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## SENATE BILL NO. 969

Offered January 14, 2020

A BILL to amend and reenact §§ 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to pharmaceutical processors; off-site dispensing locations.

Patron—Marsden

Referred to Committee on Education and Health

## Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

## § 54.1-3442.5. Definitions.

As used in this article:

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

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil 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. *"Pharmaceutical processor" includes any off-site dispensing locations established by a permitted pharmaceutical processor pursuant to subsection G of § 54.1-3442.6.*

"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.

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

## § 54.1-3442.6. Permit to operate pharmaceutical processor.

A. No person shall operate a pharmaceutical processor 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. 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 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.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. 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 and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil 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) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; (xi) a process for registering a cannabidiol oil and THC-A oil product; (xii) dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol; ~~and~~ (xiii) a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors; (xiv) *operation of off-site dispensing locations pursuant to subsection G; and (xv) the secure transportation of cannabidiol oil and THC-A oil between the premises at which a pharmaceutical processor processes such cannabidiol oil and THC-A oil and any off-site dispensing location established by the pharmaceutical processor.*

D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.

E. The Board shall require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity.

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59 F. In addition to other employees authorized by the Board, a pharmaceutical processor may employ  
60 individuals who may have less than two years of experience (i) to perform cultivation-related duties  
61 under the supervision of an individual who has received a degree in horticulture or a certification  
62 recognized by the Board or who has at least two years of experience cultivating plants and (ii) to  
63 perform extraction-related duties under the supervision of an individual who has a degree in chemistry  
64 or pharmacology or at least two years of experience extracting chemicals from plants.

65 G. *A pharmaceutical processor to whom a permit has been issued by the Board may establish up to*  
66 *five off-site dispensing locations for the dispensing of cannabidiol oil and THC-A oil cultivated and*  
67 *produced on the premises of the pharmaceutical processor. Each off-site dispensing location shall (i) be*  
68 *located within the same health service area as the pharmaceutical processor, (ii) operate under the*  
69 *supervision and control of the pharmaceutical processor, (iii) dispense only cannabidiol oil and THC-A*  
70 *oil cultivated and produced by the pharmaceutical processor, and (iv) comply with all regulations of the*  
71 *Board related to health, safety, and security for pharmaceutical processors. The pharmaceutical*  
72 *processor shall submit the address of each off-site dispensing location to the Board, and the Board shall*  
73 *include the address of each off-site dispensing location on the permit issued to the pharmaceutical*  
74 *processor. Off-site dispensing locations shall operate under the permit issued to the pharmaceutical*  
75 *processor and shall not be required to obtain a separate permit.*

76 ~~G.~~ H. No person who has been convicted of (i) a felony under the laws of the Commonwealth or  
77 another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et  
78 seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense  
79 under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical  
80 processor.

81 H. I. Every pharmaceutical processor shall adopt policies for pre-employment drug screening and  
82 regular, ongoing, random drug screening of employees.

83 **§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.**

84 A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person  
85 to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered  
86 with the Board pursuant to § 54.1-3408.3, (ii) such patient's registered agent, or (iii) if such patient is a  
87 minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is  
88 a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to the initial  
89 dispensing of each written certification, the pharmacist or pharmacy technician at the location of the  
90 pharmaceutical processor shall make and maintain for two years a paper or electronic copy of the  
91 written certification that provides an exact image of the document that is clearly legible; shall view a  
92 current photo identification of the patient, registered agent, parent, or legal guardian; and shall verify  
93 current board registration of the practitioner and the corresponding patient, registered agent, parent, or  
94 legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist,  
95 pharmacy technician, or delivery agent shall view the current written certification; a current photo  
96 identification of the patient, registered agent, parent, or legal guardian; and the current board registration  
97 issued to the patient, registered agent, parent, or legal guardian. No pharmaceutical processor shall  
98 dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish  
99 in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or  
100 alleviate the symptoms of a patient's diagnosed condition or disease.

101 B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been  
102 cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. A  
103 pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

104 C. The Board shall report annually by December 1 to the Chairmen of the House and Senate  
105 Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the  
106 Board, including (i) the number of practitioners, patients, registered agents, and parents or legal  
107 guardians of patients who have registered with the Board and the number of written certifications issued  
108 pursuant to § 54.1-3408.3 and (ii) *the number and locations of all off-site dispensing locations*  
109 *established pursuant to subsection G of § 54.1-3442.6, together with the name of the pharmaceutical*  
110 *processor with which they are affiliated.*

111 D. The concentration of tetrahydrocannabinol in any THC-A oil on site may be up to 10 percent  
112 greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical  
113 processor shall ensure that such concentration in any THC-A onsite is within such range and shall  
114 establish a stability testing schedule of THC-A oil.