

2022 SESSION

LEGISLATION NOT PREPARED BY DLS
INTRODUCED

22104985D

SENATE BILL NO. 772

Offered January 21, 2022

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, relating to the Board of Pharmacy; cannabis registration.*

Patron—Marsden

Referred to Committee on Education and Health

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 as follows:

§ 54.1-3408.3. Certification for use of cannabis oil 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 oil" means any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of delta-9-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 acquired and formulated with cannabis plant extract by a pharmaceutical processor.

"Cannabis product" means a product that is (i) produced by a pharmaceutical processor, registered with the Board, and compliant with testing requirements and (ii) composed of cannabis oil or botanical cannabis.

"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 care center licensed pursuant to § 63.2-1701.

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

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

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

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. *A written certification shall not be issued to a patient by more than one practitioner during any given time period.* The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine, provided that the use of telemedicine includes the delivery of patient care through real-time interactive audio-visual technology. If a practitioner determines it is consistent with the standard of care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such dispensing. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature or authentic electronic signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in

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59 such written certification an earlier expiration.

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

66 E. A practitioner who issues a written certification to a patient pursuant to this section shall register
67 with the Board and shall hold sufficient education and training to exercise appropriate professional
68 judgment in the certification of patients. The Board shall not limit the number of patients to whom a
69 practitioner may issue a written certification. The Board may report information to the applicable
70 licensing board on unusual patterns of certifications issued by a practitioner.

71 F. A patient who has been issued a written certification shall register with the Board or, if such
72 patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian
73 shall register and shall register such patient with the Board. No patient shall be required to physically
74 present the written certification after the initial dispensing by any pharmaceutical processor or cannabis
75 dispensing facility under each written certification, provided that the pharmaceutical processor or
76 cannabis dispensing facility maintains an electronic copy of the written certification.

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

82 H. Upon delivery of cannabis oil by a pharmaceutical processor or cannabis dispensing facility to a
83 designated caregiver facility, any employee or contractor of a designated caregiver facility, who is
84 licensed or registered by a health regulatory board and who is authorized to possess, distribute, or
85 administer medications, may accept delivery of the cannabis oil on behalf of a patient or resident for
86 subsequent delivery to the patient or resident and may assist in the administration of the cannabis oil to
87 the patient or resident as necessary.

88 I. The Board shall promulgate regulations to implement the registration process. Such regulations
89 shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification,
90 the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an
91 incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for
92 ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a
93 prohibition for the patient to be issued a written certification by more than one practitioner during any
94 given time period.

95 ~~H.~~ Information obtained under the registration process shall be confidential and shall not be subject
96 to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However,
97 reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee
98 for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local
99 law enforcement for the purpose of investigating or prosecuting a specific individual for a specific
100 violation of law, (iii) licensed practitioners or pharmacists, or their agents, for the purpose of providing
101 patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv)
102 a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered
103 patient, or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated
104 adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to
105 information related to such registered patient agent.

106 **ARTICLE 4.2. PERMITTING OF PHARMACEUTICAL PROCESSORS TO PRODUCE AND**
107 **DISPENSE CANNABIS PRODUCTS.**

108 **§ 54.1-3442.5. Definitions.**

109 As used in this article:

110 "Botanical cannabis," "cannabis oil," "cannabis product," and "usable cannabis" have the same
111 meanings as specified in § 54.1-3408.3.

112 "Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant
113 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 registered patient, his registered agent,
115 or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or
116 legal guardian.

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

118 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to
119 § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil,
120 botanical cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis products to

a registered patient pursuant to a written certification, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

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

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

2017, c. 613; 2018, cc. 246, 809; 2019, c. 690; 2020, c. 1278; 2021, Sp. Sess. I, cc. 205, 227, 228.

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

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

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

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

D. The Board shall require that, after processing and before dispensing any cannabis products, a pharmaceutical processor shall make a sample available from each batch of cannabis product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate cannabis oil that fails any quality testing standard. Following remediation, all remediated cannabis oil shall be subject to laboratory testing and approved upon satisfaction of testing standards applied to cannabis oil generally. If the batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Stability testing shall not be required for any cannabis oil product with an expiration date assigned by the pharmaceutical processor of six months or less from the date of packaging.

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

185 F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under the
186 personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or
187 cannabis dispensing facility. The pharmaceutical processor shall ensure that security measures are
188 adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have
189 concurrent responsibility for preventing diversion from the dispensing area.

190 Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation
191 and production areas of the pharmaceutical processor and shall provide such information to the Board.
192 The Board shall direct all communications related to enforcement of requirements related to cultivation
193 and production of cannabis oil products by the pharmaceutical processor to such designated person.

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

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

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

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

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

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

227 M. A pharmaceutical processor may acquire industrial hemp extract processed in Virginia, and in
228 compliance with state or federal law, from a registered industrial hemp dealer or processor. A
229 pharmaceutical processor may process and formulate such oil extract with cannabis plant extract into an
230 allowable dosage of cannabis oil. Industrial hemp extract acquired by a pharmaceutical processor is
231 subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing
232 shall be performed by a laboratory located in Virginia and in compliance with state law. The industrial
233 hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor
234 before industrial hemp extract may be acquired.

235 N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act
236 (§ 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the
237 adoption of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this
238 section, the Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia
239 Register of Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of
240 opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the
241 proposed regulation; and (iii) the name, address, and telephone number of the agency contact person
242 responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the
243 last date prescribed in such notice for submittals of public comment. The legislative review provisions of

subsections A and B of § 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section. The Board of Pharmacy shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

O. The Board shall register all cannabis products that meet testing, labeling, and packaging standards. 2017, c. 613; 2018, c. 567; 2019, cc. 417, 681, 690; 2020, cc. 831, 928, 944, 1278; 2021, Sp. Sess. I, cc. 205, 227, 228, 550, 551.

§ 54.1-3442.7. Dispensing cannabis products; report.

A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia as made evident to the Board, and has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3; (ii) such patient's registered agent; or (iii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident or temporarily resides in Virginia as made evident to the Board and is registered with the Board pursuant to § 54.1-3408.3. A companion may accompany a registered patient into a pharmaceutical processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing of cannabis products or pursuant to each written certification, a pharmacist or pharmacy technician employed by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or remotely by electronic means, for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view, in person or by audiovisual means, a current photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, registered agent, parent, or legal guardian if applicable. Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian, or designated caregiver facility. Prior to any subsequent dispensing of cannabis products or pursuant to each written certification, an employee or delivery agent shall view a current photo identification of the patient, registered agent, parent, or legal guardian and the current board registration issued to the patient, registered agent, parent, or legal guardian if applicable. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a 90-day supply, of a cannabis product, as determined by the dispensing pharmacist or certifying practitioner, for any patient during any 90-day period. A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day supply of a cannabis product for any patient during any 90-day period; however, a pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day supply. The Board shall establish in regulation an amount of cannabis oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease. In determining the appropriate amount of a cannabis product to be dispensed to a patient, a pharmaceutical processor or cannabis dispensing facility shall consider all cannabis products dispensed to the patient and adjust the amount dispensed accordingly.

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

C. The Board shall report annually by December 1 to the Chairmen of the House Committee for Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, including the number of practitioners, patients, registered agents, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

D. The concentration of delta-9-tetrahydrocannabinol in any cannabis product on site may be up to 10 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any cannabis product on site is within such range. A pharmaceutical processor producing cannabis products shall establish a stability testing schedule of cannabis products.