

## 1 VIRGINIA ACTS OF ASSEMBLY — CHAPTER

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

4 [H 391]

5 Approved

6 **Be it enacted by the General Assembly of Virginia:**7 **1. That §§ 4.1-1600, 4.1-1602, and 4.1-1603 of the Code of Virginia are amended and reenacted as**  
 8 **follows:**9 **§ 4.1-1600. Definitions.**

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

11 "Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same parts of  
 12 the same chemovar of cannabis plant.13 "Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to  
 14 § 4.1-1602; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis products  
 15 produced by a pharmaceutical processor to a patient, his registered agent, or, if such patient is a minor or a  
 16 vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.17 "Cannabis oil" means any formulation of processed Cannabis plant extract, which may include industrial  
 18 hemp extracts, including isolates and distillates, acquired by a pharmaceutical processor pursuant to  
 19 § 4.1-1602, or a dilution of the resin of the Cannabis plant that contains, except as otherwise provided in this  
 20 chapter, no more than 10 milligrams of tetrahydrocannabinol per dose. "Cannabis oil" does not include  
 21 industrial hemp, as defined in § 3.2-4112, that is grown, handled, or processed in compliance with state or  
 22 federal law, unless it has been grown and processed in the Commonwealth by a registered industrial hemp  
 23 processor and acquired and formulated by a pharmaceutical processor.24 "Cannabis product" means a product that (i) is formulated with cannabis oil or botanical cannabis; (ii) is  
 25 produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing  
 26 facility; (iii) is registered with the Board; (iv) contains, except as otherwise provided in this chapter, no more  
 27 than 10 milligrams of tetrahydrocannabinol per dose; and (v) is compliant with testing requirements.28 "*Delivery agent*" means an independent contractor that transports or delivers usable cannabis, botanical  
 29 cannabis, cannabis oil, or cannabis products on behalf of a pharmaceutical processor or cannabis  
 30 dispensing facility.31 "Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-162.3, or  
 32 home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home health  
 33 services, private provider licensed by the Department of Behavioral Health and Developmental Services  
 34 pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility licensed pursuant  
 35 to § 63.2-1701, or adult day center licensed pursuant to § 63.2-1701.

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

37 "*Edible cannabis product*" means a cannabis product that is intended to be ingested and is (i) formulated  
 38 with cannabis oil or botanical cannabis, (ii) produced by a pharmaceutical processor and sold by a  
 39 pharmaceutical processor or cannabis dispensing facility, (iii) registered with the Board, and (iv) compliant  
 40 with testing requirements.41 "*Inhalable cannabis product*" means a cannabis product that is intended to be inhaled and is (i)  
 42 formulated with cannabis oil or botanical cannabis, (ii) produced by a pharmaceutical processor and sold by  
 43 a pharmaceutical processor or cannabis dispensing facility, (iii) registered with the Board, and (iv)  
 44 compliant with testing requirements.45 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to  
 46 § 4.1-1602 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil, botanical  
 47 cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis products to a patient  
 48 pursuant to a written certification, his registered agent, or, if such patient is a minor or a vulnerable adult as  
 49 defined in § 18.2-369, such patient's parent or legal guardian.

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

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

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

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

54 "Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a  
 55 physician assistant licensed by the Board of Medicine, or an advanced practice registered nurse jointly  
 56 licensed by the Boards of Nursing and Medicine.

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

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

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

68 **§ 4.1-1602. Permit to operate pharmaceutical processor or cannabis dispensing facility.**

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

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

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

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

119 any cannabis product with an expiration date assigned by the pharmaceutical processor of 12 months or less  
 120 from the date of the cannabis product registration approval testing. Stability testing required for assignment  
 121 of an expiration date longer than 12 months shall be limited to microbial testing, on a pass/fail basis, and  
 122 potency testing, on a 15 percent deviation basis, of total THC and total CBD. No cannabis product shall have  
 123 an expiration date longer than 12 months from the date of the cannabis product registration approval testing  
 124 unless supported by stability testing.

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

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

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

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

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

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

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

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

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

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

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

181 testing results to the pharmaceutical processor before industrial hemp extracts may be acquired.

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

186 1. The product name;

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

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

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

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

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

197 7. Such other information required by the Board.

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

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

212 **§ 4.1-1603. Dispensing cannabis products; report.**

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

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

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

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

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

ENROLLED

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