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SENATE BILL NO. 701

Offered January 21, 2016

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 54.1-3442.10, relating to cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

Patrons—Marsden; Delegate: Filler-Corn

Referred to Committee on Education and Health

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 54.1-3442.10, 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 to a patient a written certification pursuant to this section shall register with the Board. The Board shall 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.

Article 4.2.

Permitting of Pharmaceutical processors to Manufacture and provide Cannabidiol Oil and THC-A Oil.

§ 54.1-3442.5. Definitions.

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

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

"Pharmaceutical processor" means a facility that manufactures and provides cannabidiol oil or THC-A oil.

"Marijuana" has the same meaning as specified in § 18.2-247.

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

§ 54.1-3442.6. Supervision by pharmacist.

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

§ 54.1-3442.7. Permit to conduct pharmaceutical processor.

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

63 B. Each permit shall expire annually on a date determined by the Board in regulation. No more than
64 12 permits shall be issued or renewed in any one year and, to the extent possible, permits shall be
65 issued in a manner to ensure that pharmaceutical processor services are available in all regions of the
66 Commonwealth. Permits shall be displayed in a conspicuous place in the pharmaceutical processor.

67 C. The Board shall adopt regulations establishing health, safety, and security requirements for
68 permitted pharmaceutical processors. Such regulations shall include requirements for (i) physical
69 standards, (ii) security systems and controls, (iii) minimum equipment and resources, (iv) recordkeeping,
70 (v) labeling and packaging, (vi) annual inspections, and (vii) any other necessary requirements.

71 **§ 54.1-3442.8. Manufacturing cannabidiol oil and THC-A oil.**

72 A. A permitted pharmaceutical processor may manufacture cannabidiol oil and THC-A oil. Such
73 manufacture shall be in accordance with § 54.1-3410.2 and other applicable statutory and regulatory
74 requirements for the compounding of drug products. The permitted pharmaceutical processor shall
75 maintain a complete compounding formula listing all ingredients, procedures, necessary equipment,
76 necessary environmental considerations, and any other information required by the Board.

77 B. The Board shall set a limit for the number of marijuana plants a permitted pharmaceutical
78 processor may possess at any one time and shall prescribe a process for the secure disposal of plant
79 remains.

80 **§ 54.1-3442.9. Providing cannabidiol oil and THC-A oil.**

81 A permitted pharmaceutical processor may provide cannabidiol oil and THC-A oil. No permitted
82 pharmaceutical processor shall provide cannabidiol oil or THC-A oil except to a patient or the primary
83 caregiver of a patient who has been issued a valid written certification pursuant to § 54.1-3408.3. Prior
84 to dispensing, the permitted pharmaceutical processor shall verify that both the patient or primary
85 caregiver and the issuing practitioner have registered with the Board. No permitted pharmaceutical
86 processor shall provide more than a 30-day supply to any patient or primary caregiver during any
87 30-day period.

88 **§ 54.1-3442.10. Criminal liability.**

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

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