

South Carolina General Assembly
120th Session, 2013-2014

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R229, S1035

STATUS INFORMATION

General Bill

Sponsors: Senators Davis, Rankin, Shealy, Cleary, L. Martin, Grooms, Bright, Pinckney, Coleman, Bryant, Verdin and Campbell

Document Path: I:\s-res\td\013medi.kmm.td.docx

Companion/Similar bill(s): 4803

Introduced in the Senate on February 19, 2014

Introduced in the House on April 1, 2014

Last Amended on May 20, 2014

Passed by the General Assembly on May 22, 2014

Summary: Medical Cannabis Therapeutic Treatment Research Act

HISTORY OF LEGISLATIVE ACTIONS

Date	Body	Action Description with journal page number
2/19/2014	Senate	Introduced and read first time (Senate Journal-page 8)
2/19/2014	Senate	Referred to Committee on Medical Affairs (Senate Journal-page 8)
3/20/2014	Senate	Committee report: Favorable with amendment Medical Affairs (Senate Journal-page 14)
3/21/2014		Scrivener's error corrected
3/25/2014	Senate	Committee Amendment Adopted (Senate Journal-page 14)
3/26/2014	Senate	Amended (Senate Journal-page 56)
3/26/2014	Senate	Read second time (Senate Journal-page 56)
3/26/2014	Senate	Roll call Ayes-42 Nays-0 (Senate Journal-page 56)
3/27/2014	Senate	Read third time and sent to House (Senate Journal-page 20)
4/1/2014	House	Introduced and read first time (House Journal-page 13)
4/1/2014	House	Referred to Committee on Medical, Military, Public and Municipal Affairs (House Journal-page 13)
4/2/2014	House	Recalled from Committee on Medical, Military, Public and Municipal Affairs (House Journal-page 101)
4/2/2014	House	Referred to Committee on Judiciary (House Journal-page 101)
5/7/2014	House	Committee report: Favorable with amendment Judiciary (House Journal-page 6)
5/8/2014		Scrivener's error corrected
5/14/2014	House	Amended (House Journal-page 22)
5/14/2014	House	Read second time (House Journal-page 22)
5/14/2014	House	Roll call Yeas-78 Nays-19 (House Journal-page 26)
5/15/2014	House	Read third time and returned to Senate with amendments (House Journal-page 25)

5/15/2014		Scrivener's error corrected
5/20/2014	Senate	House amendment amended (Senate Journal-page 44)
5/20/2014	Senate	Roll call Ayes-38 Nays-0 (Senate Journal-page 44)
5/20/2014	Senate	Returned to House with amendments (Senate Journal-page 44)
5/21/2014		Scrivener's error corrected
5/22/2014	House	Concurred in Senate amendment and enrolled (House Journal-page 24)
5/22/2014	House	Roll call Yeas-92 Nays-5 (House Journal-page 25)
5/29/2014		Ratified R 229

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VERSIONS OF THIS BILL

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(R229, S1035)

AN ACT TO AMEND SECTION [44-53-110](#), AS AMENDED, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO DEFINITIONS APPLICABLE TO NARCOTICS AND CONTROLLED SUBSTANCES, SO AS TO CHANGE THE DEFINITION FOR "MARIJUANA" AND TO MAKE TECHNICAL CHANGES TO EXISTING DEFINITIONS; BY ADDING ARTICLE 18 TO CHAPTER 53, TITLE 44 SO AS TO CREATE JULIAN'S LAW, TO AUTHORIZE THE ESTABLISHMENT OF STATEWIDE INVESTIGATION OF NEW DRUG APPLICATIONS APPROVED BY THE FEDERAL DRUG ADMINISTRATION THAT ALLOW TREATMENT OF PATIENTS WITH CERTAIN FORMS OF EPILEPSY WITH CANNABIDIOL AS PART OF CLINICAL TRIALS, TO PROVIDE IMMUNITY FROM ARREST, PROSECUTION, AND OTHER PENALTIES; TO REPEAL SECTION [44-53-150](#) RELATING TO A REVIEW OF CRIMINAL PENALTIES FOR SALE AND USE OF MARIJUANA; AND TO CREATE A STUDY COMMITTEE TO DEVELOP A PLAN FOR THE SALE AND USE OF MEDICAL MARIJUANA.

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

Definitions

SECTION 1. Section [44-53-110](#) of the 1976 Code, as last amended by Act 127 of 2005, is further amended to read:

"Section [44-53-110](#). As used in this article and Sections [44-49-10](#), [44-49-40](#), and [44-49-50](#):

- (1) 'Administer' means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:
 - (a) a practitioner (or, in his presence, by his authorized agent); or
 - (b) the patient or research subject at the direction and in the presence of the practitioner.
- (2) 'Agent' means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser, except that this term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual or lawful course of the carrier's or warehouseman's business.
- (3) 'Bureau' means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice, or its successor agency.
- (4) 'Commission' means the South Carolina Department of Alcohol and Other Drug Abuse Services.
- (5) 'Confidant' means a medical practitioner, a pharmacist, a pharmacologist, a psychologist, a psychiatrist, a full-time staff member of a college or university counseling bureau, a guidance counselor or a teacher in an elementary school or in a junior or senior high school, a full-time staff member of a hospital, a duly ordained and licensed member of the clergy, accredited Christian Science practitioner, or any professional or paraprofessional staff member of a drug treatment, education, rehabilitation, or referral center who has received a communication from a holder of the privilege.
- (6) 'Controlled substance' means a drug, substance, or immediate precursor in Schedules I through V in Sections [44-53-190](#), [44-53-210](#), [44-53-230](#), [44-53-250](#), and [44-53-270](#).
- (7) 'Controlled substance analogue' means a substance that is intended for human consumption and that either has a chemical structure substantially similar to that of a controlled substance in Schedules I, II, or III or has a stimulant, depressant, analgesic, or hallucinogenic effect on the central nervous system that is substantially similar to that of a controlled substance in Schedules I, II, or III. Controlled substance analogue does not include a controlled substance; any substance generally recognized as safe and effective within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq.; any substance for which there is an approved new drug application; or, with respect to a particular person, any substance if an exemption is in effect for investigational use for that person under Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355.
- (8) 'Counterfeit substance' means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who, in fact, manufactured, distributed, or dispensed such substance and which, thereby, falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.
- (9) 'Cocaine base' means an alkaloidal cocaine or freebase form of cocaine, which is the end product of a chemical alteration whereby the cocaine in salt form is converted to a form suitable for smoking. Cocaine

base is commonly referred to as 'rock' or 'crack cocaine'.

(10) 'Deliver' or 'delivery' means the actual, constructive, or attempted transfer of a controlled drug or paraphernalia whether or not there exists an agency relationship.

(11) 'Department' means the State Department of Health and Environmental Control.

(12) 'Depressant or stimulant drug' means:

(a) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid, or any derivative of barbituric acid which has been designated as habit forming by the appropriate federal agency or by the department;

(b) a drug which contains any quantity of amphetamine or any of its optical isomers, any salt of amphetamine or any salt of any optical isomer of amphetamine, or any other substance which the appropriate federal agency or the department, after investigation, has found to be capable of being, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(c) lysergic acid diethylamide or mescaline, or any other substance which the appropriate federal agency or the department, after investigation, has found to have, and by regulation designates as having a potential for abuse because of its stimulant or depressant effect on the central nervous system or its hallucinogenic effect.

(13) 'Detoxification treatment' means the dispensing, for a period not in excess of twenty-one days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within this period.

(14) 'Director' means the Director of the Department of Narcotics and Dangerous Drugs under the South Carolina Law Enforcement Division.

(15) 'Dispense' means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for the delivery.

(16) 'Dispenser' means a practitioner who delivers a controlled substance to the ultimate user or research subject.

(17) 'Distribute' means to deliver (other than by administering or dispensing) a controlled substance.

(18) 'Distributor' means a person who so delivers a controlled substance.

(19) 'Drug' means a substance:

(a) recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

(b) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and animals;

(c) other than food intended to affect the structure or any function of the body of man and animals; and

- (d) intended for use as a component of any substance specified in subitem (a), (b), or (c) of this paragraph but does not include devices or their components, parts, or accessories.
- (20) 'Drug problem' means a mental or physical problem caused by the use or abuse of a controlled substance.
- (21) 'Holder of the privilege' means a person with an existing or a potential drug problem who seeks counseling, treatment, or therapy regarding such drug problem.
- (22) 'Imitation controlled substance' means a noncontrolled substance which is represented to be a controlled substance and is packaged in a manner normally used for the distribution or delivery of an illegal controlled substance.
- (23) 'Immediate precursor' means a substance which the appropriate federal agency or the department has found to be and by regulation has designated as being, or can be proven by expert testimony as being, the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, or is a reagent, solvent, or catalyst used in the manufacture of controlled substances, the control of which is necessary to prevent, curtail, or limit such manufacture.
- (24) 'Maintenance treatment' means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.
- (25) 'Manufacture' means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging, or labeling of a controlled substance:
- (a) by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or
 - (b) by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.
- (26) 'Manufacturer' means any person who packages, repackages, or labels any container of any controlled substance, except practitioners who dispense or compound prescription orders for delivery to the ultimate consumer.
- (27)(a) 'Marijuana' means:
- (i) all species or variety of the marijuana plant and all parts thereof whether growing or not;
 - (ii) the seeds of the marijuana plant;
 - (iii) the resin extracted from any part of the marijuana plant; or
 - (iv) every compound, manufacture, salt, derivative, mixture, or preparation of the marijuana plant,

marijuana seeds, or marijuana resin.

(b) 'Marijuana' does not mean:

- (i) the mature stalks of the marijuana plant or fibers produced from these stalks;
- (ii) oil or cake made from the seeds of the marijuana plant, including cannabidiol derived from the seeds of the marijuana plant;
- (iii) any other compound, manufacture, salt, derivatives, mixture, or preparation of the mature stalks (except the resin extracted therefrom), including cannabidiol derived from mature stalks;
- (iv) the sterilized seed of the marijuana plant which is incapable of germination;
- (v) 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; or
- (vi) 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 nine-tenths of one percent or less of tetrahydrocannabinol and more than fifteen percent of cannabidiol.

(c) 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.

(d) 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.

(28) 'Methamphetamine' includes any salt, isomer, or salt of an isomer, or any mixture or compound containing amphetamine or methamphetamine. Methamphetamine is commonly referred to as 'crank', 'ice', or 'crystal meth'.

(29) 'Narcotic drug' means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

- (a) opium, coca leaves, and opiates;
- (b) a compound, manufacture, salt, derivative or preparation of opium, coca leaves, or opiates;
- (c) a substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in subitem (a) or (b). This term does not include

decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

(30) 'Noncontrolled substance' means any substance of chemical or natural origin which is not included in the schedules of controlled substances set forth in this article or included in the federal schedules of controlled substances set forth in Title 21, Section 812 of the United States Code or in Title 21, Part 1308 of the Code of Federal Regulations.

(31) 'Opiate' means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under this article, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include racemic and levorotatory forms.

(32) 'Opium poppy' means the plant of the species *Papaver somniferum* L., except the seed thereof.

(33) 'Paraphernalia' means any instrument, device, article, or contrivance used, designed for use, or intended for use in ingesting, smoking, administering, manufacturing, or preparing a controlled substance and does not include cigarette papers and tobacco pipes but includes, but is not limited to:

- (a) metal, wooden, acrylic, glass, stone, plastic, or ceramic marijuana or hashish pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;
- (b) water pipes designed for use or intended for use with marijuana, hashish, hashish oil, or cocaine;
- (c) carburetion tubes and devices;
- (d) smoking and carburetion masks;
- (e) roach clips;
- (f) separation gins designed for use or intended for use in cleaning marijuana;
- (g) cocaine spoons and vials;
- (h) chamber pipes;
- (i) carburetor pipes;
- (j) electric pipes;
- (k) air-driven pipes;
- (l) chilams;
- (m) bongs;
- (n) ice pipes or chillers.

(34) 'Peyote' means all parts of the plant presently classified botanically as *Lophophora Williamsii* Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or extracts.

- (35) 'Poppy straw' means all parts, except the seeds, of the opium poppy, after mowing.
- (36) 'Practitioner' means:
- (a) a physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this State;
 - (b) a pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this State.
- (37) 'Production' includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.
- (38) 'Ultimate user' means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administration to an animal owned by him or a member of his household."

Julian's Law, created, allows for FDA approved clinical trials to treat patients who have certain forms of epilepsy with cannabidiol

SECTION 2. Chapter 53, Title 44 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, and other hospital research programs conducting research as a subrecipient with the academic medical center as the prime awardee.
- (2) 'Approved source' means a provider approved by the United States Food and Drug Administration which produces cannabidiol that:
- (a) has been manufactured and tested in a facility approved or certified by the United States Food and Drug Administration or similar national regulatory agency in another country which has been approved by the United States 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 98 percent cannabidiol and not more than 0.90 percent tetrahydrocannabinol by volume that has been extracted from marijuana or synthesized in a laboratory.
- (4) 'Designated caregiver' means a person who provides informal or formal care to a qualifying patient, with or without compensation, on a temporary or permanent or full-time or part-time basis and includes a relative, household member, day care personnel, and personnel of a public or private institution or facility.

(5) 'Pharmacist' means an individual health care provider licensed by this State to engage in the practice of pharmacy.

(6) 'Physician' means a doctor of medicine or doctor of osteopathic medicine licensed by the South Carolina Board of Medical Examiners.

(7) '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 United States 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 such clinical trials if such physician:

(1) applies to and is approved by the United States Food and Drug Administration as the principal investigator in a statewide investigational new drug application; and

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

(C) Such 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. Such subinvestigators shall comply with subsection (B)(2) of this section.

(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 United States Food and Drug Administration, the United States Drug Enforcement Administration, and the National Institute on Drug Abuse.

(E) Nothing in this article prohibits a physician licensed in South Carolina from applying for Investigational New Drug authorization from the United States Food and Drug Administration.

Section [44-53-1830](#). (A) Expanded access clinical trials conducted pursuant to a statewide investigational new drug application established pursuant to this chapter only shall utilize cannabidiol which is:

(1) from an approved source; and

(2) approved by the United States 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."

Repeal

SECTION 3. Section [44-53-150](#) of the 1976 Code is repealed.

Study committee, created, develop a plan for sale and use of medical marijuana

SECTION 4. (A) There is created a study committee whose purpose is to develop a plan for the sale and use of medical marijuana in the State should the Drug Enforcement Administration declassify or reclassify marijuana as a controlled substance.

(B)(1) Members of the study committee must include:

- (a) the Director or a designee of the Department of Agriculture;
- (b) the Director or a designee of the Department of Health and Environmental Control;
- (c) the Director or a designee of the Department of Revenue;
- (d) the Director or a designee of the State Law Enforcement Division;
- (e) two members of the House of Representatives appointed by the Speaker of the House, one of whom the Speaker shall designate as a cochair of the study committee;
- (f) two members of the Senate appointed by the President Pro Tempore of the Senate, one of whom the President Pro Tempore shall designate as a cochair of the study committee;
- (g) one member of the public appointed by the Speaker of the House of Representatives;
- (h) one member of the public appointed by the President Pro Tempore of the Senate;
- (i) the President or a designee of the Medical University of South Carolina;
- (j) the President or a designee of Clemson University; and
- (k) the President or a designee of the South Carolina Medical Association.

(2) The study committee also may invite representatives of nonprofit entities with expertise in the production of CBD oil to participate in the study committee process.

(3) The House of Representatives Judiciary Committee and the Senate Medical Affairs Committee shall designate staff to assist the study committee.

(C) The study committee shall provide a report with findings and recommendations to the House of Representatives and the Senate by March 15, 2015, at which the study committee shall dissolve. The report must address, at a minimum, methods and procedures for cultivating medical marijuana in the State, the amount of tax to impose on the sale of medical marijuana, the need for an agricultural marketing plan for the sale and use of medical marijuana, and the impact of the sale and use of medical marijuana on public health and wellness.

Time effective

SECTION 5. This act takes effect upon approval by the Governor.

Ratified the 29th day of May, 2014.

President of the Senate

Speaker of the House of Representatives

Approved the _____ day of _____ 2014.

Governor

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