House Bill 885 (COMMITTEE SUBSTITUTE)

By: Representatives Peake of the 141st, Watson of the 166th, Channell of the 120th, Kaiser of the 59th, Gravley of the 67th, and others

A BILL TO BE ENTITLED AN ACT

- 1 To amend Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated,
- 2 relating to the use of cannabis for treatment of cancer and glaucoma, so as to provide for
- 3 continuing research into the benefits of medical cannabis to treat certain conditions; to
- 4 provide for a short title; to provide for legislative findings and intent; to provide for the
- 5 continuation of the Controlled Substances Therapeutic Research Program; to provide for
- 6 definitions; to provide for selection of academic medical centers to conduct the research; to
- 7 provide for expansion of the review board and its duties; to establish the responsibilities of
- 8 academic medical centers; to provide for the selection of approved pediatric neurologists; to
- 9 provide for cultivation and processing by a selected academic medical center; to provide for
- 10 storage and distribution of research medical cannabis by the Georgia Drugs and Narcotics
- 11 Agency; to provide for immunity; to provide for employer and employee rights and
- obligations; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

14 SECTION 1.

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

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- 19 WHEREAS, nothing in this legislation should be construed as encouraging or sanctioning
- 20 the recreational use of cannabis, nor is this legislation to be construed as any intent of the
- 21 General Assembly to be moving in the direction of the legalization of recreational cannabis.

SECTION 2.

23 Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to the

- 24 use of cannabis for treatment of cancer and glaucoma, is amended by revising the article as
- 25 follows:
- 26 "ARTICLE 5
- 27 43-34-120.
- This article shall be known and may be cited as the 'Controlled Substances Therapeutic
- 29 Research 'Haleigh's Hope Act.'
- 30 43-34-121.
- 31 (a) The General Assembly finds and declares that the potential medicinal value of
- 32 marijuana has received insufficient study due to a lack of financial incentives for the
- 33 undertaking of appropriate research by private drug manufacturing concerns. Individual
- 34 physicians cannot feasibly utilize marijuana in clinical trials because of federal
- 35 governmental controls which involve expensive, time-consuming approval and monitoring
- 36 procedures this legislation's purpose is the compassionate potentially life-saving use of
- 37 <u>medical cannabis and is not intended to sanction, encourage, or otherwise be construed as</u>
- 38 <u>a movement toward the legalization of recreational cannabis. Clinical research performed</u>
- 39 over the past decades continues to show benefits arising from medical cannabis. Presently
- 40 <u>there are in excess of one million United States medical cannabis patients and an increasing</u>
- 41 <u>number of physicians are recommending the therapeutic use of cannabis to their patients</u>
- in accordance with their respective state law. New extracts and compounds have been
- 43 <u>developed demonstrating that cannabidiol, one of the most prevalent nonpsychoactive</u>
- 44 <u>cannabinoids</u>, has significant health and wellness benefits as shown by recent publication
- of the positive treatment of certain seizure disorders afflicting children.
- 46 (b) The General Assembly further finds and declares that limited continuing studies
- 47 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
- and vomiting which routinely accompany chemotherapy and irradiation used to
- treat cancer patients. Marijuana Cannabis also may be effective in reducing intraocular
- 51 pressure in glaucoma patients who do not respond well in adjunct to conventional
- medications. <u>Cannabis derivatives have recently shown to be effective in the treatment of</u>
- seizure disorders.
- 54 (c) The General Assembly further finds and declares that, in enabling individual
- 55 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

(d) It is the intent of the General Assembly in enacting this article to permit research into the therapeutic <u>and treatment</u> applications of <u>marijuana cannabis</u> and its derivatives in cancer, <u>and</u> glaucoma, <u>and seizure disorder</u> patients. This would allow qualified <u>physicians academic medical centers</u> approved by the Patient Qualification Review Board created by Code Section 43-34-124 to <u>provide authorize use of</u> the drug on a compassionate basis to seriously ill persons suffering from the severe side effects of chemotherapy or radiation treatment, <u>and</u> to persons suffering from glaucoma who are not responding to conventional treatment, <u>and to persons suffering from seizure disorders</u>, which persons would otherwise have no lawful access to it. It is the further intent of the General Assembly to facilitate clinical trials of <u>marijuana cannabis</u> and its derivatives, particularly with respect to persons suffering from cancer, <u>and</u> glaucoma, <u>and seizure disorders</u> who would be benefited by 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 encouraging or sanctioning the social use of cannabis 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.
- 79 43-34-122.

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- 80 As used in this article, the term:
- 81 (1) 'Academic medical center' means a research hospital that operates a medical
- 82 <u>residency program for physicians and conducts research that involves human subjects,</u>
- 83 <u>including medical schools within the state that conduct translational research or clinical</u>
- 84 <u>research programs.</u>
- 85 (1)(2) 'Board' means the Georgia Composite Medical Board.
- 86 (2)(3) 'Cannabis' 'Marijuana' means marijuana or tetrahydrocannabinol, as defined or
- listed in Article 2 of Chapter 13 of Title 16.
- 88 (4) 'Medical cannabis for the treatment of seizure disorders' means cannabis extracts and
- 89 compounds of cannabis, including, but not limited to, those strains used to manufacture
- 90 <u>cannabidiol</u>, a nonpsychoactive cannabinoid, that is delivered to the patient in a

91 <u>nonsmoking delivery system whether it be in the form of liquid, pill, or injection or other</u>

- 92 <u>delivery method that does not include smoking.</u>
- 93 (5) 'Medical research cannabis' means cannabis, medical cannabis for the treatment of
- 94 <u>seizure disorders, including, but not limited to, cannabis extracts and compounds</u>
- 95 <u>approved under this article.</u>
- 96 (6) 'Pediatric neurologist' means a pediatric neurologist specializing in seizure disorders
- 97 <u>in children approved under this article to utilize medical cannabis treatment in</u>
- 98 <u>conjunction with an approved academic medical center.</u>
- 99 (3)(7) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of
- this chapter.
- 101 (4)(8) 'Program' means the Controlled Substances Therapeutic Research Program
- established pursuant to Code Section 43-34-123.
- 103 (5)(9) 'Review board' means the Patient Qualification Review Board established pursuant
- to Code Section 43-34-124.
- 105 43-34-123.
- 106 (a) There is established under the Georgia Composite Medical Board the Controlled
- Substances Therapeutic Research Program, which shall be administered by the board.
- 108 Under the program, the board shall act as a sponsor of state-wide investigational studies,
- 109 utilizing as drug investigators individual physicians who elect academic medical centers
- and approved pediatric neurologists selected by the board 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 medical research 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 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
- 118 consideration those pertinent rules and regulations promulgated by the Federal United
- 119 <u>States</u> Drug Enforcement Agency Administration, the Food and Drug Administration, and
- the National Institute on Drug Abuse.
- 121 (b) The program shall be limited to patients who are certified to the board by a physician
- selected academic medical center and pediatric neurologists as being:
- 123 (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
- 126 (3) Seizure disorder patients.

127 (c) No patient may be admitted to the program without full disclosure by the physician

- academic medical center of the experimental nature of the program and of the possible
- risks and side effects of the proposed treatment.
- 130 (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 or through the program, donated
- research or study funds, or other funding 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 medical research cannabis
- has been prescribed under this article:
- 136 (1) The board;
- 137 (2) The review board created by Code Section 43-34-124;
- 138 (3) The Attorney General or his or her designee;
- 139 (4) Any person directly connected with the program who has a legitimate need for the
- information; and
- 141 (5) Any federal agency having responsibility for the program:
- (6) Any academic medical center operating a program under this article;
- 143 (7) Any approved pediatric neurologist working in conjunction with an academic
- medical center operating a program under this article; and
- 145 (8) Any patient program participant's attending physician.
- 146 43-34-124.
- 147 (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;
- 151 (2) A board certified physician in surgery;
- 152 (3) A board certified physician in internal medicine and medical oncology;
- 153 (4) A board certified physician in psychiatry;
- 154 (5) A board certified physician in radiology; and
- (6) A pharmacist licensed under Chapter 4 of Title 26, relating to pharmacists, pharmacy,
- and drugs:
- 157 (7) A board certified physician in pediatric neurology;
- 158 (8) A board certified physician in pain management; and
- (9) A board certified pediatric epitologist.
- 160 (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.
- 166 (c) The board shall adopt such rules and regulations as it deems necessary for the
- performance of the duties of the review board.
- 168 (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
- 174 50
- (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
- 181 <u>under this article;</u>
- 182 (4) Shall approve or deny applications for pediatric neurologists to utilize medical
- cannabis in the treatment of patients in conjunction with an approved academic medical
- 184 <u>center.</u>
- 185 (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;
- 187 (6) Shall set application fees and renewal fees that cover its expenses in reviewing and
- approving applications and providing oversight to programs; and
- 189 (7) May accept any gifts, donations, contributions, grants, bequests of funds or property,
- or other funds.
- 191 43-34-125.
- (a) The board An academic medical center operating a program approved under this article
- shall may apply to contract with the National Institute on Drug Abuse for receipt of
- marijuana cannabis pursuant to this article and pursuant to regulations promulgated by the
- National Institute on Drug Abuse, the Food and Drug Administration, and the Federal
- 196 <u>United States</u> Drug Enforcement Agency Administration or obtain such cannabis,
- cannabinoid, or any other derivative, compound, or substantially similar products from any
- 198 <u>available legal source</u>.

(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. An academic medical center approved under this article may obtain research cannabis, cannabinoid, or any other derivative, compound, or substantially similar products from an academic medical center designated under Code Section 43-34-127.

(c) Upon receipt of the research cannabis, its extracts, compounds, or derivatives, or any

- other substantially similar product, regardless of its source including the product produced
 pursuant to Code Section 43-34-127, the academic medical center shall test the
 specifications of such product. Upon completion of its testing of such product, the
- 212 <u>academic medical center shall notify the Georgia Drugs and Narcotics Agency.</u>
- 213 (d) Upon notification by the academic medical center, the Georgia Drugs and Narcotics
- 214 Agency shall take possession of the research product acquired under subsection (a) of this
- 215 Code section and retain such product until such time as the product shall be distributed by
- 216 <u>the agency to the academic medical center.</u>
- 217 (e) The Georgia Drugs and Narcotics Agency shall establish rules and regulations for the
- 218 <u>storage and distribution of the research cannabis.</u>
- 219 (f) An approved pediatric neurologist shall be authorized to receive research cannabis
- 220 <u>through his or her approved affiliated academic medical center.</u>
- 221 43-34-126.

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- 222 Patient participants in the program are immune from state prosecution for possession of
- 223 marijuana as authorized by this article and under the program established in this article.
- 224 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.
- 227 Physician, pharmacy, and pharmacist participants in the program are immune from state
- 228 prosecution for possession, distribution, and any other use of marijuana, which use is
- 229 authorized such persons by this article. Any such possession, distribution, or other use not
- 230 authorized by this article shall be enforced and punished as provided in Chapter 13 of Title
- 231 16, relating to controlled substances and dangerous drugs, and Chapter 4 of Title 26,
- 232 relating to pharmacists and pharmacies.

233 (a) The academic medical center operating a program approved under this article shall

- 234 report annually or more frequently as the board deems necessary to the board in a manner
- specified by the board that includes the following:
- 236 (1) The number of patients served through the program and their county of residence;
- 237 (2) The conditions treated under the program; and
- 238 (3) Any outcome data on the results of the treatment through the program.
- 239 (b) An academic medical center operating a program approved under this article shall
- 240 apply annually to the board for renewal of approval of the program, in accordance with
- 241 <u>procedures established by the board.</u>
- 242 (c) An academic medical center operating a program under this article shall be subject to
- 243 <u>inspection by the board to ensure that the program is operating according to the conditions</u>
- of approval established by the board.
- 245 <u>43-34-127.</u>
- 246 (a) The board shall approve at least one academic medical center to cultivate and process
- 247 <u>medical research cannabis to provide medical research cannabis to programs approved for</u>
- 248 <u>operation under this article.</u>
- 249 (b) The academic medical center approved to cultivate and process medical research
- 250 cannabis under this Code section shall cultivate, process, and transfer such cannabis
- pursuant to Code Section 43-34-125.
- 252 (c) The board shall establish requirements for security and the manufacturing process that
- 253 <u>such academic medical center shall meet in order to be approved for the cultivation and</u>
- 254 processing of such cannabis under this article, including a requirement for the tracking of
- such cannabis.
- 256 (d) The board may revoke this agreement if the academic medical center is found by the
- board to have violated any of the requirements established under this Code section.
- 258 <u>43-34-128.</u>
- 259 <u>Reserved.</u>
- 260 <u>43-34-129.</u>
- 261 Any of the following persons acting in accordance with the provisions of this article shall
- 262 <u>not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil</u>
- 263 penalty or disciplinary action by a professional licensing board, or be denied any right or
- 264 privilege, for the medical use, prescription, administration, manufacture, or distribution of
- 265 medical research cannabis:

266	(1) A patient enrolled in a program approved under this article who is in possession of
267	an amount of medical research cannabis authorized under the program or such patient's
268	caregiver, parent, or guardian; or
269	(2) An academic medical center, an employee of an academic medical center, or any
270	other person associated with the operation of a program approved under this article for
271	activities conducted in accordance with the program approved under this article.
272	<u>43-34-130.</u>
273	A state employee is eligible for reimbursement for incurred counsel fees under Code
274	Section 45-12-26 in the event of a federal criminal investigation or prosecution solely
275	related to the employee's good faith discharge of public responsibilities under this article.
276	<u>43-34-131.</u>
277	(a) The consumption of medical cannabis in accordance with this article shall be an
278	acceptable explanation to a positive test under subsection (d) of Code Section 34-9-415 of
279	the Drug Free Workplace Act or any other lawful drug test administered by an employer.
280	(b) Nothing in this article shall affect an employer's rights under Code Section 34-9-17.
281	(c) A patient's participation in treatment under this article and the consumption of medical
282	cannabis shall not relieve the patient of the obligation to notify his or her employer if such
283	participation impairs his or her ability to safely perform the duties of his or her job.
284	(d) Nothing in this article shall require an employer to accommodate an employee's use
285	of medical cannabis as an approved treatment."

286 **SECTION 3.**

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