

HOUSE BILL NO. 1846

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Rehabilitation and Social Services

on February 17, 2023)

(Patron Prior to Substitute--Delegate Head)

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 Virginia and to amend the Code of Virginia by adding sections numbered 54.1-3442.7:1, 54.1-3442.7:2, and 54.1-3442.7:3, relating to medical marijuana program; product, registration, dispensing, and recordkeeping requirements; advertising.

Be it enacted by the General Assembly of Virginia:

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 amended and reenacted and that the Code of Virginia is amended by adding sections numbered 54.1-3442.7:1, 54.1-3442.7:2, and 54.1-3442.7:3 as follows:

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

A. As used in this section:

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

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

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

54 practitioner is on the premises of a pharmaceutical processor or cannabis dispensing facility; however, a
55 practitioner may issue a written certification via telemedicine to a patient who is located on the premises
56 of a pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor or cannabis
57 dispensing facility may make available on its premises technology that uncertified persons may use to
58 contact a practitioner of the person's choice to request a written certification. A pharmaceutical processor
59 shall not (i) endorse or promote any practitioner who issues certifications to patients or (ii) advertise that
60 it facilitates the issuance of written certifications. If a practitioner determines it is consistent with the
61 standard of care to dispense botanical cannabis to a minor, the written certification shall specifically
62 authorize such dispensing. If not specifically included on the initial written certification, authorization for
63 botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.
64 A practitioner who issues written certifications shall not directly or indirectly accept, solicit, or receive
65 anything of value from a pharmaceutical processor, cannabis dispensing facility, or any person associated
66 with a pharmaceutical processor, cannabis dispensing facility, or provider of paraphernalia, excluding
67 information on products or educational materials on the benefits and risks of cannabis products.

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

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

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

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

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

103 H. Upon delivery of a cannabis product by a pharmaceutical processor or cannabis dispensing
104 facility to a designated caregiver facility, any employee or contractor of a designated caregiver facility,
105 who is licensed or registered by a health regulatory board and who is authorized to possess, distribute, or
106 administer medications, may accept delivery of the cannabis product on behalf of a patient or resident for

107 subsequent delivery to the patient or resident and may assist in the administration of the cannabis product
108 to the patient or resident as necessary.

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

118 **§ 54.1-3442.5. Definitions.**

119 As used in this article:

120 "Botanical cannabis," "cannabis oil," "cannabis product," "designated caregiver facility,"
121 "practitioner," "registered agent," and "usable cannabis" have the same meanings as specified in § 54.1-
122 3408.3.

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

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

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

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

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

135 **§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.**

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

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

146 C. The Board shall adopt regulations establishing health, safety, and security requirements for
147 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements
148 for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum
149 equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical
150 cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and
151 packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and
152 securely dispensing and delivering in person cannabis products to a patient, his registered agent, or, if
153 such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal
154 guardian; (ix) dosage limitations for cannabis-oil products that provide that each dispensed dose of a
155 cannabis-oil product not exceed 10 milligrams of ~~delta-9-tetrahydrocannabinol~~ total tetrahydrocannabinol,
156 except as permitted under § 54.1-3442.7:2; (x) a process for the wholesale distribution of and the transfer
157 of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical
158 processors, between a pharmaceutical processors and a cannabis dispensing facility, and between cannabis
159 dispensing facilities; (xi) an allowance for the sale of devices for administration of dispensed cannabis
160 products and hemp-based CBD products that meet the applicable standards set forth in state and federal

161 law, including the laboratory testing standards set forth in subsection M; (xii) an allowance for the use
162 and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively
163 at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale,
164 without the need for a written certification; (xiii) a process for acquiring industrial hemp extracts and
165 formulating such extracts into cannabis products; and (xiv) an allowance for the advertising and promotion
166 of the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical
167 processor from the provision of educational material to practitioners who issue written certifications and
168 patients. The Board shall also adopt regulations for pharmaceutical processors that include requirements
169 for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis
170 products, (b) the ~~secure~~ disposal of agricultural waste, and (c) a process for registering cannabis-~~oil~~
171 products.

172 D. The Board shall require that, after processing and before dispensing any cannabis products, a
173 pharmaceutical processor shall make a sample available from each batch of cannabis product for testing
174 by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for
175 testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and
176 laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing
177 or distribution from each homogenized batch of cannabis oil is required to achieve a representative
178 cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing
179 laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis
180 sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol
181 (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals;
182 mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with
183 generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate botanical
184 cannabis or cannabis oil that fails any quality testing standard except pesticides. Following remediation,
185 all remediated botanical cannabis or cannabis oil shall be subject to laboratory testing ~~and approved upon~~
186 ~~satisfaction of applicable testing standards~~, which shall not be more stringent than initial testing prior to
187 remediation. Remediated botanical cannabis or cannabis oil that passes such quality testing may be

188 packaged and labeled. If a batch of botanical cannabis fails retesting after remediation, it shall be
189 considered usable cannabis and may be processed into cannabis oil. Stability testing shall not be required
190 for any cannabis product with an expiration date assigned by the pharmaceutical processor of ~~six~~ 12
191 months or less from the date of the cannabis product registration approval or the date of packaging and
192 labeling, whichever is later. Stability testing required for assignment of an expiration date longer than ~~six~~
193 12 months shall be limited to microbial testing, on a pass/fail basis, and potency testing, on a ~~40~~ 15 percent
194 deviation basis, of ~~active ingredients~~ total THC and total CBD. No cannabis product shall have an
195 expiration date longer than 12 months from the date of the cannabis product registration approval or the
196 date of packaging and labeling, whichever is later, unless supported by stability testing.

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

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

206 Every pharmaceutical processor shall designate a person who shall have oversight of the
207 cultivation and production areas of the pharmaceutical processor and shall provide such information to
208 the Board. The Board shall direct all communications related to enforcement of requirements related to
209 cultivation and production of ~~cannabis oil~~ and cannabis products by the pharmaceutical processor to such
210 designated person.

211 G. The Board shall require the material owners of an applicant for a pharmaceutical processor or
212 cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive
213 information to be forwarded along with his fingerprints through the Central Criminal Records Exchange
214 to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information

215 regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search
216 shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the
217 criminal history background check to the Board or its designee, which shall be a governmental entity. A
218 pharmaceutical processor shall maintain evidence of criminal background checks for all employees and
219 delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery
220 agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

221 H. In addition to other employees authorized by the Board, a pharmaceutical processor may
222 employ individuals who may have less than two years of experience (i) to perform cultivation-related
223 duties under the supervision of an individual who has received a degree in a field related to the cultivation
224 of plants or a certification recognized by the Board or who has at least two years of experience cultivating
225 plants, (ii) to perform extraction-related duties under the supervision of an individual who has a degree in
226 chemistry or pharmacology or at least two years of experience extracting chemicals from plants, and (iii)
227 to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a
228 pharmacy technician.

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

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

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

238 L. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing
239 facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician
240 trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise

241 more than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical
242 processor's dispensing area or cannabis dispensing facility.

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

251 N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§
252 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption
253 of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the
254 Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of
255 Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to
256 comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation;
257 and (iii) the name, address, and telephone number of the agency contact person responsible for receiving
258 public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such
259 notice for submittals of public comment. The legislative review provisions of subsections A and B of §
260 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section.
261 The Board of Pharmacy shall consider and keep on file all public comments received for any regulation
262 adopted pursuant to this section.

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

265 **§ 54.1-3442.7. Dispensing cannabis products; report.**

266 A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis
267 products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia and

268 has been issued a valid written certification; (ii) such patient's registered agent; or (iii) if such patient is a
269 minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian who is a
270 Virginia resident or temporarily resides in Virginia. A companion may accompany a patient into a
271 pharmaceutical processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing
272 of cannabis products pursuant to each written certification, a pharmacist or pharmacy technician employed
273 by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or
274 remotely by electronic means, for two years a paper or electronic copy of the written certification that
275 provides an exact image of the document that is clearly legible; shall view, in person or by audiovisual
276 means, a current photo identification of the patient, registered agent, parent, or legal guardian; and shall
277 verify current board registration of ~~the practitioner and~~ the corresponding registered agent if applicable.
278 Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian,
279 or designated caregiver facility. Prior to any subsequent dispensing of cannabis products pursuant to each
280 written certification, an employee or delivery agent shall view a current photo identification of the patient,
281 registered agent, parent, or legal guardian and the current board registration issued to the registered agent
282 if applicable. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a 90-
283 day supply, as determined by the dispensing pharmacist or certifying practitioner, for any patient during
284 any 90-day period. A pharmaceutical processor or cannabis dispensing facility may dispense less than a
285 90-day supply of a cannabis product for any patient during any 90-day period; however, a pharmaceutical
286 processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one
287 time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which
288 botanical cannabis is dispensed. ~~The Board shall establish in regulation an amount of cannabis oil that~~
289 ~~constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.~~
290 In determining the appropriate amount of a cannabis product to be dispensed to a patient, a pharmaceutical
291 processor or cannabis dispensing facility shall consider all cannabis products dispensed to the patient and
292 adjust the amount dispensed accordingly.

293 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis
294 products produced on the premises of a pharmaceutical processor permitted by the Board or cannabis

295 products that have been formulated with extracts from industrial hemp acquired by a pharmaceutical
296 processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6. A
297 pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

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

301 D. The concentration of ~~delta-9 tetrahydrocannabinol~~ total tetrahydrocannabinol in any cannabis
302 product on site may be up to ~~10~~ 15 percent greater than or less than the level of ~~delta-9~~
303 ~~tetrahydrocannabinol measured for labeling~~ total tetrahydrocannabinol listed in the approved cannabis
304 product registration. A pharmaceutical processor and cannabis dispensing facility shall ensure that such
305 concentration in any cannabis product on site is within such range. A pharmaceutical processor producing
306 cannabis products shall establish a stability testing schedule of cannabis products that have an expiration
307 date longer than 12 months.

308 **§ 54.1-3442.7:1. Packaging and labeling; corrections; records.**

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

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

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

318 **§ 54.1-3442.7:2. Cannabis product registration; approval, deviation, and modification.**

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

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

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

325 2. A product name;

326 3. A proposed product package; and

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

329 C. The Board shall register all cannabis products that meet testing, labeling, and packaging
330 standards within 14 days after an application for registration is submitted. If the cannabis product fails to
331 meet such standards or the application was deficient, the Board shall notify the applicant of the specific
332 reasons for such failure or deficiency within 14 days of the date the application for registration was
333 submitted. If the Board fails to respond within 14 days, the application shall be deemed approved.

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

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

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

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

346 3. A deviation in labeling, including a variation made in accordance with § 54.1-3442.7:1, that
347 reflects allowable deviations in total THC or total CBD or that makes a minor text, font, design, or similar

348 modification, provided that the labeling is substantially similar to the approved labeling and otherwise
349 complies with applicable labeling requirements; and

350 4. Any other insignificant changes.

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

357 **§ 54.1-3442.7:3. Advertising and marketing.**

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

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

362 1. Include false or misleading statements;

363 2. Promote overconsumption;

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

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

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

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

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

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

378 3. That the Board of Pharmacy shall amend its regulations, including 18VAC110-60-270,
379 18VAC110-60-285, 18VAC110-60-290, and 18VAC110-60-310, to replace any references to "brand"
380 with "registered cannabis product name."

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

384 #