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SENATE BILL NO. 1719

Senate Amendments in [] - January 28, 2019

A BILL to amend and reenact §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to cannabidiol oil and THC-A oil; registered agent; pharmaceutical processors.

Patron Prior to Engrossment—Senator Marsden

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 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:

§ 18.2-250.1. Possession of marijuana unlawful.

A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.).

Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such person either knowingly or intentionally possessed such marijuana.

Any person who violates this section is guilty of a misdemeanor and shall be confined in jail not more than 30 days and fined not more than \$500, either or both; any person, upon a second or subsequent conviction of a violation of this section, is guilty of a Class 1 misdemeanor.

B. The provisions of this section shall not apply to members of state, federal, county, city, or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of marijuana is necessary for the performance of their duties.

C. In any prosecution under this section involving marijuana in the form of cannabidiol oil or THC-A oil as those terms are defined in § 54.1-3408.3, it shall be an affirmative defense that the individual possessed such oil pursuant to a valid written certification issued by a practitioner in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the individual's diagnosed condition or disease, or (ii) if such individual is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease, or (iii) if such individual has been designated as a registered agent pursuant to § 54.1-3408.3, the diagnosed condition or disease of his principal or, if the principal is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease. If the individual files the valid written certification with the court at least 10 days prior to trial and causes a copy of such written certification to be delivered to the attorney for the Commonwealth, such written certification shall be prima facie evidence that such oil was possessed pursuant to a valid written certification.

§ 54.1-3408.3. Certification for use of cannabidiol oil or THC-A oil for treatment.

A. As used in this section:

"Cannabidiol oil" means a processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine.

"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.

"THC-A oil" means a processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

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

66 D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing
67 cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's diagnosed
68 condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this
69 section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly
70 evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for
71 evaluating or treating medical conditions.

72 E. A practitioner who issues a written certification to a patient pursuant to this section shall register
73 with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number
74 of patients to whom a practitioner may issue a written certification.

75 F. A patient who has been issued a written certification shall register with the Board or, if such
76 patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian
77 shall register and shall register such patient with the Board.

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

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

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

100 § 54.1-3442.5. Definitions.

101 As used in this article:

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

103 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to
104 § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or
105 THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a
106 registered patient, *his registered agent*, or, if such patient is a minor or an incapacitated adult as defined
107 in § 18.2-369, such patient's parent or legal guardian.

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

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

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

111 § 54.1-3442.6. Permit to operate pharmaceutical processor.

112 A. No person shall operate a pharmaceutical processor without first obtaining a permit from the
113 Board. The application for such permit shall be made on a form provided by the Board and signed by a
114 pharmacist who will be in full and actual charge of the pharmaceutical processor. The Board shall
115 establish an application fee and other general requirements for such application.

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

120 C. The Board shall adopt regulations establishing health, safety, and security requirements for

121 pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii)
 122 location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v)
 123 recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and
 124 securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing
 125 cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil
 126 to a registered patient, *his registered agent*, or, if such patient is a minor or an incapacitated adult as
 127 defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana
 128 plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains;
 129 ~~and~~ (xi) a process for registering a cannabidiol oil and THC-A oil product; ~~and (xii) a process for the~~
 130 ~~wholesale[sale distribution] of and the transfer of cannabidiol oil and THC-A oil products between~~
 131 ~~pharmaceutical processors.~~

132 D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist
 133 on the premises of the pharmaceutical processor [~~except as provided in this subsection or Board~~
 134 ~~regulations~~] . [~~A pharmacist in charge of a pharmaceutical processor may authorize certain employees~~
 135 ~~access to secured areas designated for cultivation and extraction and other areas approved by the~~
 136 ~~Board. No pharmacist shall be required to be on the premises during such authorized access.~~]

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

144 F. ~~In addition to other employees authorized by the Board, a pharmaceutical processor may employ~~
 145 ~~individuals who may have less than two years of experience (i) to perform cultivation-related duties~~
 146 ~~under the supervision of an individual who has received a degree in horticulture or a certification [or~~
 147 ~~training approved recognized] by the Board or who has at least two years of experience cultivating~~
 148 ~~plants and (ii) to perform extraction-related duties under the supervision of an individual who has a~~
 149 ~~degree in chemistry or pharmacology or at least two years of experience extracting chemicals from~~
 150 ~~plants.~~

151 G. No person who has been convicted of a felony or of any offense in violation of Article 1
 152 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 shall be employed by
 153 or act as an agent of a pharmaceutical processor.

154 **§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.**

155 A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person
 156 to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered
 157 with the Board pursuant to § 54.1-3408.3, (ii) ~~such patient's registered agent~~, or ~~(ii)~~ (iii) if such patient
 158 is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who
 159 is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to the initial
 160 dispensing of each written certification, the pharmacist or pharmacy technician at the location of the
 161 pharmaceutical processor shall make and maintain for two years a paper or electronic copy of the
 162 written certification that provides an exact image of the document that is clearly legible; shall view a
 163 current photo identification of the patient, *registered agent*, parent, or legal guardian; and shall verify
 164 current board registration of the practitioner and the corresponding patient, *registered agent*, parent, or
 165 legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist,
 166 pharmacy technician, or delivery agent shall view the current written certification; a current photo
 167 identification of the patient, *registered agent*, parent, or legal guardian; and the current board registration
 168 issued to the patient, *registered agent*, parent, or legal guardian. No pharmaceutical processor shall
 169 dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish
 170 in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or
 171 alleviate the symptoms of a patient's diagnosed condition or disease.

172 B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been
 173 cultivated and produced on the premises of ~~such a~~ pharmaceutical processor *permitted by the Board*. *A*
 174 *pharmaceutical processor may begin cultivation upon being issued a permit by the Board [; however,*
 175 *no production of cannabidiol oil or THC-A oil shall occur prior to sixty days of the opening date listed*
 176 *in its application]* .

177 C. The Board shall report annually by December 1 to the Chairmen of the House and Senate
 178 Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the
 179 Board, including the number of practitioners, patients, *registered agents*, and parents or legal guardians
 180 of patients who have registered with the Board and the number of written certifications issued pursuant
 181 to § 54.1-3408.3.

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

187 **2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this**
188 **act to be effective [no later than September 1, 2019. The Board's initial adoption of regulations**
189 **necessary to implement the provisions of this act shall be exempt from the Administrative Process**
190 **Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board shall provide an opportunity**
191 **for public comment on the regulations prior to adoption within 280 days of its enactment] .**