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HOUSE BILL NO. 1460

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions on February 4, 2020)

(Patron Prior to Substitute—Delegate O'Quinn)

A BILL to amend and reenact §§ 54.1-3408.3 and 54.1-3442.7 of the Code of Virginia, relating to cannabidiol oil and THC-A oil; telemedicine; non-Virginia residents.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3 and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 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 any formulation of 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 dose but not more than five percent tetrahydrocannabinol. "Cannabidiol oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.

"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 any formulation of 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 dose 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. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine, consistent with federal requirements for the prescribing of Schedule II through V controlled substances.

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

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

H. The Board shall promulgate regulations to implement the registration process. Such regulations shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification,

HOUSE SUBSTITUTE

HB1460H1

60 the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an
61 incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for
62 ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a
63 prohibition for the patient to be issued a written certification by more than one practitioner during any
64 given time period.

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

75 **§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.**

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

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

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

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