Senate Bill 185

By: Senators Tippins of the 37th, Unterman of the 45th, Millar of the 40th, Thompson of the 14th, Miller of the 49th and others

A BILL TO BE ENTITLED
AN ACT

To amend Title 31 of the Official Code of Georgia Annotated, relating to health, so as to provide for a program of clinical trials of cannabidiol or cannabidiol-containing products for use in treating certain residents of this state under 18 years of age who have medication-resistant epilepsies; to provide for immunity from criminal prosecution; to amend Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to physicians, acupuncture, physician assistants, cancer and glaucoma treatment, respiratory care, clinical perfusionists, and orthotics and prosthetics practice, so as to provide for continuing research into the benefits of cannabidiol to treat debilitating or life-threatening seizures in children; to provide for definitions; to provide for legislative findings and intent; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

PART I
SECTION 1-1.

Title 31 of the Official Code of Georgia Annotated, relating to health, is amended by adding a new chapter to read as follows:

″CHAPTER 50

31-50-1.

(a) The Board of Regents of the University System of Georgia shall cause to be designed, developed, implemented, and administered a cannabidiol or cannabidiol-containing product research program to develop rigorous data that will inform and expand the scientific community's understanding of potential treatments for persons under 18 years of age with medication-resistant epilepsies.

(b) Such program shall adhere to the regulatory process established by the federal Food, Drug, and Cosmetic Act, as well as other federal laws and regulations governing the

development of new drugs containing controlled substances as defined under the federal Controlled Substances Act of 1970.

31-50-2.

To the extent permissible under this chapter, such program shall be designed to permit the voluntary enrollment of all persons under 18 years of age having medication-resistant epilepsies who are residents of this state and who:

(1) Have been residents of this state for the 24 month period immediately preceding their entry into the program; or

(2) Have been residents of this state continuously since birth if they are less than 24 months old at the time of their entry into the program.

31-50-3.

(a) For purposes of this chapter, the board of regents may act through a unit of the University System of Georgia, a nonprofit corporation research institute, or both.

(b) Any nonprofit corporation research institute approved by the board of regents to participate in the program established under this chapter shall be required to have the necessary experience, expertise, industry standards and security procedures, and infrastructure to implement such research in accordance with accepted scientific and regulatory standards.

(c) The board of regents and its authorized agent may enter into such agreements, among themselves and with other parties, as are reasonable and necessary to implement the provisions of this chapter.

31-50-4.

(a) The board of regents or its authorized agent shall designate a supplier of cannabidiol or cannabidiol-containing products and shall collaborate with a designated supplier to develop a clinical trial protocol to study cannabidiol or cannabidiol-containing products in the treatment of persons under 18 years of age with medication-resistant epilepsies, which trial shall be conducted at one or more locations in this state. The supplier shall be required to supply a source of cannabidiol or cannabidiol-containing product that has been standardized and tested in keeping with such standards.

(b) The board of regents or its authorized agent shall require the supplier of cannabidiol or cannabidiol-containing product to commit personnel and other resources to such collaboration and to supply cannabidiol or cannabidiol-containing product for a collaborative study under reasonable terms and conditions to be agreed upon mutually.

31-50-5.

Any public record, as defined by Code Section 50-18-70, produced pursuant to this chapter shall be exempt from disclosure to the extent provided by Code Section 50-18-72.

31-50-6.

All activities undertaken pursuant to this chapter shall be subject to availability of funds appropriated to the board of regents or otherwise made available for purposes of this chapter.

31-50-7.

(a) Patient participants and their parents or legal guardians, designated employees of the board of regents, program agents and collaborators and their designated employees, and suppliers of cannabidiol or cannabidiol-containing product to the program and their designated employees shall be immune from state prosecution for possession, distribution, sale, purchase, administration, and any other use of a substance otherwise prohibited or regulated under Chapter 13 of Title 16 which is present in a cannabidiol-containing product authorized for purposes of this chapter. A patient authorized under this chapter and program and his or her parent or legal guardian shall not possess an amount of cannabidiol or cannabidiol-containing product in excess of the amount prescribed under the authority of this chapter. The amount prescribed shall be maintained in the container in which it was placed at the time the prescription was filled. Physician, clinical research, pharmacy, pharmacist participants, and all medical personnel in the program shall be immune from state prosecution for possession, distribution, sale, purchase, administration, and any other use of a substance otherwise prohibited or regulated under Chapter 13 of Title 16 which is present in a cannabidiol-containing product authorized for purposes of this chapter. Any possession, distribution, sale, purchase, administration, or other use not authorized for purposes of this chapter shall be punishable under Chapter 13 of Title 16, relating to controlled substances and dangerous drugs, or Chapter 4 of Title 26, relating to pharmacists and pharmacies, as applicable.

(b) For purposes of subsection (a) of this Code section, the board of regents or its agent which administers the program authorized under this chapter shall provide appropriate certificates, suitable for carrying on their persons or display, as applicable, to patient participants and their parents or legal guardians, designated employees of the board of regents, program agents and collaborators and their designated employees, suppliers of cannabidiol or cannabidiol-containing product to the program and their designated employees, and physician, clinical research, pharmacy, and pharmacist participants in the program as proof of authorization to possess, distribute, sell, purchase, administer, and

otherwise use cannabidiol or cannabidiol-containing product as authorized for purposes of this chapter.

31-50-8.

The board of regents may establish fees for program participants in such amounts as are reasonable to offset program costs.

31-50-9.

The board of regents may adopt such rules and regulations as are reasonable and necessary for purposes of this chapter.

31-50-10.

This chapter shall stand repealed on July 1, 2020."

PART II

SECTION 2-1.

WHEREAS, the General Assembly finds and declares that clinical research has shown certain benefits arising from the utilization of medical research cannabidiol, and most recently, the State of Georgia has sponsored a clinical study with GW Pharmaceuticals to quantify the benefits of a particular strain delivered orally for the treatment of seizure disorders among children; and

WHEREAS, nothing in this legislation should be construed as encouraging or sanctioning the use of marijuana or controlled substances in a manner which violates the "Controlled Substances Therapeutic Research Act," nor is this legislation to be construed as any intent of the General Assembly to be moving in the direction of the legalization of the recreational use of marijuana or other controlled substances.

SECTION 2-2.

Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to physicians, acupuncture, physician assistants, cancer and glaucoma treatment, respiratory care, clinical perfusionists, and orthotics and prosthetics practice, is amended by revising Article 5, relating to the use of marijuana for treatment of cancer and glaucoma, as follows:

″ARTICLE 5

43-34-120.

This article shall be known and may be cited as the 'Controlled Substances Therapeutic Research Act.'

43-34-121.

(a) The General Assembly finds and declares that ~~the potential medicinal value of marijuana has received insufficient study due to a lack of financial incentives for the undertaking of appropriate research by private drug manufacturing concerns. Individual physicians cannot feasibly utilize marijuana in clinical trials because of federal governmental controls which involve expensive, time-consuming approval and monitoring procedures~~ this legislation's purpose is the compassionate, potentially life-saving use of medical cannabidiol. Studies indicate that cannabidiol, a nonpsychoactive cannabinoid, has significant health and wellness benefits for the treatment of certain seizure disorders afflicting children.

(b) The General Assembly further finds and declares that limited studies throughout the nation indicate that ~~marijuana and certain of its derivatives possess~~ cannabidiol possesses valuable and, in some cases, unique therapeutic properties, including the ~~ability to relieve nausea and vomiting which routinely accompany chemotherapy and irradiation used to treat cancer patients. Marijuana also may be effective in reducing intraocular pressure in glaucoma patients who do not respond well to conventional medications~~ treatment of seizure disorders in children.

(c) The General Assembly further finds and declares that, in enabling individual physicians and their patients to participate in a state-sponsored ~~program~~ clinical study for the investigational use of ~~marijuana and its derivatives~~ cannabidiol, qualified physicians ~~and surgeons~~ throughout ~~the~~ this state will be able to study the benefits of the drug in a controlled clinical setting, and additional knowledge will be gained with respect to dosage and effects.

(d) It is the intent of the General Assembly in enacting this article to permit research into the therapeutic applications of ~~marijuana and its derivatives in cancer and glaucoma patients~~ cannabidiol in seizure disorder patients. This would allow qualified physicians ~~approved by the Patient Qualification Review Board created by Code Section 43-34-124~~ to provide the drug on a compassionate basis to seriously ill ~~persons suffering from the severe side effects of chemotherapy or radiation treatment and to persons suffering from glaucoma who are not responding to conventional treatment~~ children suffering from seizure disorders, which ~~persons~~ children would otherwise have no lawful access to it. It is the

further intent of the General Assembly to facilitate clinical trials of ~~marijuana and its derivatives~~ cannabidiol, particularly with respect to ~~persons~~ children suffering from ~~cancer and glaucoma~~ seizure disorders who would be benefited by use of the drug.

(e) This article is limited to clinical trials and research into therapeutic applications of ~~marijuana~~ cannabidiol only for use in treating ~~glaucoma and in treating the side effects of chemotherapeutic agents and radiation~~ seizure disorders and should not be construed as either encouraging or sanctioning the social use of marijuana. ~~Nothing in this article shall be construed to encourage the use of marijuana in lieu of or in conjunction with other accepted medical treatment, but only as an adjunct to such accepted medical treatment.~~

43-34-122.

As used in this article, the term:

(1) ~~'Board' means the Georgia Composite Medical Board.~~ 'Cannabidiol' means an extract derived from any plant of the genus cannabis which contains cannabinols and cannabidiols and has a purity of at least 95 percent or higher cannabidiol in combination with .3 percent or less of tetrahydrocannabinols as defined by subparagraph (P) of paragraph (3) of Code Section 16-13-25 and is delivered to the patient in the form of a liquid, pill, transdermal patch, or injection but which does not include smoking.

(2) 'Designated caregiver' means the patient's parent or legal guardian.

~~(2)~~(3) 'Marijuana' means marijuana or tetrahydrocannabinol, as defined or listed in Article 2 of Chapter 13 of Title 16.

(4) 'Patient' means a person under the age of 21 who is under the care of a pediatric neurologist.

~~(3)~~(5) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of this chapter and is a pediatric neurologist.

~~(4) 'Program' means the Controlled Substances Therapeutic Research Program established pursuant to Code Section 43-34-123.~~

~~(5) 'Review board' means the Patient Qualification Review Board established pursuant to Code Section 43-34-124.~~

(6) 'Smoking' means inhaling, exhaling, burning, vaporizing, or carrying any lighted marijuana or cannabis product.

(7) '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 or other seizures of unknown etiology that is not adequately treated by traditional medical therapies.

43-34-123.

~~(a) There is established under the Georgia Composite Medical Board the Controlled Substances Therapeutic Research Program, which shall be administered by the board. Under the program, the board shall act as a sponsor of state-wide investigational studies, utilizing as drug investigators individual physicians who elect to participate in accordance with the guidelines and protocols developed by the board. Such guidelines and protocols shall be designed to ensure that stringent security and record-keeping requirements for research drugs are met and that participants in the program meet those research standards necessary to establish empirical bases for the evaluation of marijuana as a medically recognized therapeutic substance. The board shall promulgate such rules and regulations as it deems necessary or advisable to administer the program. In promulgating such guidelines, protocols, rules, and regulations, the board shall take into consideration those pertinent rules and regulations promulgated by the Federal Drug Enforcement Agency, the Food and Drug Administration, and the National Institute on Drug Abuse.~~

~~(b) The program shall be limited to patients who are certified to the board by a physician as being:~~

~~(1) Cancer patients involved in a life-threatening situation in which treatment by chemotherapy or radiology has produced severe side effects; or~~

~~(2) Glaucoma patients who are not responding to conventional controlled substances.~~

~~(c) No patient may be admitted to the program without full disclosure by the physician of the experimental nature of the program and of the possible risks and side effects of the proposed treatment.~~

~~(d) The cost of any blood test required by the federal Food and Drug Administration prior to entrance into the program shall be paid by the patient seeking entrance into the program.~~

~~(e) Only the following persons shall have access to the names and other identifying characteristics of patients in the program for whom marijuana has been prescribed under this article:~~

~~(1) The board;~~

~~(2) The review board created by Code Section 43-34-124;~~

~~(3) The Attorney General or his or her designee;~~

~~(4) Any person directly connected with the program who has a legitimate need for the information; and~~

~~(5) Any federal agency having responsibility for the program~~ Reserved.

43-34-124.

~~(a) The board shall appoint the Patient Qualification Review Board. Each member of the review board shall be approved for such membership by a majority vote of the board and shall serve at the pleasure of the board. The review board shall be composed of:~~

~~(1) A board certified physician in ophthalmology;~~

~~(2) A board certified physician in surgery;~~

~~(3) A board certified physician in internal medicine and medical oncology;~~

~~(4) A board certified physician in psychiatry;~~

~~(5) A board certified physician in radiology; and~~

~~(6) A pharmacist licensed under Chapter 4 of Title 26, relating to pharmacists, pharmacy, and drugs.~~

~~(b) The review board shall elect from its members a chairperson and a vice chairperson. The review board shall hold regular meetings at least once every 60 days and shall meet at such additional times as shall be called by the chairperson of the review board or the chairperson of the board. Each member of the review board shall receive for services for each day's attendance upon meetings of such board the same amount authorized by law for members of the General Assembly for attendance upon meetings of the General Assembly.~~

~~(c) The board shall adopt such rules and regulations as it deems necessary for the performance of the duties of the review board.~~

~~(d) The review board shall review all patient applicants for the program and their physicians and shall certify those qualified for participation in the program. The review board shall additionally certify pharmacies which are licensed by the state and which are otherwise qualified and certify physicians regarding the distribution of marijuana pursuant to Code Section 43-34-125. Meetings of the review board to certify patients, physicians, or pharmacies shall not be open to the public, as otherwise required by Chapter 14 of Title 50~~ Reserved.

43-34-125.

~~(a) The board shall apply to contract with the National Institute on Drug Abuse for receipt of marijuana pursuant to this article and pursuant to regulations promulgated by the National Institute on Drug Abuse, the Food and Drug Administration, and the Federal Drug Enforcement Agency.~~

~~(b) The board shall cause marijuana approved for use in the program to be transferred to a certified pharmacy, licensed by the state, for distribution to the certified patient by a licensed pharmacist upon a written order for research medication of the certified physician, pursuant to this article. Any reasonable costs incurred by the board in obtaining or testing~~

~~marijuana shall be charged to participating physicians who may seek reimbursement from their research subjects utilizing the marijuana.~~

Any cannabidiol distributed or dispensed by a physician or pharmacy shall be kept by the patient in the original container in which it was dispensed and is labeled according to Code Section 26-3-8.

43-34-126.

~~Patient participants in the program are immune from state prosecution for possession of marijuana as authorized by this article and under the program established in this article. A person authorized under this program shall not possess an amount of marijuana in excess of the amount prescribed under the authority of this article. The amount prescribed shall be maintained in the container in which it was placed at the time the prescription was filled. Physician, pharmacy, and pharmacist participants in the program are immune from state prosecution for possession, distribution, and any other use of marijuana, which use is authorized such persons by this article. Any such possession, distribution, or other use not authorized by this article shall be enforced and punished as provided in Chapter 13 of Title 16, relating to controlled substances and dangerous drugs, and Chapter 4 of Title 26, relating to pharmacists and pharmacies.~~

(a) Any patient with a written certification who uses, purchases, possesses, or has under his or her control an amount of cannibidiol which such patient has been authorized under this article to use, purchase, possess, or have under his or her control shall not be subject to arrest or prosecution for a violation of Code Section 16-13-30.

(b) Any parent or legal guardian of a patient who possesses a written certification for cannibidiol who purchases, possesses, administers, or has under his or her control an amount of cannibidiol which such patient has been authorized under this article to use shall not be subject to arrest or prosecution for a violation of Code Section 16-13-30.

(c) A pediatric neurologist or any medical employee associated with the state sponsored clinical study on cannabidiol who possesses cannabidiol as defined in this article shall not be subject to arrest or prosecution under Code Section 16-13-30.

(d) An agency of this state or a political subdivision thereof, including any law enforcement agency, may not initiate proceedings to remove a child from the home of a parent based solely upon the parent's or child's or legal guardian's possession or administration of cannabidiol as authorized by this article.″

PART III

SECTION 3-1.

This Act shall become effective upon its approval by the Governor or upon its becoming law without such approval.

SECTION 3-2.

All laws and parts of laws in conflict with this Act are repealed.