

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

AS PASSED SENATE

A BILL TO BE ENTITLED

AN ACT

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

11 **BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:**

12 **PART I**

13 **SECTION 1-1.**

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

16 "CHAPTER 50

17 31-50-1.

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

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

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

27 31-50-2.

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

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

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

35 31-50-3.

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

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

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

46 31-50-4.

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

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

58 31-50-5.

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

61 31-50-6.

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

65 31-50-7.

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

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

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

95 31-50-8.

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

98 31-50-9.

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

101 31-50-10.

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

103

PART II

104

SECTION 2-1.

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

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

115

SECTION 2-2.

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

120 "ARTICLE 5

121 43-34-120.

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

124 43-34-121.

125 (a) The General Assembly finds and declares that ~~the potential medicinal value of~~
126 ~~marijuana has received insufficient study due to a lack of financial incentives for the~~
127 ~~undertaking of appropriate research by private drug manufacturing concerns. Individual~~
128 ~~physicians cannot feasibly utilize marijuana in clinical trials because of federal~~
129 ~~governmental controls which involve expensive, time-consuming approval and monitoring~~
130 ~~procedures~~ this legislation's purpose is the compassionate, potentially life-saving use of
131 medical cannabidiol. Studies indicate that cannabidiol, a nonpsychoactive cannabinoid,
132 has significant health and wellness benefits for the treatment of certain seizure disorders
133 afflicting children.134 (b) The General Assembly further finds and declares that limited studies throughout the
135 nation indicate that ~~marijuana and certain of its derivatives possess~~ cannabidiol possesses
136 valuable and, in some cases, unique therapeutic properties, including the ability to relieve
137 nausea and vomiting which routinely accompany chemotherapy and irradiation used to
138 treat cancer patients. Marijuana also may be effective in reducing intraocular pressure in
139 glaucoma patients who do not respond well to conventional medications treatment of
140 seizure disorders in children.141 (c) The General Assembly further finds and declares that, in enabling individual
142 physicians and their patients to participate in a state-sponsored ~~program~~ clinical study for
143 the investigational use of ~~marijuana and its derivatives~~ cannabidiol, qualified physicians
144 ~~and surgeons~~ throughout the this state will be able to study the benefits of the drug in a
145 controlled clinical setting, and additional knowledge will be gained with respect to dosage
146 and effects.147 (d) It is the intent of the General Assembly in enacting this article to permit research into
148 the therapeutic applications of ~~marijuana and its derivatives in cancer and glaucoma~~
149 ~~patients~~ cannabidiol in seizure disorder patients. This would allow qualified physicians
150 ~~approved by the Patient Qualification Review Board created by Code Section 43-34-124~~
151 to provide the drug on a compassionate basis to seriously ill ~~persons suffering from the~~
152 ~~severe side effects of chemotherapy or radiation treatment and to persons suffering from~~
153 ~~glaucoma who are not responding to conventional treatment~~ children suffering from seizure
154 disorders, which ~~persons~~ children would otherwise have no lawful access to it. It is the

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

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

164 43-34-122.

165 As used in this article, the term:

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

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

173 ~~(2)~~(3) 'Marijuana' means marijuana or tetrahydrocannabinol, as defined or listed in
 174 Article 2 of Chapter 13 of Title 16.

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

177 ~~(3)~~(5) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of
 178 this chapter and is a pediatric neurologist.

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

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

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

185 (7) 'Written certification' means a document dated and signed by a physician stating that
 186 the patient has been diagnosed with Lennox-Gastaut Syndrome, Dravet Syndrome, also
 187 known as severe myoclonic epilepsy of infancy, or any other severe form of epilepsy or
 188 other seizures of unknown etiology that is not adequately treated by traditional medical
 189 therapies.

190 43-34-123.

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

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

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

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

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

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

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

217 ~~(1) The board;~~

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

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

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

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

223 43-34-124.

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

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

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

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

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

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

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

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

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

242 ~~(d) The review board shall review all patient applicants for the program and their~~
 243 ~~physicians and shall certify those qualified for participation in the program. The review~~
 244 ~~board shall additionally certify pharmacies which are licensed by the state and which are~~
 245 ~~otherwise qualified and certify physicians regarding the distribution of marijuana pursuant~~
 246 ~~to Code Section 43-34-125. Meetings of the review board to certify patients, physicians,~~
 247 ~~or pharmacies shall not be open to the public, as otherwise required by Chapter 14 of Title~~
 248 ~~50 Reserved.~~

249 43-34-125.

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

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

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

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

263 43-34-126.

264 ~~Patient participants in the program are immune from state prosecution for possession of~~
265 ~~marijuana as authorized by this article and under the program established in this article.~~

266 ~~A person authorized under this program shall not possess an amount of marijuana in excess~~
267 ~~of the amount prescribed under the authority of this article. The amount prescribed shall~~
268 ~~be maintained in the container in which it was placed at the time the prescription was filled.~~

269 ~~Physician, pharmacy, and pharmacist participants in the program are immune from state~~
270 ~~prosecution for possession, distribution, and any other use of marijuana, which use is~~
271 ~~authorized such persons by this article. Any such possession, distribution, or other use not~~
272 ~~authorized by this article shall be enforced and punished as provided in Chapter 13 of Title~~
273 ~~16, relating to controlled substances and dangerous drugs, and Chapter 4 of Title 26,~~
274 ~~relating to pharmacists and pharmacies.~~

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

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

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

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

290

PART III

291

SECTION 3-1.

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

294

SECTION 3-2.

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