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Indicates New Matter

COMMITTEE REPORT

March 20, 2014

**S. 1035**

Introduced by Senators Davis, Rankin, Shealy, Cleary, L. Martin, Grooms, Bright, Pinckney, Coleman, Bryant and Verdin

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Read the first time February 19, 2014.

**THE COMMITTEE ON MEDICAL AFFAIRS**

To whom was referred a Bill (S. 1035) 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, 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. Section 44-53-110 of the 1976 Code is 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:

~~(1)~~(a) a practitioner (or, in his presence, by his authorized agent); or

~~(2)~~(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 ~~Commission on Alcohol and Drug Abuse~~.

(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:

~~(1)~~(a) by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

~~(2)~~(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;

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

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

(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 United States Food and Drug Administration.

(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:

~~(1)~~(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;

~~(2)~~(b) water pipes designed for use or intended for use with marijuana, hashish, hashish oil, or cocaine;

~~(3)~~(c) carburetion tubes and devices;

~~(4)~~(d) smoking and carburetion masks;

~~(5)~~(e) roach clips;

~~(6)~~(f) separation gins designed for use or intended for use in cleaning marijuana;

~~(7)~~(g) cocaine spoons and vials;

~~(8)~~(h) chamber pipes;

~~(9)~~(i) carburetor pipes;

~~(10)~~(j) electric pipes;

~~(11)~~(k) air‑driven pipes;

~~(12)~~(l) chilams;

~~(13)~~(m) bongs;

~~(14)~~(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:

~~(1)~~(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;

~~(2)~~(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." /

SECTION 2. Chapter 53, Title 44 is amended by adding:

"Article 18

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 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 0.30 percent tetrahydrocannabinol 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.

Section 44-53-1830. (A) Expanded access clinical trials conducted pursuant to a statewide investigational new drug application established pursuant to this chapter shall only 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) An academic medical center pharmacy may receive cannabidiol directly from an approved source or authorized distributor for an approved source for use in the expanded access clinical trials. The medication shall be housed in the academic medical center pharmacy and dispensed by the academic medical center licensed pharmacist only to a qualifying patient in a clinical trial study or designated caregiver.

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. Section 44-53-150 is repealed.

SECTION 4. This act takes effect upon approval by the Governor. /

Renumber sections to conform.

Amend title to conform.

HARVEY S. PEELER, JR. for Committee.

**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~~ 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 therapeuti~~c research program and to 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 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.

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