

1 HOUSE BILL NO. 1846

2 AMENDMENT IN THE NATURE OF A SUBSTITUTE

3 (Proposed by the House Committee on Health Welfare and Institutions
4 on February 2, 2023)

5 (Patron Prior to Substitute--Delegate Head)

6 A BILL to amend and reenact §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of
7 Virginia and to amend the Code of Virginia by adding sections numbered 54.1-3442.7:1, 54.1-
8 3442.7:2, and 54.1-3442.7:3, relating to medical marijuana program; product, registration,
9 dispensing, and recordkeeping requirements; advertising.

10 **Be it enacted by the General Assembly of Virginia:**

11 **1. That §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are**
12 **amended and reenacted and that the Code of Virginia is amended by adding sections numbered**
13 **54.1-3442.7:1, 54.1-3442.7:2, and 54.1-3442.7:3 as follows:**

14 **§ 54.1-3408.3. Certification for use of cannabis products for treatment.**

15 A. As used in this section:

16 "Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same
17 parts of the same chemovar of cannabis plant.

18 "Cannabis dispensing facility" means the same as that term is defined in § 54.1-3442.5.

19 "Cannabis oil" means any formulation of processed Cannabis plant extract, which may include
20 industrial hemp extracts, including isolates and distillates, acquired by a pharmaceutical processor
21 pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains, except as otherwise
22 provided in Article 4.2 (§ 54.1-3442.5 et seq.), no more than 10 milligrams of ~~delta-9-~~
23 ~~tetrahydrocannabinol~~ tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as
24 defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, unless it
25 has been grown and processed in the Commonwealth by a registered industrial hemp processor and
26 acquired and formulated by a pharmaceutical processor.

27 "Cannabis product" means a product that ~~is~~ (i) is formulated with cannabis oil or botanical
28 cannabis; (ii) is produced by a pharmaceutical processor; and sold by a pharmaceutical processor or
29 cannabis dispensing facility; (iii) is registered with the Board; (iv) contains, except as otherwise provided
30 in Article 4.2 (§ 54.1-3442.5 et seq.), no more than 10 milligrams of tetrahydrocannabinol per dose; and
31 (v) is compliant with testing requirements ~~and (ii) composed of cannabis oil or botanical cannabis.~~

32 "Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-
33 162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home
34 health services, private provider licensed by the Department of Behavioral Health and Developmental
35 Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility
36 licensed pursuant to § 63.2-1701, or adult day care center licensed pursuant to § 63.2-1701.

37 "Pharmaceutical processor" means the same as that term is defined in § 54.1-3442.5.

38 "Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine,
39 a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the
40 Board of Medicine and the Board of Nursing.

41 "Registered agent" means an individual designated by a patient who has been issued a written
42 certification, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, designated by
43 such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

44 "Usable cannabis" means any cannabis plant material, including seeds, but not (i) resin that has
45 been extracted from any part of the cannabis plant, its seeds, or its resin; (ii) the mature stalks, fiber
46 produced from the stalks, or any other compound, manufacture, salt, or derivative, mixture, or preparation
47 of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

48 B. A practitioner in the course of his professional practice may issue a written certification for the
49 use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease
50 determined by the practitioner to benefit from such use. The practitioner shall use his professional
51 judgment to determine the manner and frequency of patient care and evaluation and may employ the use
52 of telemedicine, provided that the use of telemedicine includes the delivery of patient care through real-
53 time interactive audio-visual technology. If a practitioner determines it is consistent with the standard of

54 care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such
55 dispensing. If not specifically included on the initial written certification, authorization for botanical
56 cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.

57 C. The written certification shall be on a form provided by the Board of Pharmacy. Such written
58 certification shall contain the name, address, and telephone number of the practitioner; the name and
59 address of the patient issued the written certification; the date on which the written certification was made;
60 and the signature or authentic electronic signature of the practitioner. Such written certification issued
61 pursuant to subsection B shall expire ~~no later than~~ one year after its issuance unless the practitioner
62 provides in such written certification an earlier expiration. A written certification shall not be issued to a
63 patient by more than one practitioner during any given time period.

64 D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for the issuance of a
65 certification for the use of cannabis products for the treatment or to alleviate the symptoms of a patient's
66 diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing
67 in this section shall preclude ~~the Board of Medicine~~ a practitioner's professional licensing board from
68 sanctioning ~~a~~ the practitioner for failing to properly evaluate or treat a patient's medical condition or
69 otherwise violating the applicable standard of care for evaluating or treating medical conditions.

70 E. A practitioner who issues a written certification to a patient pursuant to this section ~~shall register~~
71 ~~with the Board and~~ (i) shall hold sufficient education and training to exercise appropriate professional
72 judgment in the certification of patients; (ii) shall not offer a discount or any other thing of value to a
73 patient or a patient's parent, guardian, or registered agent that is contingent on or encourages the person's
74 decision to use a particular pharmaceutical processor or cannabis product; (iii) shall not issue a
75 certification to himself or his family members, employees, or coworkers; (iv) shall not provide product
76 samples containing cannabis other than those approved by the U.S. Food and Drug Administration; and
77 (v) shall not accept compensation from a pharmaceutical processor or cannabis dispensing facility. The
78 Board shall not limit the number of patients to whom a practitioner may issue a written certification. The
79 Board may report information to the applicable licensing board on unusual patterns of certifications issued
80 by a practitioner.

81 F. No patient shall be required to physically present the written certification after the initial
82 dispensing by any pharmaceutical processor or cannabis dispensing facility under each written
83 certification, provided that the pharmaceutical processor or cannabis dispensing facility maintains an
84 electronic copy of the written certification. Pharmaceutical processors and cannabis dispensing facilities
85 shall electronically transmit, on a monthly basis, all new written certifications received by the
86 pharmaceutical processor or cannabis dispensing facility to the Board.

87 G. A patient, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such
88 patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes
89 of receiving cannabis products pursuant to a valid written certification. Such designated individual shall
90 register with the Board. The Board may set a limit on the number of patients for whom any individual is
91 authorized to act as a registered agent.

92 H. Upon delivery of a cannabis product by a pharmaceutical processor or cannabis dispensing
93 facility to a designated caregiver facility, any employee or contractor of a designated caregiver facility,
94 who is licensed or registered by a health regulatory board and who is authorized to possess, distribute, or
95 administer medications, may accept delivery of the cannabis product on behalf of a patient or resident for
96 subsequent delivery to the patient or resident and may assist in the administration of the cannabis product
97 to the patient or resident as necessary.

98 I. Information obtained under the patient certification or agent registration process shall be
99 confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information
100 Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the
101 Chairmen of the House Committee for Courts of Justice and the Senate Committee on the Judiciary, (ii)
102 state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a
103 specific individual for a specific violation of law, (iii) licensed practitioners or pharmacists, or their agents,
104 for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained
105 by a patient, (iv) a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a
106 patient, or (v) a registered agent, but only with respect to information related to such patient.

107 **§ 54.1-3442.5. Definitions.**

108 As used in this article:

109 "Botanical cannabis," "cannabis oil," "cannabis product," "designated caregiver facility,"
110 "practitioner," "registered agent," and "usable cannabis" have the same meanings as specified in § 54.1-
111 3408.3.

112 "Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board
113 pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses
114 cannabis products produced by a pharmaceutical processor to a patient, his registered agent, or, if such
115 patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.

116 ~~"Designated caregiver facility" has the same meaning as defined in § 54.1-3408.3.~~

117 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant
118 to ~~§ 54.1-3408.3~~ 54.1-3442.6 and (ii) cultivates Cannabis plants intended only for the production of
119 cannabis oil, botanical cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis
120 products to a patient pursuant to a written certification, his registered agent, or, if such patient is a minor
121 or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.

122 ~~"Practitioner" has the same meaning as specified in § 54.1-3408.3.~~

123 ~~"Registered agent" has the same meaning as specified in § 54.1-3408.3.~~

124 **§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.**

125 A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without
126 first obtaining a permit from the Board. The application for such permit shall be made on a form provided
127 by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical
128 processor's dispensing area or cannabis dispensing facility. The Board shall establish an application fee
129 and other general requirements for such application.

130 B. Each permit shall expire annually on a date determined by the Board in regulation. The number
131 of permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and
132 up to five cannabis dispensing facilities for each health service area established by the Board of Health.
133 Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and
134 cannabis dispensing facility.

135 C. The Board shall adopt regulations establishing health, safety, and security requirements for
136 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements
137 for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum
138 equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical
139 cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and
140 packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and
141 securely dispensing and delivering in person cannabis products to a patient, his registered agent, or, if
142 such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal
143 guardian; (ix) dosage limitations for cannabis-oil products that provide that each dispensed dose of a
144 cannabis-oil product not exceed 10 milligrams of ~~delta-9 tetrahydrocannabinol~~ total tetrahydrocannabinol,
145 except as permitted under § 54.1-3442.7:2; (x) a process for the wholesale distribution of and the transfer
146 of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical
147 processors, between a pharmaceutical processors and a cannabis dispensing facility, and between cannabis
148 dispensing facilities; (xi) an allowance for the sale of devices for administration of dispensed cannabis
149 products and hemp-based CBD products that meet the applicable standards set forth in state and federal
150 law, including the laboratory testing standards set forth in subsection M; (xii) an allowance for the use
151 and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively
152 at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale,
153 without the need for a written certification; (xiii) a process for acquiring industrial hemp extracts and
154 formulating such extracts into cannabis products; and (xiv) an allowance for the advertising and promotion
155 of the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical
156 processor from the provision of educational material to practitioners who issue written certifications and
157 patients. The Board shall also adopt regulations for pharmaceutical processors that include requirements
158 for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis
159 products, (b) the ~~secure~~ disposal of agricultural waste, and (c) a process for registering cannabis-~~oil~~
160 products.

161 D. The Board shall require that, after processing and before dispensing any cannabis products, a
162 pharmaceutical processor shall make a sample available from each batch of cannabis product for testing
163 by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for
164 testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and
165 laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing
166 or distribution from each homogenized batch of cannabis oil is required to achieve a representative
167 cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing
168 laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis
169 sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol
170 (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals;
171 mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with
172 generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate botanical
173 cannabis or cannabis oil that fails any quality testing standard except pesticides. Following remediation,
174 all remediated botanical cannabis or cannabis oil shall be subject to laboratory testing ~~and approved upon~~
175 ~~satisfaction of applicable testing standards~~, which shall not be more stringent than initial testing prior to
176 remediation. Remediated botanical cannabis or cannabis oil that passes such quality testing may be
177 packaged and labeled. If a batch of botanical cannabis fails retesting after remediation, it shall be
178 considered usable cannabis and may be processed into cannabis oil. Stability testing shall not be required
179 for any cannabis product with an expiration date assigned by the pharmaceutical processor of ~~six~~ 12
180 months or less from the date of the cannabis product registration approval or the date of packaging and
181 labeling, whichever is later. Stability testing required for assignment of an expiration date longer than ~~six~~
182 12 months shall be limited to microbial testing, on a pass/fail basis, and potency testing, on a ~~10~~ 15 percent
183 deviation basis, of ~~active ingredients~~ total THC and total CBD. No cannabis product shall have an
184 expiration date longer than 12 months from the date of the cannabis product registration approval or the
185 date of packaging and labeling, whichever is later, unless supported by stability testing.

186 E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances
187 registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the
188 Board in regulation.

189 F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under
190 the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or
191 cannabis dispensing facility unless all cannabis products are contained in a vault or other similar container
192 to which only the pharmacist has access controls. The pharmaceutical processor shall ensure that security
193 measures are adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge
194 shall have concurrent responsibility for preventing diversion from the dispensing area.

195 Every pharmaceutical processor shall designate a person who shall have oversight of the
196 cultivation and production areas of the pharmaceutical processor and shall provide such information to
197 the Board. The Board shall direct all communications related to enforcement of requirements related to
198 cultivation and production of ~~cannabis-oil~~ cannabis products by the pharmaceutical processor to such
199 designated person.

200 G. The Board shall require the material owners of an applicant for a pharmaceutical processor or
201 cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive
202 information to be forwarded along with his fingerprints through the Central Criminal Records Exchange
203 to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information
204 regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search
205 shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the
206 criminal history background check to the Board or its designee, which shall be a governmental entity. A
207 pharmaceutical processor shall maintain evidence of criminal background checks for all employees and
208 delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery
209 agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

210 H. In addition to other employees authorized by the Board, a pharmaceutical processor may
211 employ individuals who may have less than two years of experience (i) to perform cultivation-related
212 duties under the supervision of an individual who has received a degree in a field related to the cultivation

213 of plants or a certification recognized by the Board or who has at least two years of experience cultivating
214 plants, (ii) to perform extraction-related duties under the supervision of an individual who has a degree in
215 chemistry or pharmacology or at least two years of experience extracting chemicals from plants, and (iii)
216 to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a
217 pharmacy technician.

218 I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to
219 five cannabis dispensing facilities for the dispensing of cannabis products that have been cultivated and
220 produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing
221 facility shall be located within the same health service area as the pharmaceutical processor.

222 J. No person who has been convicted of a felony under the laws of the Commonwealth or another
223 jurisdiction within the last five years shall be employed by or act as an agent of a pharmaceutical processor
224 or cannabis dispensing facility.

225 K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for pre-
226 employment drug screening and regular, ongoing, random drug screening of employees.

227 L. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing
228 facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician
229 trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise
230 more than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical
231 processor's dispensing area or cannabis dispensing facility.

232 M. A pharmaceutical processor may acquire industrial hemp extracts grown and processed in
233 Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or
234 processor. A pharmaceutical processor may process and formulate such extracts into an allowable dosage
235 of cannabis product. Industrial hemp extracts acquired and formulated by a pharmaceutical processor are
236 subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall
237 be performed by a laboratory located in Virginia and in compliance with state law governing the testing
238 of cannabis products. The industrial hemp dealer or processor shall provide such third-party testing results
239 to the pharmaceutical processor before industrial hemp extracts may be acquired.

240 N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§
241 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption
242 of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the
243 Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of
244 Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to
245 comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation;
246 and (iii) the name, address, and telephone number of the agency contact person responsible for receiving
247 public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such
248 notice for submittals of public comment. The legislative review provisions of subsections A and B of §
249 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section.
250 The Board of Pharmacy shall consider and keep on file all public comments received for any regulation
251 adopted pursuant to this section.

252 ~~O. The Board shall register all cannabis products that meet testing, labeling, and packaging~~
253 ~~standards.~~

254 **§ 54.1-3442.7. Dispensing cannabis products; report.**

255 A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis
256 products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia and
257 has been issued a valid written certification; (ii) such patient's registered agent; or (iii) if such patient is a
258 minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian who is a
259 Virginia resident or temporarily resides in Virginia. A companion may accompany a patient into a
260 pharmaceutical processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing
261 of cannabis products pursuant to each written certification, a pharmacist or pharmacy technician employed
262 by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or
263 remotely by electronic means, for two years a paper or electronic copy of the written certification that
264 provides an exact image of the document that is clearly legible; shall view, in person or by audiovisual
265 means, a current photo identification of the patient, registered agent, parent, or legal guardian; and shall
266 verify current board registration of ~~the practitioner and~~ the corresponding registered agent if applicable.

267 Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian,
268 or designated caregiver facility. Prior to any subsequent dispensing of cannabis products pursuant to each
269 written certification, an employee or delivery agent shall view a current photo identification of the patient,
270 registered agent, parent, or legal guardian and the current board registration issued to the registered agent
271 if applicable. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a 90-
272 day supply, as determined by the dispensing pharmacist or certifying practitioner, for any patient during
273 any 90-day period. A pharmaceutical processor or cannabis dispensing facility may dispense less than a
274 90-day supply of a cannabis product for any patient during any 90-day period; however, a pharmaceutical
275 processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one
276 time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which
277 botanical cannabis is dispensed. ~~The Board shall establish in regulation an amount of cannabis oil that~~
278 ~~constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.~~
279 In determining the appropriate amount of a cannabis product to be dispensed to a patient, a pharmaceutical
280 processor or cannabis dispensing facility shall consider all cannabis products dispensed to the patient and
281 adjust the amount dispensed accordingly.

282 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis
283 products produced on the premises of a pharmaceutical processor permitted by the Board or cannabis
284 products that have been formulated with extracts from industrial hemp acquired by a pharmaceutical
285 processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6. A
286 pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

287 C. The Board shall report annually by December 1 to the Chairmen of the House Committee for
288 Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of
289 pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board.

290 D. The concentration of ~~delta-9-tetrahydrocannabinol~~ total tetrahydrocannabinol in any cannabis
291 product on site may be up to ~~10~~ 15 percent greater than or less than the level of ~~delta-9-~~
292 ~~tetrahydrocannabinol measured for labeling~~ total tetrahydrocannabinol listed in the approved cannabis
293 product registration. A pharmaceutical processor and cannabis dispensing facility shall ensure that such

294 concentration in any cannabis product on site is within such range. A pharmaceutical processor producing
295 cannabis products shall establish a stability testing schedule of cannabis products that have an expiration
296 date longer than 12 months.

297 **§ 54.1-3442.7:1. Packaging and labeling; corrections; records.**

298 A. Pharmaceutical processors shall comply with all packaging and labeling requirements set forth
299 in this article and Board regulations.

300 B. No cannabis product shall be packaged in a container or wrapper that bears, or is otherwise
301 labeled to bear the trademark, trade name, famous mark as defined in 15 U.S.C. § 1125, or other
302 identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or
303 distributor of a product intended for human consumption other than the manufacturer, processor, packer,
304 or distributor that did in fact so manufacture, process, pack, or distribute such cannabis product.

305 C. Pharmaceutical processors may correct typographical errors made on cannabis product labels
306 and any documents generated as the result of a wholesale transaction.

307 **§ 54.1-3442.7:2. Cannabis product registration; approval, deviation, and modification.**

308 A. A pharmaceutical processor shall register with the Board each cannabis product it manufactures.
309 Applications for cannabis product registration shall be submitted to the Board on a form prescribed by the
310 Board.

311 B. An application for cannabis product registration shall include:

312 1. The total tetrahydrocannabinol and total cannabidiol in such cannabis product, based on
313 laboratory testing results for the cannabis product formulation;

314 2. A product name;

315 3. A proposed product package; and

316 4. A proposed product label, which shall not be required to contain an expiration date at the time
317 of application.

318 C. The Board shall register all cannabis products that meet testing, labeling, and packaging
319 standards within 14 days after an application for registration is submitted. If the cannabis product fails to
320 meet such standards or the application was deficient, the Board shall notify the applicant of the specific

321 reasons for such failure or deficiency within 14 days of the date the application for registration was
322 submitted. If the Board fails to respond within 14 days, the application shall be deemed approved.

323 D. Within two business days of the Board's approval or deemed approval, the Board shall enter the
324 cannabis product's national drug code number into the Prescription Monitoring Program.

325 E. The following cannabis product deviations from an approved cannabis product registration shall
326 be permitted without any requirement for a new cannabis product registration or notice to the Board:

327 1. A deviation in the concentration of total tetrahydrocannabinol (THC) or total cannabidiol (CBD)
328 in a cannabis product or dose thereof of up to 15 percent greater than or less than the concentration of total
329 tetrahydrocannabinol or total cannabidiol, either or both, listed in the approved cannabis product
330 registration; however, for a cannabis product with five milligrams or less of total THC or total CBD per
331 dose, the total THC or total CBD concentration shall be within 0.5 milligrams of the single dose total THC
332 or total CBD concentrations approved for that cannabis product;

333 2. A variation in packaging, provided that the packaging is substantially similar to the approved
334 packaging and otherwise complies with applicable packaging requirements;

335 3. A deviation in labeling, including a variation made in accordance with § 54.1-3442.7:1, that
336 reflects allowable deviations in total THC or total CBD or that makes a minor text, font, design, or similar
337 modification, provided that the labeling is substantially similar to the approved labeling and otherwise
338 complies with applicable labeling requirements; and

339 4. Any other insignificant changes.

340 F. A pharmaceutical processor may submit a request to modify an existing cannabis product
341 registration in the event of a cannabis product deviation that is not set forth in subsection E. Upon receipt,
342 the Board shall respond to such request within 14 days. The Board may grant or deny the request, propose
343 a reasonable revision, or require the pharmaceutical processor to provide additional information. If the
344 Board fails to respond to a request for modification within 14 days of its submission, the proposed
345 modification shall be deemed approved.

346 **§ 54.1-3442.7:3. Advertising and marketing.**

347 A. Pharmaceutical processors and cannabis dispensing facilities may (i) advertise and promote
348 products and operations and (ii) provide educational material to practitioners, patients, and the public.

349 B. Pharmaceutical processors and cannabis dispensing facilities may engage in advertising or
350 marketing that does not:

351 1. Include false or misleading statements;

352 2. Promote overconsumption;

353 3. Depict a person younger than 21 years of age;

354 4. Appeal particularly to persons younger than 21 years of age, including by using cartoons in any
355 way;

356 5. Associate cannabis products with candy or similar products or depicts any images that bear a
357 reasonable resemblance to a candy or similar product; or

358 6. Contain any seal, flag, crest, coat of arms, or other insignia that is likely to mislead patients or
359 the public to believe that the cannabis product is made or endorsed by the Commonwealth.

360 C. All advertising and marketing by pharmaceutical processors and cannabis dispensing facilities
361 shall (i) accurately and legibly identify the pharmaceutical processor or cannabis dispensing facility
362 responsible for its content and (ii) include a statement that cannabis products are for use by certified
363 patients only.

364 **2. That pharmaceutical processors and cannabis dispensing facilities shall collect and provide to the**
365 **Board of Pharmacy by July 1, 2024, data regarding the impact of this act on program participation,**
366 **reductions in the price of cannabis products, and improved operational efficiencies.**

367 **3. That the Board of Pharmacy shall amend its regulations, including 18VAC110-60-270,**
368 **18VAC110-60-285, 18VAC110-60-290, and 18VAC110-60-310, to replace any references to "brand"**
369 **with "registered cannabis product name."**

370 **4. That the Board of Pharmacy may assess and collect regulatory fees from each pharmaceutical**
371 **processor and cannabis dispensing facility in an amount sufficient to implement the provisions of**
372 **this act.**

373 #