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SENATE BILL NO. 701

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee for Courts of Justice on March 2, 2016)

(Patron Prior to Substitute—Senator Marsden)

A BILL to amend and reenact §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, relating to cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, 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 intractable epilepsy 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 intractable epilepsy. 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 to treat intractable epilepsy.

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 50 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 who is a neurologist or who specializes in the treatment of epilepsy.

"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 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

B. A practitioner of medicine or osteopathy licensed by the Board of Medicine 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 a patient's intractable epilepsy.

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 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 such written certification an

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60 earlier expiration.

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

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

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

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

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

89 Article 4.2.

90 *Permitting of Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil.*

91 **§ 54.1-3442.5. Definitions.**

92 As used in this article:

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

94 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant
95 to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil
96 or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a
97 registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such
98 patient's parent or legal guardian for the treatment of intractable epilepsy.

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

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

101 **§ 54.1-3442.6. Permit to operate pharmaceutical processor.**

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

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

110 C. The Board shall adopt regulations establishing health, safety, and security requirements for
111 pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii)
112 location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v)
113 recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and
114 securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing
115 cannabidiol oil and THC-A oil, and dispensing cannabidiol oil and THC-A oil to a registered patient or,
116 if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or
117 legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at
118 any one time; and (x) the secure disposal of plant remains.

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

121 E. No person who has been convicted of a felony or of any offense in violation of Article 1

122 (*§ 18.2-247 et seq.*) or Article 1.1 (*§ 18.2-265.1*) of Chapter 7 of Title 18.2 shall be employed by or act
123 as an agent of a pharmaceutical processor.

124 **§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.**

125 A. A pharmaceutical processor shall dispense cannabidiol oil or THC-A oil only in person to (i) a
126 patient who is a Virginia resident, has been issued a valid written certification, and is registered with
127 the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as
128 defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is
129 registered with the Board pursuant to § 54.1-3408.3. Prior to dispensing, the pharmaceutical processor
130 shall verify that the practitioner issuing the written certification, the patient, and if such patient is a
131 minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board.
132 No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any
133 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that
134 constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

135 B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been
136 cultivated and produced on the premises of such pharmaceutical processor.

137 C. The Board shall report annually by December 1 to the Chairmen of the House and Senate
138 Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the
139 Board, including the number of practitioners, patients, and parents or legal guardians of patients who
140 have registered with the Board and the number of written certifications issued pursuant to
141 § 54.1-3408.3.

142 **§ 54.1-3442.8. Criminal liability; exceptions.**

143 In any prosecution of an agent or employee of a pharmaceutical processor under § 18.2-248,
144 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession,
145 manufacture, or distribution of cannabidiol oil or THC-A oil, it shall be an affirmative defense that such
146 agent or employee (i) possessed or manufactured such marijuana for the purposes of producing
147 cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or
148 (ii) possessed, manufactured, or distributed such cannabidiol oil or THC-A oil in accordance with the
149 provisions of this article and Board regulations. If such agent or employee files a copy of the permit
150 issued to the pharmaceutical processor pursuant to § 54.1-3442.6 with the court at least 10 days prior
151 to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such
152 permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the
153 purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article
154 and Board regulations or (b) such cannabidiol oil or THC-A oil was possessed, manufactured, or
155 distributed in accordance with the provisions of this article and Board regulations.

156 **2. That, except as provided in the third enactment of this act, the provisions of the first enactment**
157 **of this act shall not become effective unless reenacted by the 2017 Session of the General**
158 **Assembly.**

159 **3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of the**
160 **first enactment of this act within 280 days of its initial enactment. Such regulations shall not**
161 **become effective unless the provisions of the first enactment of this act are reenacted by the 2017**
162 **Session of the General Assembly.**