House Bill 196 (RULES COMMITTEE SUBSTITUTE)

By: Representatives Powell of the 33<sup>rd</sup>, Washburn of the 144<sup>th</sup>, Wilkerson of the 38<sup>th</sup>, Daniel of the 117<sup>th</sup>, McCollum of the 30<sup>th</sup>, and others

# A BILL TO BE ENTITLED AN ACT

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

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### BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

**SECTION 1.** 18 Article 9 of Chapter 12 of Title 16 of the Official Code of Georgia Annotated, relating to 19 access to medical cannabis, is amended by revising Code Section 16-12-202, relating to the 20 creation of Georgia Access to Medical Cannabis Commission, terms, designation, meetings, 21 vacancy, and compensation, by adding a new subsection to read as follows: 22 "(f) The commission shall be subject to the provisions of Article 3 of Chapter 5, Chapter 23 13, Chapter 14, and Article 4 of Chapter 18 of Title 50, except as otherwise provided in this

article." 24

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### **SECTION 2.**

26 Said article is further amended by revising paragraphs (2) and (17) of Code Section 16-12-203, relating to powers, duties, and responsibilities of the Georgia Access to 27 28 Medical Cannabis Commission, as follows:

29 "(2) To execute a contract or contracts to purchase or obtain low THC oil, cannabis, 30 cannabinoids, or any other derivative, compound, or substantially similar products from 31 any available legal source and to provide logistics related thereto in accordance with this 32 article. Such contract or contracts may be executed with one or more qualified 33 corporations or with one or more governmental entities. Purchases made and contracts 34 entered into pursuant to this paragraph shall not be subject to state purchasing laws 35 contained in Article 3 of Chapter 5 of Title 50 or in other provisions of the Official Code 36 of Georgia Annotated;"

37 "(17) To levy fines for failure by a Class 1 production licensee, Class 2 production 38 licensee, or dispensing licensee to operate in accordance with rules and regulations 39 established by the commission within 14 days of written notice by the commission of 40 specific violations. Such fines shall not exceed \$25,000.00 for a first offense, \$50,000.00 41 for a failure to remedy the offense within 60 days after written notice of a first offense, 42 and \$75,000.00 for subsequent failures to remedy noncompliance within 90 days after

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written notice of a first offense. Following a third written notice of a recurring violation,
the commission may also order a licensee to cease operations for a period of up to 30
days to correct the violation. Any such fines or orders to cease operations shall be subject
to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act<del>:'</del>:' provided,
however, that any appeal from a final decision shall be made to the Georgia State-wide
Business Court in accordance with Code Section 16-12-221.1."

49 **SECTION 3.** Said article is further amended by revising Code Section 16-12-206, relating to annual, 50 51 nontransferable dispensing license, adoption of rules, and fees, as follows: 52 "16-12-206. (a)(1) Upon request by a licensed pharmacy in this state, the State Board of Pharmacy 53 54 shall be authorized to develop an annual, nontransferable specialty dispensing license for 55 an independent pharmacy with a registered office located within this state to dispense low 56 THC oil and products to registered patients. The State Board of Pharmacy shall develop 57 rules and regulations regarding dispensing pharmacies in this state in accordance with the 58 requirements contained in subsection (b) of this Code section. 59 (2) The commission shall be authorized to issue five dispensing licenses to each Class 60 1 production licensee and each Class 2 production licensee for retail outlets to dispense 61 low THC oil and products to registered patients. In addition, the commission shall be 62 authorized to issue a dispensing license for a retail outlet to each Class 1 production 63 licensee and each Class 2 production licensee for the purpose of establishing a retail 64 outlet for the dispensing of low THC oil and products to registered patients at the location 65 of the Class 1 production licensee's production facility or at the location of the Class 2 production licensee's production facility. The commission shall ensure that dispensing 66 licenses shall be issued so that retail outlets are dispersed throughout the state. The 67

commission shall develop rules and regulations regarding retail dispensing licensees in

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69 this state in accordance with the requirements contained in subsection (b) of this Code 70 section. The commission shall be authorized to issue one additional dispensing license 71 to each Class 1 and Class 2 production licensee when the Low THC Oil Patient Registry 72 established and maintained pursuant to Code Section 31-2A-18 reaches 25,000 patients 73 and for every increase of 10,000 patients thereafter.

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

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

81 (2) Standards, procedures, and protocols for the dispensing of low THC oil and products
82 by a pharmacy with a dispensing license and by retail dispensing licensees and for the
83 utilization of a tracking system;

84 (3) Procedures and protocols to provide that no low THC oil or products may be sold to
85 or transferred to a location outside of this state;

(4) The establishment of standards, procedures, and protocols for determining the
amount of usable low THC oil and products that is necessary to constitute an adequate
supply for registered patients in this state to ensure uninterrupted availability for a period
of one month, including amounts for topical treatments;

90 (5) The establishment of standards, procedures, and protocols to ensure that all low THC
91 oil and products dispensed are consistently pharmaceutical grade;

92 (6) The establishment of standards and procedures for the revocation, suspension, and

93 nonrenewal of dispensing licenses;

94 (7) The establishment of other licensing, renewal, and operational standards which are
95 deemed necessary by the State Board of Pharmacy and the commission;

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- (8) The establishment of standards and procedures for testing low THC oil and products
  for levels of tetrahydrocannabinol or other testing parameters deemed appropriate by the
  State Board of Pharmacy and the commission;
- (9) The establishment of health, safety, and security requirements for pharmacies andretail dispensing licensees dispensing low THC oil and products; and
- (10) Requirements for the issuance of dispensing licenses to pharmacies and Class 1 and
   Class 2 production licensees.
- (c) The commission shall be authorized, by rules and regulations, to establish fees for
   dispensing licenses to Class 1 and Class 2 production licensees commensurate with the
- 105 location of the retail outlet and demand for low THC oil and products at such location.
- 106 (d) Each dispensing location shall be authorized to sell low THC oil and products from any
- 107 <u>Class 1 or Class 2 production licensee in this state.</u>"
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# **SECTION 4.**

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

112 ″16-12-207.

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

(b) The commission shall promptly provide any document or information requested by the
 oversight committee that is in its possession, provided that the commission shall not <u>be</u>
 required to share documents containing data identifying individual patients or physicians,
 information marked as trade secrets by applicants or licensees, information that in the view

122 of the commission would interfere with an ongoing licensing applicant selection process, 123 or information that in the judgment of the commission would create law enforcement or 124 security risks to the citizens of Georgia any information that would be exempt from public 125 disclosure pursuant to Code Section 50-18-72 or pursuant to state or federal privacy laws. (c) No later than August 1, 2021, the oversight committee shall recommend to the 126 commission a process and plan for providing accredited lab testing of products produced 127 128 by licensees and for labeling such products. The commission shall consider the 129 recommendations of the oversight committee in adopting policies, procedures, and 130 regulations regarding such testing and labeling Reserved. 131 (d) The oversight committee may regularly seek input from patients and physicians as to

(d) The oversight committee may regularly seek input from patients and physicians as to
 the availability and quality of products produced pursuant to this chapter, and recommend
 to the commission changes to policies, procedures, and regulations to improve availability
 and quality. The commission shall consider such recommendations in adopting policies,
 procedures, and regulations."

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#### **SECTION 5.**

Said article is further amended by revising subsection (a) of Code Section 16-12-211, relating
to Class 1 production licenses, application fees, revocation, and limitation of ownership, as
follows:

"(a) The commission may issue up to two <u>initial</u> Class 1 production licenses. <u>The</u>
<u>commission shall issue four additional Class 1 production licenses pursuant to subsection</u>
(a) of Code Section 16-12-221, provided that the total number of Class 1 and Class 2
<u>production licenses shall not exceed 15 production licenses</u>. A Class 1 production licensee
shall be authorized to:
(1) Grow cannabis only in indoor facilities for use in producing low THC oil, limited to
100,000 square feet of cultivation space; and

147 (2) Manufacture low THC oil and products."

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148	SECTION 6.
149	Said article is further amended by revising subsection (a) of Code Section 16-12-212, relating
150	to Class 2 production licenses, application fees, revocation, and limitation of ownership, as
151	follows:
152	"(a) The commission may issue up to four <u>initial</u> Class 2 production licenses. <u>The</u>
153	commission shall issue seven additional Class 2 production licenses pursuant to subsection
154	(a) of Code Section 16-12-221, provided that the total number of Class 1 and Class 2
155	production licenses shall not exceed 15 production licenses. A Class 2 production licensee
156	shall be authorized to:
157	(1) Grow cannabis only in indoor facilities for use in producing low THC oil, limited
158	to 50,000 square feet of cultivation space; and
159	(2) Manufacture low THC oil and products."
160	SECTION 7.
160 161	<b>SECTION 7.</b> Said article is further amended by revising Code Section 16-12-220, relating to confidential
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161 162 163 164	<ul> <li>Said article is further amended by revising Code Section 16-12-220, relating to confidential nature of data, exclusion, and patient privacy, as follows:</li> <li>"16-12-220.</li> <li>(a) All working papers, recorded information, documents, and copies produced by,</li> </ul>
161 162 163 164 165	<ul> <li>Said article is further amended by revising Code Section 16-12-220, relating to confidential nature of data, exclusion, and patient privacy, as follows:</li> <li>"16-12-220.</li> <li>(a) All working papers, recorded information, documents, and copies produced by, obtained by, or disclosed to the commission pursuant to the activities conducted pursuant</li> </ul>
161 162 163 164 165 166	<ul> <li>Said article is further amended by revising Code Section 16-12-220, relating to confidential nature of data, exclusion, and patient privacy, as follows:</li> <li>"16-12-220.</li> <li>(a) All working papers, recorded information, documents, and copies produced by, obtained by, or disclosed to the commission pursuant to the activities conducted pursuant to this part, other than information published in an official commission report regarding the</li> </ul>
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161 162 163 164 165 166 167 168	<ul> <li>Said article is further amended by revising Code Section 16-12-220, relating to confidential nature of data, exclusion, and patient privacy, as follows:</li> <li>"16-12-220.</li> <li>(a) All working papers, recorded information, documents, and copies produced by, obtained by, or disclosed to the commission pursuant to the activities conducted pursuant to this part, other than information published in an official commission report regarding the activities conducted pursuant to this article, shall be confidential data and shall not be subject to Article 4 of Chapter 18 of Title 50; provided, however, that any contract,</li> </ul>

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

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#### **SECTION 8.**

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

179 ''(a)(1) The commission shall grant initial licenses under this part pursuant to contracts 180 awarded through competitive sealed bids or competitive sealed proposals as provided for 181 in Article 3 of Chapter 5 of Title 50. After issuance of two initial Class 1 production licenses pursuant to Code Section 16-12-211 and four initial Class 2 production licenses 182 183 pursuant to Code Section 16-12-212, and in the commission shall issue one additional 184 Class 2 production license for every increase of 5,000 patients in the Low THC Oil 185 Patient Registry established and maintained pursuant to Code Section 31-2A-18 and one additional Class 1 production license for every increase of 10,000 patients in the Low 186 187 THC Oil Patient Registry, subject to the overall limit of total number of Class 1 and Class 188 2 production licenses contained in Code Sections 16-12-211 and 16-12-212. The initial 189 increase in the number of patients in the Low THC Oil Patient Registry shall be based on 190 the number of patients in the registry as of January 1, 2023. 191 (2) In the event that the commission revokes a Class 1 or Class 2 production license, a

192 Class 1 or <u>Class</u> 2 production license is surrendered for any reason, or the commission 193 issues an additional Class 1 production license pursuant to Code Section 16-12-214, the 194 commission shall be authorized to issue any replacement Class 1 or Class 2 production 195 licenses in accordance with <del>rules and regulations established by the commission for such</del> 196 <del>purpose. Such rules and regulations shall not otherwise conflict with this article, and to</del>

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197	the extent practicable, such rules and regulations shall incorporate provisions and
198	processes similar to Article 3 of Chapter 5 of Title 50."
199	SECTION 9.
200	Said article is further amended by adding a new Code section to read as follows:
201	″ <u>16-12-221.1.</u>
202	(a) The Georgia State-wide Business Court shall exercise exclusive jurisdiction over any
203	appeal by a party aggrieved by a final decision of the commission pursuant to this article.
204	The Georgia State-wide Business Court shall conduct expedited hearings on any such
205	appeals, and review by the court shall be confined to the record.
206	(b) The court shall not substitute its judgment for that of the commission as to the weight
207	of the evidence on questions of fact committed to the discretion of the commission. The
208	court may affirm any decision of the commission in whole or in part. The court shall
209	reverse or remand any case for further proceedings if material rights of the appellant have
210	been prejudiced because the commission's findings, inferences, conclusions, or decisions
211	are:
212	(1) In violation of constitutional or statutory provisions or applicable procurement rules;
213	(2) Made upon unlawful procedures;
214	(3) Affected by other error of law;
215	(4) Not reasonably supported by substantial evidence in view of the reliable and
216	probative evidence in the record as a whole; or
217	(5) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted
218	exercise of discretion.
219	(c) The court shall require a litigation bond or other form of surety payable to the state
220	from any protesting party in an amount determined by the court, which shall be forfeited
221	if the court affirms, in whole, the decision of the commission."

	23 LC 48 0911S
222	SECTION 10.
223	Said article is further amended by revising subsection (c) of Code Section 16-12-222, relating
224	to transfer of ownership, appeals, meaning of license, and transfer fees, as follows:
225	"(c) A licensee who has been denied transfer approval by the commission may file an
226	appeal with the Georgia State-wide Business Court in accordance with Code Section
227	16-12-221.1. in the Superior Court of Fulton County in accordance with Chapter 13 of
228	Title 50, the 'Georgia Administrative Procedure Act.'"
229	SECTION 11.
230	Said article is further amended by revising subsection (b) of Code Section 16-12-223,
231	relating to revocation of license and appeal, as follows:
232	"(b) A licensee whose license has been revoked by the commission may file an appeal $\underline{\text{with}}$
233	the Georgia State-wide Business Court in accordance with Code Section 16-12-221.1. in
234	the Superior Court of Fulton County in accordance with Chapter 13 of Title 50, the
235	'Georgia Administrative Procedure Act."
236	SECTION 12.
237	Said article is further amended by revising Code Section 16-12-224, relating to limitation on
238	ownership by member or former member of commission, limitation on physician's
239	involvement, and identification when contributing to political campaigns, as follows:
240	<i>"</i> 16-12-224.
241	(a) No current member of the commission, or former member of the commission for a
242	period of five years from the date such individual ceased to be a member, shall own,
243	operate, have a financial interest in, or be employed by a low THC oil or product
244	manufacturer or distributor, including any licensee under this part.
245	(b) No physician who, presently or during the period of such business relationship,
246	certifies individuals to the commission pursuant to Code Section 31-2A-18 for the use of

low THC oil and products to treat certain conditions shall own, operate, have a financial
interest in, or be employed by a low THC oil or product manufacturer or distributor,
including any licensee under this part. This subsection shall not prohibit a physician from
furnishing a registered patient or his or her caregiver, upon request, with the names of low
THC oil and product manufacturers or distributors. Any physician violating this Code
section shall be guilty of a misdemeanor.

- 253 (c) Each member of the commission shall file an annual financial disclosure statement for
- 254 the preceding calendar year with the Office of Inspector General no later than July 1 of
- 255 each year. Such financial disclosure shall include ownership interests in businesses,
- income, and source or sources of income for the previous calendar year. For any
   commissioner serving as of May 1, 2023, such disclosure for the 2022 calendar year shall
   be filed with the Office of Inspector General no later than May 31, 2023.
- 259 (c)(d) A licensee that makes a campaign contribution pursuant to Article 2 of Chapter 5
- of Title 21 shall identify itself as a licensee under this part to the recipient of suchcampaign contribution."
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### **SECTION 13.**

263 Code Section 31-2A-18 of the Official Code of Georgia Annotated, relating to the Low THC

264 Oil Patient Registry, is amended by revising paragraph (3) of subsection (a) as follows:

265 "(3) 'Condition' means:

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

- 268 (B) Amyotrophic lateral sclerosis, when such disease is diagnosed as severe or end
  269 stage;
- 270 (C) Seizure disorders related to a diagnosis of epilepsy or trauma related head injuries;
- (D) Multiple sclerosis, when such disease is diagnosed as severe or end stage;
- 272 (E) Crohn's disease;

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273	(F) Mitochondrial disease;
274	(G) Parkinson's disease, when such disease is diagnosed as severe or end stage;
275	(H) Sickle cell disease, when such disease is diagnosed as severe or end stage;
276	(I) Tourette's syndrome, when such syndrome is diagnosed as severe;
277	(J) Autism spectrum disorder, when such disorder is diagnosed for a patient who is at
278	least 18 years of age, or severe autism, when diagnosed for a patient who is less than
279	18 years of age;
280	(K) Epidermolysis bullosa;
281	(L) Alzheimer's disease, when such disease is diagnosed as severe or end stage;
282	(M) Acquired immune deficiency syndrome, when such syndrome is diagnosed as
283	severe or end stage;
284	(N) Peripheral neuropathy, when such symptoms are diagnosed as severe or end stage;
285	(O) Post-traumatic stress disorder resulting from direct exposure to or the witnessing
286	of a trauma for a patient who is at least 18 years of age; or
287	(P) Intractable pain;
288	(Q) Ulcerative colitis; or
289	(R) Myasthenia Gravis."
290	SECTION 14.
291	This Act shall become effective upon its approval by the Governor or upon its becoming law
292	without such approval.
293	SECTION 15.

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