The Senate Health and Human Services Committee offered the following substitute to HB 885:

A BILL TO BE ENTITLED
AN ACT

To amend Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to the use of cannabis for treatment of cancer and glaucoma, so as to provide for continuing research into the benefits of medical cannabis to treat certain conditions; to provide for a short title; to provide for legislative findings and intent; to provide for the continuation of the Controlled Substances Therapeutic Research Program; to provide for definitions; to provide for selection of academic medical centers to conduct the research; to provide for expansion of the review board and its duties; to establish the responsibilities of academic medical centers; to provide for the selection of approved pediatric neurologists; to provide for storage and distribution of research medical cannabis by the Georgia Drugs and Narcotics Agency; to provide for immunity; to provide for employer and employee rights and obligations; to amend Article 1 of Chapter 24 of Title 33 of the Official Code of Georgia Annotated, relating to general provisions regarding insurance generally, so as to provide for certain insurance coverage of autism spectrum disorders; to provide for definitions; to provide for limitations; to provide for premium cap and other conditions; to provide for applicability; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

WHEREAS, the General Assembly finds and declares that clinical research has shown certain benefits arising from the utilization of medical research cannabis and, most recently, significant benefits of a particular strain delivered orally for the treatment of seizure disorders among children.

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 Georgia Controlled Substances Act, nor is this legislation to be construed as any intent of the General Assembly to encourage or sanction the use of marijuana or controlled substances.
Assembly to be moving in the direction of the legalization of the recreational use of marijuana or other controlled substances.

SECTION 2.

Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to the use of cannabis for treatment of cancer and glaucoma, is amended by revising the article as follows:

"ARTICLE 5

43-34-120.

This article shall be known and may be cited as the 'Controlled Substances Therapeutic Research Haleigh's Hope 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 cannabis and is not intended to sanction, encourage, or otherwise be construed as a movement in the direction of the legalization of the recreational use of marijuana or other controlled substances. Clinical research performed over the past decades continues to show benefits arising from certain forms of medical cannabis. Presently there are in excess of one million United States medical cannabis patients and an increasing number of physicians are recommending the therapeutic use of cannabis to their patients in accordance with their respective state law. New extracts and compounds have been developed demonstrating that cannabidiol, one of the most prevalent nonpsychoactive cannabinoids, has significant health and wellness benefits as shown by recent publication of the positive treatment of certain seizure disorders afflicting children.

(b) The General Assembly further finds and declares that limited continuing studies throughout the nation indicate that marijuana cannabis and certain of its derivatives possess 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 Cannabis also may be effective in reducing intraocular pressure in glaucoma patients who do not respond well in adjunct to conventional
medications. Cannabis derivatives have also been shown to be effective in the treatment of seizure disorders.

(c) The General Assembly further finds and declares that, in enabling individual physicians and their patients to participate in a state-sponsored program for the investigational use of marijuana cannabis and its derivatives, qualified physicians and surgeons throughout the state academic medical centers 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 and treatment applications of marijuana cannabis and its derivatives in cancer, and glaucoma, and seizure disorder patients. This would allow qualified physicians and academic medical centers approved by the Patient Qualification Review Board created by Code Section 43-34-124 to provide authorize use of 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, and to persons suffering from seizure disorders, which persons would otherwise have no lawful access to it. It is the further intent of the General Assembly to facilitate clinical trials of marijuana cannabis and its derivatives, particularly with respect to persons suffering from cancer, and glaucoma, and seizure disorders who would be benefited by medically benefit from use of the drug.

(e) This article is limited to clinical trials and research into therapeutic applications of marijuana cannabis only for use in treating glaucoma, and in treating the side effects of chemotherapeutic agents and radiation, and utilizing medical cannabis for the treatment of seizure disorders and should not be construed as either authorizing, encouraging, or sanctioning the social use of marijuana or other controlled substances in violation of the Controlled Substances Act. 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.

As used in this article, the term:

(1) 'Academic medical center' means a research hospital that operates a medical residency program for physicians and conducts research that involves human subjects, including medical schools within the state that conduct translational research or clinical research programs.

(2) 'Board' means the Georgia Composite Medical Board.
(3) 'Cannabis' means any extract derived from any plant of the genus cannabis and which contain cannabinoids and cannabidiols which has a purity of at least 5 percent or higher cannabidiol in combination with 2 percent or less of tetrahydrocannabinols as defined by paragraph (3) of Code Section 16-13-21, that is delivered to the patient in the form of a liquid, pill, or injection or other delivery method approved by the board but which does not include smoking.

(4) 'Designated caregiver' means a person who has been approved by the board to assist with a qualifying patient's medical use of cannabis, provided that any person approved as a designated caregiver shall be not less than 21 years of age and shall not have been convicted of a felony under the laws of this state, any other state, or the United States including its territories, possessions, and dominions. No person approved as a designated caregiver may assist more than five qualifying patients with the medical use of cannabis.

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

(6) 'Patient' means a person who has been certified by the board and admitted to the program pursuant to Code Section 43-34-123.

(7) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of this chapter and approved under this article to administer cannabis, including but not limited to a pediatric neurologist.

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

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

(10) 'Smoking' means inhaling, exhaling, burning, or carrying any lighted marijuana or cannabis product including cigarettes, cigars, or other product prepared in such manner as to be suitable for smoking in a cigarette, cigar, pipe, or similar device.

(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 or academic medical centers who elect to participate in accordance with the rules, regulations, guidelines, and protocols developed adopted by the board. Such guidelines and protocols shall be designed to ensure that stringent security and record-keeping requirements for research drugs cannabis are met and that participants in the program meet those research standards necessary to establish empirical bases for the evaluation of marijuana cannabis as a medically recognized...
therapeutic substance. The board shall promulgate such rules, regulations, guidelines, and protocols 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 United States 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 or academic medical center 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; or

(3) Seizure disorder patients.

c) No patient may be admitted to the program without full disclosure by the physician or academic medical center 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 or through the program, donated research or study funds, or other funding.

e) Except as provided in subsection (b) of Code Section 43-34-127, only the following persons shall have access to the names and other identifying characteristics of patients in the program for whom marijuana cannabis 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;

(6) Any academic medical center operating a program under this article; and

(7) Any patient program participant's attending physician.

(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;
(7) A board certified physician in pediatric neurology;
(8) A board certified physician in pain management; and
(9) A board certified pediatric epitologist.

(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:
(1) Shall review, evaluate, and rate applications for medical cannabis use programs submitted by academic medical centers and approved pediatric neurologists based on the procedures and guidelines established by the board;
(2) Shall develop request applications for programs;
(3) Shall approve or deny applications for programs, approve or deny applications for renewal of such programs, and monitor and oversee programs approved for operation under this article;
(4) Shall approve or deny applications for physicians to utilize medical research cannabis in the treatment of patients in conjunction with an approved academic medical center;
(5) May rescind approval of a program if the board finds that the program is not in compliance with the conditions of approval established by the board; and
(6) Shall set application fees and renewal fees that cover its expenses in reviewing and approving applications and providing oversight to programs.

(e) Meetings of the review board to certify patients, physicians, or pharmacies or academic medical centers shall not be open to the public, as otherwise required by Chapter 14 of Title
nor shall the records of such meetings be subject to the provisions of Article 4 of 43-34-125.

(a) The board shall An academic medical center operating a program approved under this article or a pharmacy may apply to contract with the National Institute on Drug Abuse for receipt of marijuana. An academic medical center operating a program approved under this article or a pharmacy may 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 United States Drug Enforcement Agency. Administration or obtain such cannabis from any available legal source approved by the board.

(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. The board shall adopt rules or regulations requiring any academic medical center or pharmacy to submit any cannabis received from a legal source other than National Institute on Drug Abuse, the Food and Drug Administration, and the United States Drug Enforcement Administration, to submit such cannabis to a testing facility designated by the board to insure that such cannabis complies with the provisions of this article. Any cannabis that is not submitted for testing or which after testing is found not to comply with the provisions of this article shall not be distributed or used and shall be submitted to the Georgia Drugs and Narcotics Agency for destruction.

(c) The Georgia Drugs and Narcotics Agency shall establish rules and regulations for the manufacture, storage, transportation, and distribution of cannabis which shall be in addition to the requirements of Code Section 16-13-39. Cannabis may be distributed or dispensed to a patient or designated caregiver by a pharmacy or academic medical center only upon a prescription complying with the provisions of Code Section 16-13-41 or a written order in a form prescribed by the board.

(d) Any cannabis which is distributed or dispensed by a physician, pharmacy, or academic medical center shall be kept by the patient or designated caregiver in the original container in which they were dispensed by the physician, pharmacist, or academic medical center and are labeled according to Code Section 26-3-8.

(e) Any physician, pharmacy, or academic medical center authorized to prescribe, dispense, or distribute cannabis pursuant to this article shall be subject to inspection by the director of the Georgia Drugs and Narcotics Agency and such law enforcement personnel as may be designated by the director as provided by Code Section 16-13-46.
(f) Any physician, pharmacy, academic medical center, patient, or designated caregiver who violates the provisions of this article or the rules or regulations of the board or the Georgia Drugs and Narcotics Agency adopted pursuant to this article shall be terminated from the program and shall be subject to such other penalties as may be authorized by law.

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)(1) Any patient enrolled in a program approved under this article who uses, purchases, possesses, or has under his or her control an amount of cannabis which such patient has been authorized to use, purchase, possess, or have under his or her control by the board shall not be subject to arrest or prosecution for a violation of Code Section 16-13-30.

(2) Any designated caregiver of a patient who purchases, possesses, administers, or has under his or her control an amount of cannabis which such patient has been authorized to use, purchase, possess, or have under his or her control by the board shall not be subject to arrest or prosecution for a violation of Code Section 16-13-30. A designated caregiver may receive payment for costs incurred in performing services necessary to assist the patient with the administration of the cannabis in accordance with directions of the prescribing physician or academic medical center.

(3) A physician, academic medical center, an employee of an academic medical center, or any other person associated with the operation of a program approved under 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 activities conducted in accordance with the program approved under this article.

(b) The Georgia Drugs and Narcotics Agency shall develop and maintain a secure system which will allow law enforcement to verify that a person claiming to be authorized to possess cannabis in accordance with this article is in fact so authorized. Any information
received by a law enforcement agency or officer confirming that a person's status as a patient or designated caregiver shall be confidential and shall not be subject to disclosure pursuant to the provisions of Article 4 of Chapter 18 of Title 50.

43-34-127.

A state employee is eligible for reimbursement for incurred counsel fees under Code Section 45-12-26 in the event of a federal criminal investigation or prosecution solely related to the employee's good faith discharge of public responsibilities under this article.

43-34-128.

(a) The consumption of cannabis in accordance with this article shall be an acceptable explanation to a positive test under subsection (d) of Code Section 34-9-415 of the Drug Free Workplace Act or any other lawful drug test administered by an employer.

(b) Nothing in this article shall affect an employer's rights under Code Section 34-9-17.

(c) A patient's participation in treatment under this article and the consumption of medical research cannabis shall not relieve the patient of the obligation to notify his or her employer if such participation impairs his or her ability to safely perform the duties of his or her job.

(d) Nothing in this article shall require an employer to accommodate an employee's use of medical research cannabis as an approved treatment.

SECTION 3.

Article 1 of Chapter 24 of Title 33 of the Official Code of Georgia Annotated, relating to general provisions regarding insurance generally, is amended by revising Code Section 33-24-59.10, relating to insurance coverage for autism, as follows:

"33-24-59.10.

(a) As used in this Code section, the term:

(1) 'Accident and sickness contract, policy, or benefit plan' shall have the same meaning as found in Code Section 33-24-59.1. Accident and sickness contract, policy, or benefit plan shall also include without limitation any health benefit plan established pursuant to Article 1 of Chapter 18 of Title 45. Accident and sickness contract, policy, or benefit plan' shall not include limited benefit insurance policies designed, advertised, and marketed to supplement major medical insurance such as accident only, CHAMPUS supplement, dental, disability income, fixed indemnity, long-term care, medicare supplement, specified disease, vision, and any other type of accident and sickness insurance other than basic hospital expense, basic medical-surgical expense, or major medical insurance.
(2) ‘Autism’ means a developmental neurological disorder, usually appearing in the first three years of life, which affects normal brain functions and is manifested by compulsive, ritualistic behavior and severely impaired social interaction and communication skills.

'Applied behavior analysis' means the design, implementation, and evaluation of environmental modifications using behavioral stimuli and consequences to produce socially significant improvement in human behavior, including the use of direct observation, measurement, and functional analysis of the relationship between environment and behavior.

(3) ‘Autism spectrum disorder’ means autism spectrum disorder as defined by the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders.

(4) 'Treatment of autism spectrum disorder' includes the following types of care prescribed, provided, or ordered for an individual diagnosed with an autism spectrum disorder:

(A) Habilitative or rehabilitative services, including applied behavior analysis or other professional or counseling services necessary to develop, maintain, and restore the functioning of an individual to the extent possible. To be eligible for coverage, applied behavior analysis shall be provided by a person professionally certified by a national board of behavior analysts or performed under the supervision of a person professionally certified by a national board of behavior analysts, except for those licensed psychologists specially trained and credentialed in applied behavioral analysis;

(B) Counseling services provided by a licensed psychiatrist, licensed psychologist, professional counselor, or clinical social worker; and

(C) Therapy services provided by a licensed or certified speech therapist, speech-language pathologist, occupational therapist, physical therapist, or marriage and family therapist.

(b) An insurer that provides benefits for neurological disorders, whether under a group or individual accident and sickness contract, policy, or benefit plan, shall not deny providing benefits in accordance with the conditions, schedule of benefits, limitations as to type and scope of treatment authorized for neurological disorders, exclusions, cost-sharing arrangements, or copayment requirements which exist in such contract, policy, or benefit plan for neurological disorders because of a diagnosis of autism. The provisions of this subsection shall not expand the type or scope of treatment beyond that authorized for any other diagnosed neurological disorder. Accident and sickness contracts, policies, or benefit plans shall provide coverage for autism spectrum disorders for an individual covered under a policy or contract who is six years of age or under in accordance with the following:
(1) The policy or contract shall provide coverage for any assessments, evaluations, or tests by a licensed physician or licensed psychologist to diagnose whether an individual has an autism spectrum disorder;

(2) The policy or contract shall provide coverage for the treatment of autism spectrum disorders when it is determined by a licensed physician or licensed psychologist that the treatment is medically necessary health care. A licensed physician or licensed psychologist may be required to demonstrate ongoing medical necessity for coverage provided under this Code section at least annually;

(3) The policy or contract shall not include any limits on the number of visits;

(4) The policy or contract may limit coverage for applied behavior analysis to $35,000.00 per year. An insurer shall not apply payments for coverage unrelated to autism spectrum disorders to any maximum benefit established under this paragraph; and

(5) This subsection shall not be construed to require coverage for prescription drugs if prescription drug coverage is not provided by the policy or contract. Coverage for prescription drugs for the treatment of autism spectrum disorders shall be determined in the same manner as coverage for prescription drugs for the treatment of any other illness or condition is determined under the policy or contract.

(e) Except as otherwise provided in this Code section, any policy or contract that provides coverage for services under this Code section may contain provisions for maximum benefits and coinsurance and reasonable limitations, deductibles, and exclusions to the extent that these provisions are not inconsistent with the requirements of this Code section.

(d) This Code section shall not be construed to affect any obligation to provide services to an individual with an autism spectrum disorder under an individualized family service plan, an individualized education plan as required by the federal Individuals with Disabilities Education Act, or an individualized service plan. This Code section also shall not be construed to limit benefits that are otherwise available to an individual under an accident and sickness contract, policy, or benefit plan.

(e)(1) An insurer, corporation, or health maintenance organization, or a governmental entity providing coverage for such treatment pursuant to this Code section, is exempt from providing coverage for behavioral health treatment required under this Code section and not covered by the insurer, corporation, health maintenance organization, or governmental entity providing coverage for such treatment pursuant to this Code section as of December 31, 2015, if:

(A) An actuary, affiliated with the insurer, corporation, or health maintenance organization, who is a member of the American Academy of Actuaries and meets the American Academy of Actuaries' professional qualification standards for rendering an
The Commissioner that:

(i) Based on an analysis to be completed no more frequently than one time per year by each insurer, corporation, or health maintenance organization, or such governmental entity, for the most recent experience period of at least one year's duration, the costs associated with coverage of behavioral health treatment required under this Code section, and not covered as of December 31, 2015, exceeded 1 percent of the premiums charged over the experience period by the insurer, corporation, or health maintenance organization; and

(ii) Those costs solely would lead to an increase in average premiums charged of more than 1 percent for all insurance policies, subscription contracts, or health care plans commencing on inception or the next renewal date, based on the premium rating methodology and practices the insurer, corporation, or health maintenance organization, or such governmental entity, employs; and

(B) The Commissioner approves the certification of the actuary.

(2) An exemption allowed under paragraph (1) of this subsection shall apply for a one-year coverage period following inception or next renewal date of all insurance policies, subscription contracts, or health care plans issued or renewed during the one-year period following the date of the exemption, after which the insurer, corporation, or health maintenance organization, or such governmental entity, shall again provide coverage for behavioral health treatment required under this subsection.

(3) An insurer, corporation, or health maintenance organization, or such governmental entity, may claim an exemption for a subsequent year, but only if the conditions specified in this subsection again are met.

(4) Notwithstanding the exemption allowed under paragraph (1) of this subsection, an insurer, corporation, or health maintenance organization, or such governmental entity, may elect to continue to provide coverage for behavioral health treatment required under this subsection.

(f) Beginning January 1, 2015, to the extent that this Code section requires benefits that exceed the essential health benefits required under Section 1302(b) of the federal Patient Protection and Affordable Care Act, P. L. 111-148, the specific benefits that exceed the required essential health benefits shall not be required of a 'qualified health plan' as defined in such act when the qualified health plan is offered in this state through the exchange. Nothing in this subsection shall nullify the application of this Code section to plans offered outside the state's exchange.

(g) This Code section shall not apply to any accident and sickness contract, policy, or benefit plan offered by any employer with ten or fewer employees.
(h) Nothing in this Code section shall be construed to limit any coverage under any accident and sickness contract policy or benefit plan, including, but not limited to, speech therapy, occupational therapy, or physical therapy otherwise available under such plan.

(i) By January 15, 2016, and every January 15 thereafter, the department shall submit a report to the General Assembly regarding the implementation of the coverage required under this Code section. The report shall include, but shall not be limited to, the following:

1. The total number of insureds diagnosed with autism spectrum disorder;
2. The total cost of all claims paid out in the immediately preceding calendar year for coverage required by this Code section;
3. The cost of such coverage per insured per month; and
4. The average cost per insured for coverage of applied behavior analysis.

All health carriers and health benefit plans subject to the provisions of this Code section shall provide the department with all data requested by the department for inclusion in the annual report.

SECTION 4.

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