has been tested in animals to demonstrate preliminary effectiveness and to ensure that it is safe to administer to humans.

(3) ‘Cannabidiol’ means a finished preparation containing, of its total cannabinoid content, at least ninety‑eight percent cannabidiol and no more than three‑tenths of one percent tetrahydrocannabinol that has been extracted from marijuana or synthesized in a laboratory.

(4) ‘Physician’ means a doctor of medicine or doctor of osteopathic medicine licensed by the South Carolina Board of Medical Examiners.

(5) ‘Qualifying Patient’ means anyone who suffers from Lennox‑Gastaut Syndrome, Dravet Syndrome, also known as severe myoclonic epilepsy of infancy, or any other form of refractory epilepsy that is not adequately treated by traditional medical therapies.

Section 44‑53‑1820. (A) A statewide investigational new drug application may be established in this State, if approved by the federal Food and Drug Administration, to conduct expanded access clinical trials using cannabidiol on qualifying patients with severe forms of epilepsy.

(B) Any physician who is board certified and practicing in an academic medical center in this State and treating patients with severe forms of epilepsy may serve as the principal investigator for the clinical trials if the physician:

(1) Applies to and is approved by the federal Food and Drug Administration as the

principal investigator in a statewide investigational new drug application; and

(2) receives a license from the federal Drug Enforcement Administration.

(C) a physician acting as principal investigator may include subinvestigators who are also board certified and who practice in an academic medical center in this State and treat patients with severe forms of epilepsy. Subinvestigators also shall comply with subsection (B)(2).

(D) the principal investigator and all subinvestigators shall adhere to the rules and regulations established by the relevant institutional review board for each participating academic medical center and by the federal Food and Drug Administration, federal Drug Enforcement Administration, and the National Institute on Drug Abuse.

Section 44‑53‑1830. (A) Expanded access clinical trials conducted pursuant to a statewide investigational new drug application established pursuant to this article only shall utilize cannabidiol that is:

(1) from an approved source; and

(2) approved by the federal Food and Drug Administration to be used for treatment of a condition specified in an investigational new drug application.

(B) The principal investigator and any subinvestigator may receive cannabidiol directly from an approved source or authorized distributor for an approved source for use in the expanded access clinical trials.

Section 44‑53‑1840. (A) A person acting in compliance with the provisions of this article must not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil penalty or disciplinary action by a professional licensing board, or be denied any right or privilege, for the use, prescription, administration, possession, manufacture, or distribution of medical cannabis.

(B) The State must defend a state employee against a federal claim or suit that arises or by virtue of their good faith performance of official duties pursuant to this article.”

SECTION 3. This act takes effect upon approval by the Governor.

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