

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 4.1-1600, 4.1-1602, and 4.1-1603 of the Code of Virginia, relating to medical cannabis program; product labels; delivery.

[H 391]

Approved

Be it enacted by the General Assembly of Virginia:
1. That §§ 4.1-1600, 4.1-1602, and 4.1-1603 of the Code of Virginia are amended and reenacted as follows:

§ 4.1-1600. Definitions.

As used in this chapter, unless the context requires a different meaning:

"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 a facility that (i) has obtained a permit from the Board pursuant to § 4.1-1602; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis products produced by a pharmaceutical processor to a patient, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.

"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 § 4.1-1602, or a dilution of the resin of the Cannabis plant that contains, except as otherwise provided in this chapter, no more than 10 milligrams of tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, handled, 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.

"Cannabis product" means a product that (i) is formulated with cannabis oil or botanical cannabis; (ii) is produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility; (iii) is registered with the Board; (iv) contains, except as otherwise provided in this chapter, no more than 10 milligrams of tetrahydrocannabinol per dose; and (v) is compliant with testing requirements.

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

"Dispense" means the same as that term is defined in § 54.1-3300.

"Edible cannabis product" means a cannabis product that is intended to be ingested and is (i) formulated with cannabis oil or botanical cannabis, (ii) produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility, (iii) registered with the Board, and (iv) compliant with testing requirements.

"Inhalable cannabis product" means a cannabis product that is intended to be inhaled and is (i) formulated with cannabis oil or botanical cannabis, (ii) produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility, (iii) registered with the Board, and (iv) compliant with testing requirements.

"Marijuana delivery operator" means an entity licensed by the Board to take possession of usable cannabis, botanical cannabis, cannabis oil, or cannabis products from a pharmaceutical processor or cannabis dispensing facility and deliver such cannabis, cannabis oil, or cannabis products only in person to patients at their residence or business.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 4.1-1602 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil, botanical cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis products to a patient pursuant to a written certification, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.

"Pharmacist" means the same as that term is defined in § 54.1-3300.

"Pharmacy intern" means the same as that term is defined in § 54.1-3300.

"Pharmacy technician" means the same as that term is defined in § 54.1-3300.

"Pharmacy technician trainee" means the same as that term is defined in § 54.1-3300.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or an advanced practice registered nurse jointly

57 licensed by the Boards of Nursing and Medicine.

58 "Registered agent" means an individual designated by a patient who has been issued a written
59 certification, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, designated by such
60 patient's parent or legal guardian, and registered with the Board pursuant to subsection F of § 4.1-1601.

61 "*Topical cannabis product*" means a cannabis product that is intended to be applied topically to the skin
62 and is (i) formulated with cannabis oil or botanical cannabis, (ii) produced by a pharmaceutical processor
63 and sold by a pharmaceutical processor or cannabis dispensing facility, (iii) registered with the Board, and
64 (iv) compliant with testing requirements.

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

69 **§ 4.1-1602. Permit to operate pharmaceutical processor or cannabis dispensing facility.**

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

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

80 C. The Board shall adopt regulations establishing health, safety, and security requirements for
81 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements for
82 (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment
83 and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) routine inspections no more frequently
84 than once annually; (viii) processes for safely and securely dispensing and delivering in person cannabis
85 products to a patient, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in
86 § 18.2-369, such patient's parent or legal guardian; (ix) dosage limitations for cannabis products that provide
87 that each dispensed dose of a cannabis product not exceed 10 milligrams of total tetrahydrocannabinol
88 (*THC*), except as permitted under § 4.1-1603.2; (x) a process for the wholesale distribution of and the transfer
89 of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical
90 processors, between a pharmaceutical processor and a cannabis dispensing facility, and between cannabis
91 dispensing facilities; (xi) an allowance for the sale of devices for administration of dispensed cannabis
92 products and hemp-based ~~CBD~~ *cannabidiol* (*CBD*) products that meet the applicable standards set forth in
93 state and federal law, including the laboratory testing standards set forth in subsection N; (xii) an allowance
94 for the use and distribution of inert product samples containing no cannabinoids for patient demonstration
95 exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or
96 sale, without the need for a written certification; (xiii) a process for acquiring industrial hemp extracts and
97 formulating such extracts into cannabis products; and (xiv) an allowance for the advertising and promotion of
98 the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical processor
99 from the provision of educational material to practitioners who issue written certifications and patients. The
100 Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes
101 for safely and securely cultivating cannabis plants intended for producing cannabis products, (b) the disposal
102 of agricultural waste, and (c) a process for registering cannabis products.

103 D. The Board shall require pharmaceutical processors, after processing and before dispensing any
104 cannabis products, to make a sample available from each batch of cannabis product for testing by an
105 independent laboratory that is located in *the* Commonwealth and meets Board requirements. A valid sample
106 size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method,
107 and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing
108 or distribution from each homogenized batch of cannabis oil is required to achieve a representative cannabis
109 oil sample for analysis. A minimum sample size, to be determined by the certified testing laboratory, from
110 each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for
111 analysis. Botanical cannabis products shall only be tested for the following: total ~~cannabidiol~~ (*CBD*) *CBD*,
112 total ~~tetrahydrocannabinol~~ (*THC*) *THC*, terpenes, pesticide chemical residue, heavy metals, mycotoxins,
113 moisture, and microbiological contaminants. Testing thresholds shall be consistent with generally accepted
114 cannabis industry thresholds. The pharmaceutical processor may remediate botanical cannabis or cannabis oil
115 that fails any quality testing standard except pesticides. Following remediation, all remediated botanical
116 cannabis or cannabis oil shall be subject to laboratory testing, which shall not be more stringent than initial
117 testing prior to remediation. Remediated botanical cannabis or cannabis oil that passes such quality testing
118 may be packaged and labeled. If a batch of botanical cannabis fails retesting after remediation, it shall be

119 considered usable cannabis and may be processed into cannabis oil. Stability testing shall not be required for
 120 any cannabis product with an expiration date assigned by the pharmaceutical processor of 12 months or less
 121 from the date of the cannabis product registration approval testing. Stability testing required for assignment
 122 of an expiration date longer than 12 months shall be limited to microbial testing, on a pass/fail basis, and
 123 potency testing, on a 15 percent deviation basis, of total THC and total CBD. No cannabis product shall have
 124 an expiration date longer than 12 months from the date of the cannabis product registration approval testing
 125 unless supported by stability testing.

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

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

135 Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation and
 136 production areas of the pharmaceutical processor and shall provide such information to the Board. The Board
 137 shall direct all communications related to enforcement of requirements related to cultivation and production
 138 of cannabis and cannabis products by the pharmaceutical processor to such designated person.

139 G. The Board shall require the material owners of an applicant for a pharmaceutical processor or cannabis
 140 dispensing facility permit to submit to fingerprinting and provide personal descriptive information to be
 141 forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau
 142 of Investigation for the purpose of obtaining criminal history record information regarding the applicant's
 143 material owners. The cost of fingerprinting and the criminal history record search shall be paid by the
 144 applicant. The Central Criminal Records Exchange shall forward the results of the criminal history
 145 background check to the Board or its designee, which shall be a governmental entity.

146 H. A pharmaceutical processor shall maintain evidence of criminal background checks for all employees
 147 and delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery
 148 agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

149 I. In addition to other employees authorized by the Board, a pharmaceutical processor may employ
 150 individuals who may have less than one year of experience (i) to perform cultivation-related duties under the
 151 supervision of an individual who has received a degree in a field related to the cultivation of plants or a
 152 certification recognized by the Board or who has at least one year of experience cultivating plants, (ii) to
 153 perform extraction-related duties under the supervision of an individual who has a degree in chemistry or
 154 pharmacology or at least one year of experience extracting chemicals from plants, (iii) to perform duties at
 155 the pharmaceutical processor and cannabis dispensing facility upon certification as a pharmacy technician,
 156 and (iv) to serve as pharmacy technician trainees.

157 J. A pharmaceutical processor to whom a permit has been issued by the Board may (i) establish up to five
 158 cannabis dispensing facilities, subject to the permit requirement set forth in subsection B, for the dispensing
 159 of cannabis products that have been cultivated and produced on the premises of a pharmaceutical processor
 160 permitted by the Board and (ii) establish, if authorized by the Board, one additional location at which the
 161 pharmaceutical processor may cultivate cannabis plants. Each cannabis dispensing facility and the additional
 162 cultivation location shall be located within the same health service area as the pharmaceutical processor.

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

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

168 M. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing facility
 169 shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees
 170 who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than
 171 six persons performing the duties of a pharmacy technician at one time in the pharmaceutical processor's
 172 dispensing area or cannabis dispensing facility.

173 N. A pharmaceutical processor may acquire from a registered industrial hemp handler or processor
 174 industrial hemp extracts that (i) are grown and processed in Virginia in compliance with state or federal law,
 175 and (ii) notwithstanding the tetrahydrocannabinol THC limits set forth in the definition of "industrial hemp
 176 extract" in § 3.2-5145.1, contain a total tetrahydrocannabinol THC concentration of no greater than 0.3
 177 percent. A pharmaceutical processor may process and formulate such extracts into an allowable dosage of
 178 cannabis product. Industrial hemp extracts acquired and formulated by a pharmaceutical processor are subject
 179 to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall be
 180 performed by a laboratory located in Virginia the Commonwealth and in compliance with state law governing

181 the testing of cannabis products. The industrial hemp handler or processor shall provide such third-party
 182 testing results to the pharmaceutical processor before industrial hemp extracts may be acquired.

183 O. Product labels for all cannabis products and botanical cannabis shall be complete, accurate, easily
 184 discernable *discernible*, and uniform among different products and brands. Pharmaceutical processors shall
 185 affix to all cannabis products and botanical cannabis a label, which shall also be accessible on the
 186 pharmaceutical processor's website, that includes:

187 1. The product name;

188 2. All active and inactive ingredients, including cannabinoids, terpenes, additives, preservatives,
 189 flavorings, sweeteners, and carrier oils;

190 3. The total ~~percentage and~~ milligrams of ~~tetrahydrocannabinol~~ *THC* and ~~cannabidiol~~ *CBD* included in ~~the~~
 191 *an edible cannabis product or topical cannabis product* ~~and~~, the number of milligrams of
 192 ~~tetrahydrocannabinol~~ *THC* and ~~cannabidiol~~ *CBD* in each serving of *an edible cannabis product or topical*
 193 *cannabis product, and the total percentage of THC and CBD included in an inhalable cannabis product;*

194 4. The amount of product that constitutes a single serving and the amount recommended for use by the
 195 practitioner or dispensing pharmacist;

196 5. Information regarding the product's purpose and detailed usage directions;

197 6. Child and safety warnings in a conspicuous font; and

198 7. Such other information required by the Board.

199 P. A pharmaceutical processor or cannabis dispensing facility shall maintain an adequate supply of
 200 cannabis products that (i) contain ~~cannabidiol~~ *CBD* as their primary cannabinoid and (ii) have low levels of or
 201 no ~~tetrahydrocannabinol~~ *THC*.

202 Q. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§ 2.2-4000
 203 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption of any
 204 regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the Board shall
 205 publish a notice of opportunity to comment in the Virginia Register of Regulations and post the action on the
 206 Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the
 207 proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone
 208 number of the agency contact person responsible for receiving public comments. Such notice shall be made at
 209 least 60 days in advance of the last date prescribed in such notice for submittals of public comment. The
 210 legislative review provisions of subsections A and B of § 2.2-4014 shall apply to the promulgation or final
 211 adoption process for regulations pursuant to this section. The Board shall consider and keep on file all public
 212 comments received for any regulation adopted pursuant to this section.

213 **§ 4.1-1603. Dispensing cannabis products; report.**

214 A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis products
 215 only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia and has been issued
 216 a valid written certification; (ii) such patient's registered agent; or (iii) if such patient is a minor or a
 217 vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident or
 218 temporarily resides in Virginia. *A pharmaceutical processor or cannabis dispensing facility may dispense or*
 219 *deliver, either by employee or marijuana delivery operator, cannabis products to such patient or such*
 220 *patient's registered agent, parent, or legal guardian at any residence, including a temporary residence, or*
 221 *business. Notwithstanding the foregoing, a pharmaceutical processor or cannabis dispensing facility shall*
 222 *not dispense or deliver cannabis products to (a) any military base, child day center, school, or correctional*
 223 *facility; (b) the State Capitol; or (c) any public gathering places, including sporting events, festivals, fairs,*
 224 *races, concerts, and terminals of public transportation companies.* A companion may accompany a patient
 225 into a pharmaceutical processor's dispensing area or cannabis dispensing facility. Prior to the initial
 226 dispensing of cannabis products pursuant to each written certification, a pharmacist or pharmacy technician
 227 employed by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or
 228 remotely by electronic means, for two years a paper or electronic copy of the written certification that
 229 provides an exact image of the document that is clearly legible; shall view, in person or by audiovisual
 230 means, a current photo identification of the patient, registered agent, parent, or legal guardian; and shall
 231 verify current board registration of the corresponding registered agent if applicable. Thereafter, an initial
 232 dispensing may be delivered to the patient, registered agent, parent, legal guardian, or designated caregiver
 233 facility. Prior to any subsequent dispensing of cannabis products pursuant to each written certification, an
 234 employee or ~~delivery agent~~ *marijuana delivery operator* shall view a current photo identification of the
 235 patient, registered agent, parent, or legal guardian and the current board registration issued to the registered
 236 agent if applicable. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a
 237 90-day supply, as determined by the dispensing pharmacist or certifying practitioner, for any patient during
 238 any 90-day period. A pharmaceutical processor or cannabis dispensing facility may dispense less than a
 239 90-day supply of a cannabis product for any patient during any 90-day period; however, a pharmaceutical
 240 processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one
 241 time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which
 242 botanical cannabis is dispensed. In determining the appropriate amount of a cannabis product to be dispensed

243 to a patient, a pharmaceutical processor or cannabis dispensing facility shall consider all cannabis products
244 dispensed to the patient and adjust the amount dispensed accordingly.

245 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis products
246 produced on the premises of a pharmaceutical processor permitted by the Board or cannabis products that
247 have been formulated with extracts from industrial hemp acquired by a pharmaceutical processor from a
248 registered industrial hemp handler or processor pursuant to § 4.1-1602. A pharmaceutical processor may
249 begin cultivation upon being issued a permit by the Board.

250 C. The Board shall report annually by December 1 to the Chairmen of the House Committee on General
251 Laws and the Senate Committee on Rehabilitation and Social Services on the operation of pharmaceutical
252 processors and cannabis dispensing facilities issued a permit by the Board.

253 D. The concentration of total tetrahydrocannabinol (*THC*) in any cannabis product on site may be up to 15
254 percent greater than or less than the level of total ~~tetrahydrocannabinol~~ *THC* listed in the approved cannabis
255 product registration. A pharmaceutical processor and cannabis dispensing facility shall ensure that such
256 concentration in any cannabis product on site is within such range. A pharmaceutical processor producing
257 cannabis products shall establish a stability testing schedule of cannabis products that have an expiration date
258 of longer than 12 months.

259 *E. All transportation or delivery of usable cannabis, botanical cannabis, cannabis oil, or cannabis*
260 *products, whether by an employee or marijuana delivery operator, shall comply with the provisions of this*
261 *subtitle and Board regulations, including those related to background checks, proof of identification, vehicle*
262 *security, GPS tracking, secure communications, and recordkeeping. The Board may suspend or revoke the*
263 *privileges of any employee or the license of any marijuana delivery operator to transport or deliver usable*
264 *cannabis, botanical cannabis, cannabis oil, or cannabis products for failure of such employee or marijuana*
265 *delivery operator to comply with the provisions of this subtitle or Board regulations.*