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COMMITTEE REPORT

March 20, 2014

**H. 4803**

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

S. Printed 3/20/14--H.

Read the first time February 27, 2014.

**THE COMMITTEE ON JUDICIARY**

To whom was referred a Bill (H. 4803) 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, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass with amendment:

Amend the bill, as and if amended, by striking all after the enacting words and inserting:

/ 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;

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

(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.”

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. /

Renumber sections to conform.

Amend title to conform.

F. GREGORY DELLENEY, JR. for Committee.

**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.

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

SECTION 1. Article 4, Chapter 53, Title 44 of the 1976 Code is amended to read:

“Article 4

~~Controlled Substances~~ Medical Cannabis Therapeutic

Treatment Research

Section 44‑53‑610. This article may be cited as the ‘South Carolina ~~Controlled Substances~~ Medical Cannabis Therapeutic Treatment Research Act ~~of 1980~~’.

Section 44‑53‑620. As used in this article ~~unless the context clearly indicates otherwise~~:

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

(2) ‘Cannabis’ means all strains of cannabis, all tetrahydrocannabinols, or a chemical derivative of any tetrahydrocannabinol.

(3) ‘Department’ means the Department of Health and Environmental Control.

~~(a)~~(4) ‘Director’ means the Director of the Department of Health and Environmental Control~~;~~.

~~(b)~~(5) ~~‘Marijuana’ means marijuana, all tetrahydrocannabinols or a chemical derivative of any tetrahydrocannabinol;~~ ‘Medical cannabis’ means cannabis extracts, compounds or derivatives of cannabis including, but not limited to, cannabidoil, a nonpsychoactive cannabinoid, that is delivered to the patient in a nonsmoking delivery system in the form of a liquid, pill, vaporization, or injection.

~~(c)~~(6) ‘Practitioner’ means a physician licensed to practice medicine in this State and licensed to prescribe and administer drugs ~~which~~ that are subject to regulation under the provisions of Article 3, Chapter 53, ~~of~~ Title 44 ~~of the 1976 Code~~.

Section 44‑53‑630. (A) There is established in the Department of Health and Environmental Control ~~a controlled substances~~ the medical cannabis therapeutic treatment research program, ~~therapeutic research program. The program shall~~ which must be administered by the director and work in conjunction with practitioners and academic medical centers to conduct research concerning medical cannabis as an anti‑seizure medication. ~~The program shall distribute to cancer chemotherapy and radiology patients and to glaucoma patients who are certified pursuant to this article marijuana under the terms and conditions of this article for the purpose of alleviating the patient’s discomfort, nausea and other painful side effects of their disease or chemotherapy treatments. The department shall promulgate regulations necessary for the proper administration of this article and in such promulgation, the department shall take into consideration those pertinent regulations promulgated by the Drug Enforcement Agency, U. S. Department of Justice; Food and Drug Administration; the National Institute on Drug Abuse, and the National Institutes of Health.~~

(B) ~~Except as provided in subsection (c) of Section 44‑53‑640, the~~ The medical cannabis ~~controlled substances~~ therapeutic research program ~~shall~~ must be limited to patients that qualify for United States Food and Drug Administration-approved investigational new drug studies related to utilizing medical cannabis as an antiseizure medication, or other similar federally approved programs. ~~cancer chemotherapy and radiology patients~~ ~~and glaucoma patients, who are certified to the patient qualification review advisory board by a practitioner as being involved in a life‑threatening or sense‑threatening situation and who are not responding to conventional controlled substances or where the conventional controlled substances administered have proven to be effective but where the patient has incurred severe side effects.~~

(C) Treatment, or the supervision of treatment, of patients with medical cannabis, and the associated research, only may be conducted by:

(1) practitioners on the staff of an academic medical center; or

(2) anyone approved by the Food and Drug Administration; or any other appropriate federal agency.

(D) A patient may not be admitted to the program without:

(1) full disclosure by the practitioner treating, or supervising the treatment of, the patient of the experimental nature of the treatment, that the patient will be participating in a research program, and of the possible risks and side effects of the proposed treatment; or

(2) any disclosure required by the Food and Drug Administration; or any other appropriate federal agency.

(E) The name and identifying information or characteristics of a patient participating in the program shall remain confidential and only may be disclosed to a person directly connected with the program who has a legitimate need for the information including, but not limited to, the director, the patient’s attending practitioner, and practitioner, who is treating, or supervising the treatment of, the patient, and any person permitted by federal law.

Section 44‑53‑640. ~~(a)~~ ~~The director shall appoint a Patient Qualification Review Advisory Board to serve at his pleasure. The Patient Qualification Review Advisory Board shall be comprised of:~~

~~(1)~~ ~~a physician licensed to practice medicine in South Carolina and certified by the American Board of Ophthalmology;~~

~~(2)~~ ~~a physician licensed to practice medicine in South Carolina and certified by the American Board of Internal Medicine and also certified in the subspecialty of medical oncology;~~

~~(3)~~ ~~a physician licensed to practice medicine in South Carolina and certified by the American Board of Psychiatry; and~~

~~(4)~~ ~~a pharmacologist holding a Doctoral degree or its equivalent.~~

~~Members of the advisory board shall be paid the usual per diem, mileage and subsistence as provided by law for members of boards, commissions and committees~~.

~~(b)~~(A) The department shall review all applicants for the ~~controlled substances therapeutic~~ research program and determine whether the applicant qualifies for participation in the program. ~~their licensed practitioners and certify their participation in the program.~~

~~(c)~~ The department~~, in its discretion, may include other disease groups for participation in the controlled substances therapeutic research program after pertinent medical data have been presented by a practitioner to both the director and the department and after necessary approval is received by the appropriate federal agencies~~ shall coordinate with academic medical centers to administer the treatment and to conduct the related research. Medical cannabis prescribed for treatment must be safeguarded in the same manner as narcotics prescribed by practitioners.

(B) The academic medical centers in this State shall collaborate to apply for participation in existing Food and Drug Administration-approved studies concerning medical cannabis as an antiseizure medication. The department shall assist the academic medical centers to coordinate their efforts in this regard.

(C) The department must contact the Food and Drug Administration to determine how interested patients may participate in existing United States Food and Drug Administration-approved investigational new drug studies concerning medical cannabis, or similar federally approved programs, being undertaken outside of this State. The department in conjunction with the state’s academic medical centers, if necessary, shall assist interested patients with the application process.

Section 44‑53‑650. ~~(a)~~ The director shall obtain ~~marijuana~~ medical cannabis for use in the program from the Food and Drug Administration or through whatever other means he deems most appropriate and consistent with federal law.

~~(b)~~ ~~The director shall cause such analyzed marijuana to be transferred to various locations throughout the State that provide adequate security as set forth in federal and state regulations for the purpose of distributing such marijuana to the certified patient in such manner as is consistent with federal law. The patient shall not be required to pay for such marijuana but the director may charge for ancillary medical services provided by the department to compensate the department for the cost, if any, of securing such marijuana, and providing it to the patient~~.

Section 44‑53‑660. ~~The director shall annually report to the General Assembly his opinion as to the effectiveness of this program and his recommendations for any changes thereto.~~ Academic medical centers who treat, or supervise the treatment of patients, pursuant to this article shall conduct research on the effects of the treatment in a manner consistent with federal guidelines and any additional guidelines promulgated by the department.

Section 44‑53‑670. (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 44‑53‑680. The department shall promulgate regulations necessary for the proper administration of this article that shall take into consideration pertinent regulations promulgated by the United States Drug Enforcement Administration, the United States Department of Justice, the United States Food and Drug Administration, the National Institute on Drug Abuse, and the National Institutes of Health.”

SECTION 2. This act takes effect upon approval by the Governor.

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