

The Senate Committee on Regulated Industries and Utilities offered the following substitute to HB 196:

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 2 of Title 2 of the Official Code of Georgia Annotated, relating to the
2 Department of Agriculture, so as to provide for the study of the regulation of the production,
3 distribution, and use of medical cannabis; to amend Article 9 of Chapter 12 of Title 16 of the
4 Official Code of Georgia Annotated, relating to access to medical cannabis, so as to provide
5 that the Georgia Access to Medical Cannabis Commission shall be subject to the
6 Administrative Procedure Act, laws governing open meetings and open records, and state
7 purchasing laws; to provide for information to be provided to the Medical Cannabis
8 Commission Oversight Committee unless exempt from public disclosure under open records
9 laws; to authorize the location of retail outlets for the dispensing of low THC oil and
10 products to registered patients at Class 1 and Class 2 production facilities; to authorize the
11 dispensing of low THC oil and products from any Class 1 or Class 2 production licensee by
12 any dispensing licensee; to provide for additional Class 1 and Class 2 production licenses;
13 to provide for criteria; to provide for appeals to the Georgia State-wide Business Court; to
14 require each commissioner to file an annual financial disclosure statement; to amend Code
15 Section 31-2A-18 of the Official Code of Georgia Annotated, relating to the Low THC Oil
16 Patient Registry, so as to expand conditions for which low THC oil may be used for
17 treatment; to provide for related matters; to provide for an effective date; to repeal conflicting
18 laws; and for other purposes.

19 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

20 **SECTION 1.**

21 Chapter 2 of Title 2 of the Official Code of Georgia Annotated, relating to the Department
22 of Agriculture, is amended by adding a new Code section to read as follows:

23 "2-2-14.

24 Prior to September 1, 2023, the Commissioner shall undertake a thorough study of issues
25 and problems relating to regulation of the production, distribution, and use of medical
26 cannabis in the State of Georgia. No later than December 1, 2023, the Commissioner shall
27 submit a report to the Governor, Lieutenant Governor, and Speaker of the House of
28 Representatives detailing any organizational, budgetary, or legislative changes the
29 Commissioner may recommend in regard to these issues."

30 **SECTION 2.**

31 Article 9 of Chapter 12 of Title 16 of the Official Code of Georgia Annotated, relating to
32 access to medical cannabis, is amended by revising Code Section 16-12-202, relating to the
33 creation of Georgia Access to Medical Cannabis Commission, terms, designation, meetings,
34 vacancy, and compensation, by adding a new subsection to read as follows:

35 "(f) The commission shall be subject to the provisions of Article 3 of Chapter 5, Chapter
36 13, Chapter 14, and Article 4 of Chapter 18 of Title 50, except as otherwise provided in this
37 article."

38 **SECTION 3.**

39 Said article is further amended by revising paragraphs (2) and (17) of Code
40 Section 16-12-203, relating to powers, duties, and responsibilities of the Georgia Access to
41 Medical Cannabis Commission, as follows:

42 "(2) To execute a contract or contracts to purchase or obtain low THC oil, cannabis,
 43 cannabinoids, or any other derivative, compound, or substantially similar products from
 44 any available legal source and to provide logistics related thereto in accordance with this
 45 article. Such contract or contracts may be executed with one or more qualified
 46 corporations or with one or more governmental entities. Purchases made and contracts
 47 entered into pursuant to this paragraph shall ~~not~~ be subject to state purchasing laws
 48 contained in Article 3 of Chapter 5 of Title 50 ~~or in other provisions of the Official Code~~
 49 ~~of Georgia Annotated;~~"

50 "(17) To levy fines for failure by a Class 1 production licensee, Class 2 production
 51 licensee, or dispensing licensee to operate in accordance with rules and regulations
 52 established by the commission within 14 days of written notice by the commission of
 53 specific violations. Such fines shall not exceed \$25,000.00 for a first offense, \$50,000.00
 54 for a failure to remedy the offense within 60 days after written notice of a first offense,
 55 and \$75,000.00 for subsequent failures to remedy noncompliance within 90 days after
 56 written notice of a first offense. Following a third written notice of a recurring violation,
 57 the commission may also order a licensee to cease operations for a period of up to 30
 58 days to correct the violation. Any such fines or orders to cease operations shall be subject
 59 to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act-';' provided,
 60 however, that any appeal from a final decision shall be made to the Georgia State-wide
 61 Business Court in accordance with Code Section 16-12-221.1."

62 **SECTION 4.**

63 Said article is further amended by revising Code Section 16-12-206, relating to annual,
 64 nontransferable dispensing license, adoption of rules, and fees, as follows:

65 "16-12-206.

66 (a)(1) Upon request by a licensed pharmacy in this state, the State Board of Pharmacy
 67 shall be authorized to develop an annual, nontransferable specialty dispensing license for

68 an independent pharmacy with a registered office located within this state to dispense low
69 THC oil and products to registered patients. The State Board of Pharmacy shall develop
70 rules and regulations regarding dispensing pharmacies in this state in accordance with the
71 requirements contained in subsection (b) of this Code section.

72 (2) The commission shall be authorized to issue five dispensing licenses to each Class
73 1 production licensee and each Class 2 production licensee for retail outlets to dispense
74 low THC oil and products to registered patients. In addition, the commission shall be
75 authorized to issue a dispensing license for a retail outlet to each Class 1 production
76 licensee and each Class 2 production licensee for the purpose of establishing a retail
77 outlet for the dispensing of low THC oil and products to registered patients at the location
78 of the Class 1 production licensee's production facility or at the location of the Class 2
79 production licensee's production facility. The commission shall ensure that dispensing
80 licenses shall be issued so that retail outlets are dispersed throughout the state. The
81 commission shall develop rules and regulations regarding retail dispensing licensees in
82 this state in accordance with the requirements contained in subsection (b) of this Code
83 section. The commission shall be authorized to issue one additional dispensing license
84 to each Class 1 and Class 2 production licensee when the Low THC Oil Patient Registry
85 established and maintained pursuant to Code Section 31-2A-18 reaches ~~25,000~~ 75,000
86 patients and for every increase of ~~10,000~~ 50,000 patients thereafter.

87 (b) The State Board of Pharmacy and the commission shall separately adopt rules relating
88 to the dispensing of low THC oil and products, with the State Board of Pharmacy
89 promulgating rules and regulations for pharmacies that dispense low THC oil and products
90 and the commission promulgating rules and regulations for other retail outlets that dispense
91 low THC oil and products. Such rules shall include but not be limited to:

92 (1) Standards, procedures, and protocols for the effective use of low THC oil and
93 products as authorized by state law and related rules and regulations;

- 94 (2) Standards, procedures, and protocols for the dispensing of low THC oil and products
95 by a pharmacy with a dispensing license and by retail dispensing licensees and for the
96 utilization of a tracking system;
- 97 (3) Procedures and protocols to provide that no low THC oil or products may be sold to
98 or transferred to a location outside of this state;
- 99 (4) The establishment of standards, procedures, and protocols for determining the
100 amount of usable low THC oil and products that is necessary to constitute an adequate
101 supply for registered patients in this state to ensure uninterrupted availability for a period
102 of one month, including amounts for topical treatments;
- 103 (5) The establishment of standards, procedures, and protocols to ensure that all low THC
104 oil and products dispensed are consistently pharmaceutical grade;
- 105 (6) The establishment of standards and procedures for the revocation, suspension, and
106 nonrenewal of dispensing licenses;
- 107 (7) The establishment of other licensing, renewal, and operational standards which are
108 deemed necessary by the State Board of Pharmacy and the commission;
- 109 (8) The establishment of standards and procedures for testing low THC oil and products
110 for levels of tetrahydrocannabinol or other testing parameters deemed appropriate by the
111 State Board of Pharmacy and the commission;
- 112 (9) The establishment of health, safety, and security requirements for pharmacies and
113 retail dispensing licensees dispensing low THC oil and products; and
- 114 (10) Requirements for the issuance of dispensing licenses to pharmacies and Class 1 and
115 Class 2 production licensees.
- 116 (c) The commission shall be authorized, by rules and regulations, to establish fees for
117 dispensing licenses to Class 1 and Class 2 production licensees commensurate with the
118 location of the retail outlet and demand for low THC oil and products at such location.
- 119 (d) Each dispensing location shall be authorized to sell low THC oil and products from any
120 Class 1 or Class 2 production licensee in this state."

121

SECTION 5.

122 Said article is further amended by revising Code Section 16-12-207, relating to establishment
123 of Medical Cannabis Commission Oversight Committee, membership, inspections, provision
124 of information, plan for accredited lab testing, and patient and physician input, as follows:

125 "16-12-207.

126 (a) The General Assembly shall establish a Medical Cannabis Commission Oversight
127 Committee with two members appointed by the Lieutenant Governor and two members
128 appointed by the Speaker of the House of Representatives. Any member of the Medical
129 Cannabis Commission Oversight Committee shall be permitted to inspect any production
130 facility upon request and after reasonable notice is provided to the production facility.

131 (b) The commission shall promptly provide any document or information requested by the
132 oversight committee that is in its possession, provided that the commission shall not be
133 required to share documents containing data identifying individual patients or physicians,
134 information marked as trade secrets by applicants or licensees, information that in the view
135 of the commission would interfere with an ongoing licensing applicant selection process,
136 or information that in the judgment of the commission would create law enforcement or
137 security risks to the citizens of Georgia any information that would be exempt from public
138 disclosure pursuant to Code Section 50-18-72 or pursuant to state or federal privacy laws.

139 (c) ~~No later than August 1, 2021, the oversight committee shall recommend to the~~
140 ~~commission a process and plan for providing accredited lab testing of products produced~~
141 ~~by licensees and for labeling such products. The commission shall consider the~~
142 ~~recommendations of the oversight committee in adopting policies, procedures, and~~
143 ~~regulations regarding such testing and labeling~~ Reserved.

144 (d) The oversight committee may regularly seek input from patients and physicians as to
145 the availability and quality of products produced pursuant to this chapter, and recommend
146 to the commission changes to policies, procedures, and regulations to improve availability

147 and quality. The commission shall consider such recommendations in adopting policies,
148 procedures, and regulations."

149 **SECTION 6.**

150 Said article is further amended by revising Code Section 16-12-220, relating to confidential
151 nature of data, exclusion, and patient privacy, as follows:

152 "16-12-220.

153 (a) All working papers, recorded information, documents, and copies produced by,
154 obtained by, or disclosed to the commission pursuant to the activities conducted pursuant
155 to this part, ~~other than information published in an official commission report regarding the~~
156 ~~activities conducted pursuant to this article, shall be confidential data and shall not be~~
157 ~~subject to Article 4 of Chapter 18 of Title 50; provided, however, that any contract,~~
158 ~~memorandum of understanding, or cooperative endeavor agreement entered into by the~~
159 ~~commission pursuant to this article shall be subject to Article 4 of Chapter 18 of Title 50,~~
160 relating to open records.

161 (b) In no event shall the commission disclose any information that would reveal the
162 identity or health information of any registered patient or violate the federal Health
163 Insurance Portability and Accountability Act of 1996, Public Law 104-191."

164 **SECTION 7.**

165 Said article is further amended by revising subsection (a) of Code Section 16-12-221, relating
166 to contracts awarded through bids or proposals, minimum contract terms and renewals,
167 subcontracting, and giving or receiving things of value limited, as follows:

168 "(a)(1) The commission shall grant initial licenses under this part pursuant to contracts
169 awarded through competitive sealed bids or competitive sealed proposals as provided for
170 in Article 3 of Chapter 5 of Title 50. After issuance of two initial Class 1 production
171 licenses pursuant to Code Section 16-12-211 and four initial Class 2 production licenses

172 pursuant to Code Section 16-12-212, ~~and in the Department of Agriculture shall issue one~~
 173 additional class 2 production license for every increase of 50,000 patients provided that
 174 the Low THC Oil Patient Registry exceeds 250,000 patients, the current production
 175 licenses are inadequate to address the registry patient demand, and the grant of such
 176 licenses is ratified by the legislature. Thereafter, the initial increase in the number of
 177 production licenses in the Low THC Oil Patient Registry shall be based on the findings
 178 of the Commissioner of the Department of Agriculture as provided in Code Section
 179 2-2-14.

180 (2) In the event that the commission revokes a Class 1 or Class 2 production license, a
 181 Class 1 or Class 2 production license is surrendered for any reason, or the commission
 182 issues an additional Class 1 production license pursuant to Code Section 16-12-214, the
 183 commission shall be authorized to issue any replacement Class 1 or Class 2 production
 184 licenses in accordance with rules and regulations established by the commission for such
 185 purpose. Such rules and regulations shall not otherwise conflict with this article, and to
 186 the extent practicable, such rules and regulations shall incorporate provisions and
 187 processes similar to Article 3 of Chapter 5 of Title 50."

188

SECTION 8.

189 Said article is further amended by adding a new Code section to read as follows:

190 "16-12-221.1.

191 (a) The Georgia State-wide Business Court shall exercise exclusive jurisdiction over any
 192 appeal by a party aggrieved by a final decision of the commission pursuant to this article.
 193 The Georgia State-wide Business Court shall conduct expedited hearings on any such
 194 appeals, and review by the court shall be confined to the record.

195 (b) The court shall not substitute its judgment for that of the commission as to the weight
 196 of the evidence on questions of fact committed to the discretion of the commission. The
 197 court may affirm any decision of the commission in whole or in part. The court shall

198 reverse or remand any case for further proceedings if material rights of the appellant have
 199 been prejudiced because the commission's findings, inferences, conclusions, or decisions
 200 are:

- 201 (1) In violation of constitutional or statutory provisions or applicable procurement rules;
 202 (2) Made upon unlawful procedures;
 203 (3) Affected by other error of law;
 204 (4) Not reasonably supported by substantial evidence in view of the reliable and
 205 probative evidence in the record as a whole; or
 206 (5) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted
 207 exercise of discretion."

208 **SECTION 9.**

209 Said article is further amended by revising subsection (c) of Code Section 16-12-222, relating
 210 to transfer of ownership, appeals, meaning of license, and transfer fees, as follows:

211 "(c) A licensee who has been denied transfer approval by the commission may file an
 212 ~~appeal in the Superior Court of Fulton County in accordance with Chapter 13 of Title 50,~~
 213 ~~the 'Georgia Administrative Procedure Act.'~~ with the Georgia State-wide Business Court
 214 in accordance with Code Section 16-12-221.1."

215 **SECTION 10.**

216 Said article is further amended by revising subsection (b) of Code Section 16-12-223,
 217 relating to revocation of license and appeal, as follows:

218 "(b) A licensee whose license has been revoked by the commission may file an appeal ~~in~~
 219 ~~the Superior Court of Fulton County in accordance with Chapter 13 of Title 50, the~~
 220 ~~'Georgia Administrative Procedure Act.'~~ with the Georgia State-wide Business Court in
 221 accordance with Code Section 16-12-221.1."

222

SECTION 11.

223 Said article is further amended by revising Code Section 16-12-224, relating to limitation on
224 ownership by member or former member of commission, limitation on physician's
225 involvement, and identification when contributing to political campaigns, as follows:

226 "16-12-224.

227 (a) No current member of the commission, or former member of the commission for a
228 period of five years from the date such individual ceased to be a member, shall own,
229 operate, have a financial interest in, or be employed by a low THC oil or product
230 manufacturer or distributor, including any licensee under this part.

231 (b) No physician who, presently or during the period of such business relationship,
232 certifies individuals to the commission pursuant to Code Section 31-2A-18 for the use of
233 low THC oil and products to treat certain conditions shall own, operate, have a financial
234 interest in, or be employed by a low THC oil or product manufacturer or distributor,
235 including any licensee under this part. This subsection shall not prohibit a physician from
236 furnishing a registered patient or his or her caregiver, upon request, with the names of low
237 THC oil and product manufacturers or distributors. Any physician violating this Code
238 section shall be guilty of a misdemeanor.

239 (c) Each member of the commission shall file an annual financial disclosure statement for
240 the preceding calendar year with the Office of Inspector General no later than July 1 of
241 each year. Such financial disclosure shall include ownership interests in businesses,
242 income, and source or sources of income for the previous calendar year. For any
243 commissioner serving as of May 1, 2023, such disclosure for the 2022 calendar year shall
244 be filed with the Office of Inspector General no later than May 31, 2023.

245 ~~(c)~~(d) A licensee that makes a campaign contribution pursuant to Article 2 of Chapter 5
246 of Title 21 shall identify itself as a licensee under this part to the recipient of such
247 campaign contribution."

248

SECTION 12.

249 Code Section 31-2A-18 of the Official Code of Georgia Annotated, relating to the Low THC
250 Oil Patient Registry, is amended by revising paragraph (3) of subsection (a) as follows:

251 "(3) 'Condition' means:

252 (A) Cancer, when such disease is diagnosed as end stage or the treatment produces
253 related wasting illness or recalcitrant nausea and vomiting;

254 (B) Amyotrophic lateral sclerosis, when such disease is diagnosed as severe or end
255 stage;

256 (C) Seizure disorders related to a diagnosis of epilepsy or trauma related head injuries;

257 (D) Multiple sclerosis, when such disease is diagnosed as severe or end stage;

258 (E) Crohn's disease;

259 (F) Mitochondrial disease;

260 (G) Parkinson's disease, when such disease is diagnosed as severe or end stage;

261 (H) Sickle cell disease, when such disease is diagnosed as severe or end stage;

262 (I) Tourette's syndrome, when such syndrome is diagnosed as severe;

263 (J) Autism spectrum disorder, when such disorder is diagnosed for a patient who is at
264 least 18 years of age, or severe autism, when diagnosed for a patient who is less than
265 18 years of age;

266 (K) Epidermolysis bullosa;

267 (L) Alzheimer's disease, when such disease is diagnosed as severe or end stage;

268 (M) Acquired immune deficiency syndrome, when such syndrome is diagnosed as
269 severe or end stage;

270 (N) Peripheral neuropathy, when such symptoms are diagnosed as severe or end stage;

271 (O) Post-traumatic stress disorder resulting from direct exposure to or the witnessing
272 of a trauma for a patient who is at least 18 years of age; or

273 (P) Intractable pain;

274 (Q) Ulcerative colitis; or

275 (R) Myasthenia Gravis."

276 **SECTION 13.**

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

279 **SECTION 14.**

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