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SENATE BILL NO. 701

AMENDMENT IN THE NATURE OF A SUBSTITUTE
 (Proposed by the Senate Committee on Education and Health
 on February 4, 2016)

(Patron Prior to Substitute—Senator Marsden)

A BILL to amend and reenact § 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 § 54.1-3408.3 of the Code of Virginia is 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:

§ 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.

"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 earlier expiration.

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

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

F. A patient or his primary caregiver shall register with the Board after such patient has been issued a written certification.

G. The Board shall promulgate regulations to implement the registration process. Such regulations shall include (i) a mechanism for sufficiently identifying the physician issuing the written certificate and the patients being treated by the physician or their primary caregivers, (ii) a process for ensuring that any changes in the information are reported in an appropriate timeframe, and (iii) a prohibition for the patient to be issued a written certification by more than one physician during any given time period.

H. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (ii) licensed physicians or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iii) a permitted pharmaceutical processor involved in the treatment of a registered patient, or (iv) a registered patient or his primary caregiver but only with respect to information related to such registered patient.

Article 4.2.

Permitting of Pharmaceutical Processors to Produce and Provide Cannabidiol Oil and THC-A Oil.

SENATE SUBSTITUTE

SB701S1

60 **§ 54.1-3442.5. Definitions.**

61 As used in this article, unless the context requires a different meaning:

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

63 "Pharmaceutical processor" means a facility that cultivates Cannabis plants intended only for the
64 production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, or provides
65 cannabidiol oil or THC-A oil to registered patients or their primary caregivers for the treatment of
66 intractable epilepsy.

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

68 **§ 54.1-3442.6. Permit to conduct pharmaceutical processor.**

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

73 B. Each permit shall expire annually on a date determined by the Board in regulation. No more than
74 12 permits shall be issued or renewed in any one year and, to the extent possible, permits shall be
75 issued in a manner to ensure that pharmaceutical processor services are available in all regions of the
76 Commonwealth. Permits shall be displayed in a conspicuous place in the pharmaceutical processor.

77 C. The Board shall adopt regulations establishing health, safety, and security requirements for
78 permitted pharmaceutical processors. Such regulations shall include requirements for (i) physical
79 standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and
80 resources; (v) recordkeeping; (vi) labeling and packaging; (vii) annual inspections; (viii) processes for
81 safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil,
82 producing cannabidiol oil and THC-A oil, and providing cannabidiol oil and THC-A oil to registered
83 patients or their primary caregivers; (ix) a maximum number of marijuana plants a permitted
84 pharmaceutical processor may possess at any one time; and (x) the secure disposal of plant remains.

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

87 **§ 54.1-3442.7. Providing cannabidiol oil and THC-A oil.**

88 A. A permitted pharmaceutical processor may provide cannabidiol oil and THC-A oil. No permitted
89 pharmaceutical processor shall provide cannabidiol oil or THC-A oil except to a patient or the primary
90 caregiver of a patient who is a Virginia resident and has been issued a valid written certification and
91 registered with the Board pursuant to § 54.1-3408.3. Prior to dispensing, the permitted pharmaceutical
92 processor shall verify that both the patient or primary caregiver and the issuing practitioner have
93 registered with the Board. No permitted pharmaceutical processor shall provide more than a 30-day
94 supply to any patient or primary caregiver during any 30-day period. The Board shall establish an
95 amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the
96 symptoms of a patient's intractable epilepsy.

97 B. A pharmaceutical processor shall only provide cannabidiol and THC-A oil that has been
98 cultivated and produced on the premises of such pharmaceutical processor.

99 **§ 54.1-3442.8. Criminal liability.**

100 A. No person shall be prosecuted under § 18.2-250 or 18.2-250.1 for possessing marijuana or
101 tetrahydrocannabinol for the purposes of producing cannabidiol oil or THC-A oil in accordance with
102 the provisions of this article and Board regulations.

103 B. No person shall be prosecuted under § 18.2-248.1 for providing cannabidiol oil or THC-A oil in
104 accordance with the provisions of this article and Board regulations.

105 **2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this**
106 **act to be effective within 280 days of its enactment.**