S. 1035

STATUS INFORMATION

General Bill
Sponsors: Senators Davis, Rankin, Shealy, Cleary, L. Martin, Grooms, Bright, Pinckney, Coleman, Bryant and Verdin
Document Path: l:es\td\013medi.kmm.td.docx
Companion/Similar bill(s): 4803

Introduced in the Senate on February 19, 2014
Currently residing in the Senate Committee on Medical Affairs

Summary: Medical Cannabis Therapeutic Treatment Research Act

HISTORY OF LEGISLATIVE ACTIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Body</th>
<th>Action Description with journal page number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/19/2014</td>
<td>Senate</td>
<td>Introduced and read first time (Senate Journal-page 8)</td>
</tr>
<tr>
<td>2/19/2014</td>
<td>Senate</td>
<td>Referred to Committee on Medical Affairs (Senate Journal-page 8)</td>
</tr>
</tbody>
</table>

View the latest legislative information at the website

VERSIONS OF THIS BILL

2/19/2014
A BILL

TO AMEND ARTICLE 4, CHAPTER 53, TITLE 44 OF THE 1976 CODE, RELATING TO THE CONTROLLED SUBSTANCES THERAPEUTIC RESEARCH ACT OF 1980, 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; AND TO PROVIDE CRIMINAL AND CIVIL IMMUNITY FROM STATE ACTIONS OR SUITS ARISING FROM THE PROPER IMPLEMENTATION OF THIS ACT; AND 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 Research
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 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 which shall 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 medical cannabis controlled substances therapeutic research program shall 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 anti-seizure 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, may only 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) No patient may 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 may only be disclosed to any 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 to determine whether the applicant qualifies for participation in the program, their licensed practitioners and certify their participation in the program.

(e) 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 shall 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 anti-seizure 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)(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 shall 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 any 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.

----XX----