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HOUSE BILL NO. 347

Offered January 8, 2020
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A BILL to amend and reenact §§ 54.1-3408.3, 54.3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to tetrahydrocannabinol products; permits to process and dispense cannabidiol oil and THC-A oil.

Patron—Davis

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 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:

§ 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.

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, the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (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 practitioner during any given time period.

I. 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) the Chairmen of the House and Senate Committees for Courts of Justice, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed physicians or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor involved in the treatment of a registered patient, ~~or~~ (v) *a dispensing facility involved in the dispensing of cannabidiol oil or THC-A oil; or (vi)* a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

§ 54.1-3442.5. Definitions.

As used in this article:

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

"Dispensing facility" means a facility that holds a permit issued by the Board pursuant to § 54.1-3442.6 that dispenses cannabidiol oil or THC-A oil produced by a pharmaceutical processor permitted and located within the same health service area.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § ~~54.1-3408.3~~ *54.1-3442.6* and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

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

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

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

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

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

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to ~~one~~ *two pharmaceutical processors and two dispensing facilities* for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor *or the dispensing facility*.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors *and dispensing facilities*. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) ~~quarterly~~ *regular* inspections *on a schedule established by the Board*; (viii) processes for safely and securely *(a)* cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil~~,~~ *and (b)* producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains *and unwanted or expired oils*; (xi) a process for registering a cannabidiol oil and THC-A oil products; (xii) dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol; ~~and~~ (xiii) a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors*; (xiv) a process for reporting to the Prescription Monitoring Program; and (xv) operation of off-site dispensing locations pursuant to subsection I.*

D. Every pharmaceutical processor *and dispensing facility* shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor *or dispensing facility*.

E. The Board shall require an applicant for a pharmaceutical processor *or dispensing facility* permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his

fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity.

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

G. No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor *or dispensing facility*.

H. Every pharmaceutical processor *and dispensing facility* shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

I. The Board may issue permits for up to two dispensing facilities located within each health service area. A dispensing facility shall (i) have at least 50 percent common ownership with a pharmaceutical processor located in the health service area in which the dispensing facility is located; (ii) dispense only cannabidiol oil and THC-A oil cultivated and produced by the permitted pharmaceutical processor with which it has common ownership and that is located in the same health service area; and (iii) comply with all regulations of the Board related to health, safety, and security for dispensing facilities.

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

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

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board. *A dispensing facility shall only dispense cannabidiol oil and THC-A oil that has been produced by a permitted pharmaceutical processor with which it has at least 50 percent common ownership and that is located in the health service area in which the dispensing facility is located.*

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors *and dispensing facilities* issued a permit by the Board, including *(i)* the number of practitioners, patients, registered agents, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3 *and (ii) the number and locations of all off-site dispensing facilities established pursuant to subsection I of § 54.1-3442.6, together with the name of their affiliated pharmaceutical processor*.

D. The concentration of tetrahydrocannabinol in any THC-A oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor shall ensure that such concentration in any THC-A onsite is within such range and shall establish a stability testing schedule of THC-A oil. *No dispensing facility shall dispense THC-A oil*

whose concentration is not within 10 percent of the level of tetrahydrocannabinol measured for labeling.
2. That as soon as practicable but no later than September 1, 2020, the Board of Pharmacy shall issue one additional permit to operate a pharmaceutical processor for each health service area established by the Board of Health, so that the total number of permits to operate a pharmaceutical processor issued by the Board of Pharmacy equals 10, with no more than two permits issued for each health service area established by the Board of Health. Such permits shall be issued to applicants for whom an application for a permit to operate a pharmaceutical processor was received, reviewed, evaluated, and scored by the Board of Pharmacy pursuant to the Board of Pharmacy's Request for Applications No. PHR-2018-1. The Board of Pharmacy shall award such permits to the applicant that received the highest score in each health service area out of all of the applicants for that health service area to which no permit has been issued, provided that the applicant provides documentation satisfactory to the Board of Pharmacy indicating that the applicant has the existing financial, infrastructure, and technical ability to begin processing cannabidiol oil and THC-A oil product in accordance with regulations of the Board of Pharmacy.
3. That the Board of Pharmacy shall require submission of an application in accordance with regulations of the Board and payment of an application fee in an amount to be determined by the Board for issuance of any pharmaceutical processor or dispensing facility permit issued on or after January 1, 2021.
4. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act relating to permitting of dispensing facilities within 280 days of its enactment.