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HOUSE BILL NO. 1988

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions on January 28, 2021)

(Patron Prior to Substitute—Delegate Adams, D.M.)

A BILL to amend and reenact §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to Board of Pharmacy; pharmaceutical processors; processing and dispensing cannabis oil.

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 cannabis oil for treatment.

A. As used in this section:

"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of delta-9-tetrahydrocannabinol per dose. "Cannabis 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, unless it has been acquired and formulated with cannabis plant extract by a pharmaceutical processor.

"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.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis 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~~, *provided that the use of telemedicine includes the delivery of patient care through real-time interactive audio-visual technology*.

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 *or electronic 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~~ *the recommendation of or issuance of a certification for the use of* cannabis 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 *and shall hold sufficient education and training to exercise appropriate professional judgment in the certification of patients*. The Board shall~~, in consultation with the Board of Medicine, set a~~ *not* 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. *No patient shall be required to physically possess the written certification after the initial dispensing by any pharmaceutical processor or cannabis dispensing facility under each written certification, provided that the pharmaceutical processor or cannabis dispensing facility maintains an electronic copy of the written certification.*

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 cannabis 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 Committee for Courts of Justice and the Senate Committee on the Judiciary, (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 practitioners or pharmacists, *or their agents,* for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered patient, or (v) 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:

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

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis oil produced by a pharmaceutical processor 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.

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

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil, produces cannabis oil, and dispenses cannabis 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.

§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.

A. No person shall operate a pharmaceutical processor or a cannabis 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~~ *processor's dispensing area* or cannabis 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 pharmaceutical processor and up to five cannabis 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 and cannabis dispensing facility.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors and cannabis 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~~ *routine* inspections *no more frequently than once annually*; (viii) processes for safely and securely dispensing and delivering in person cannabis 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) dosage limitations, which shall provide that each dispensed dose of cannabis oil not exceed 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution of and the transfer of cannabis oil products between pharmaceutical processors ~~and~~, between a pharmaceutical processor and a cannabis dispensing facility, *and between cannabis dispensing facilities*; (xi) an allowance for the sale of devices for administration of dispensed products *and hemp-based CBD products that meet the applicable standards set forth in state and federal law, including the laboratory testing standards set forth in subsection M*; (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical

processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification; ~~and~~ (xiii) a process for acquiring oil from industrial hemp extract and formulating such oil extract with Cannabis plant extract into allowable dosages of cannabis oil*; and (xiv) an allowance for the advertising and promotion of the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical processor from the provision of educational material to practitioners who issue written certifications and registered patients*. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis oil~~;~~, (b) ~~a maximum number of marijuana plants a pharmaceutical processor may possess at any one time;~~ ~~(c)~~ the secure disposal of ~~plant remains;~~ *agricultural waste,* and ~~(d)~~ *(c)* a process for registering cannabis oil products.

D. The Board shall require that, after processing and before dispensing cannabis oil, a pharmaceutical processor shall make a sample available from each homogenized batch of product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch is required to achieve a representative sample for analysis. *The pharmaceutical processor may remediate cannabis oil that fails any quality testing standard. Following remediation, all remediated cannabis oil shall be subject to laboratory testing and approved upon satisfaction of testing standards applied to cannabis oil generally. Stability testing shall not be required for any cannabis oil product with an expiration date assigned by the pharmaceutical processor of six months or less from the date of packaging.*

E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the Board in regulation.

F. Every pharmaceutical ~~processor~~ *processor's dispensing area* or cannabis dispensing facility shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis dispensing facility. ~~A pharmacist in charge of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access. The pharmacist-in-charge~~ *The pharmaceutical processor* shall ensure *that* security measures are adequate to protect the cannabis from diversion at all times*, and the pharmacist-in-charge shall have concurrent responsibility for preventing diversion from the dispensing area*.

Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation and production areas of the pharmaceutical processor and shall provide such information to the Board. The Board shall direct all communications related to enforcement of requirements related to cultivation and production of cannabis oil products by the pharmaceutical processor to such designated person.

G. The Board shall require *the material owners of* an applicant for a pharmaceutical processor or cannabis 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~~ *applicant's material owners*. 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. *A pharmaceutical processor shall maintain evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.*

H. 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~~ *a field related to the cultivation of plants* 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*, and (iii) to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a pharmacy technician*.

I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to five cannabis dispensing facilities for the dispensing of cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

J. 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~~ *within the last five years* shall be employed by or act as an agent of a pharmaceutical processor or cannabis dispensing facility.

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

L. A pharmacist at the pharmaceutical ~~processor~~ *processor's dispensing area* and the cannabis dispensing facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than six persons performing the duties of a pharmacy technician at one time *in the pharmaceutical processor's dispensing area or cannabis dispensing facility*.

~~M. Any person who proposes to use an automated process or procedure during the production of cannabis oil that is not otherwise authorized in law or regulation or at a time when a pharmacist will not be on-site may apply to the Board for approval to use such process or procedure pursuant to subsections B through E of § 54.1-3307.2.~~

~~N.~~ *M.* A pharmaceutical processor may acquire oil from industrial hemp extract processed in Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or processor. A pharmaceutical processor may process and formulate such oil extract with cannabis plant extract into an allowable dosage of cannabis oil. Oil from industrial hemp acquired by a pharmaceutical processor is subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall be performed by a laboratory located in Virginia and in compliance with state law. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before oil from industrial hemp may be acquired.

N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment. The legislative review provisions of subsections A and B of § 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section. The Board of Pharmacy shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

§ 54.1-3442.7. Dispensing cannabis oil; report.

A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis oil only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia as made evident to the Board, 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 or temporarily resides in Virginia as made evident to the Board and is registered with the Board pursuant to § 54.1-3408.3. *A companion may accompany a registered patient into a pharmaceutical processor's dispensing area or cannabis dispensing facility.* Prior to the initial dispensing of *cannabis oil pursuant to* each written certification, ~~the~~ *a* pharmacist or pharmacy technician ~~at the location of~~ *employed by* the pharmaceutical processor or cannabis dispensing facility shall make and maintain, *on site or remotely by electronic means,* 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, *in person or by audiovisual means,* 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. *Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian, or designated caregiver facility.* Prior to any subsequent dispensing of *cannabis oil pursuant to* each written certification, ~~the pharmacist, pharmacy technician,~~ *an employee* 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 cannabis dispensing facility shall dispense more than a 90-day supply, *as determined by the dispensing pharmacist or certifying practitioner,* for any patient during any 90-day period. ~~The Board shall establish in regulation an amount of cannabis oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.~~ *A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day supply.*

B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board

or cannabis oil that has been formulated with oil from industrial hemp acquired by a pharmaceutical processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

C. The Board shall report annually by December 1 to the Chairmen of the House Committee for ~~Courts of Justice~~ *Health, Welfare and Institutions* and the Senate Committee on ~~the Judiciary~~ *Education and Health* on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, including 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.

D. The concentration of delta-9-tetrahydrocannabinol in any cannabis oil on site may be up to 10 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any cannabis oil on site is within such range. A pharmaceutical processor producing cannabis oil shall establish a stability testing schedule of cannabis oil.

2. That the Board of Pharmacy (the Board) shall promulgate regulations implementing the provisions of this act. The Board's initial adoption of regulations shall be exempt from the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board shall provide an opportunity for public comment on the regulations prior to adoption. The Board shall complete work on such regulations in order that they will be implemented no later than July 1, 2021.

3. That in promulgating the regulations implementing the provisions of this act, the Board of Pharmacy shall amend 18VAC-110-60-220 and may include reasonable restrictions on the advertising, logos, signage, and display of cannabis oil products and the appearance of pharmaceutical processors and cannabis dispensing facilities, provided that such restrictions do not prohibit (i) the reasonable promotion of their business and operations or (ii) nonpublic communications. Restrictions may include (a) prohibiting false or misleading statements, (b) prohibiting incorporating unsupported health claims, (c) prohibiting advertisements that target children and the use of statements and illustrations designed or likely to appeal to children, (d) prohibiting online advertising intended to target or otherwise appeal to children, (e) restricting the proximity of advertising to schools, and (f) restricting the posting of advertisements on public property, including public transit vehicles and facilities.

4. That the Board of Pharmacy shall solicit input from stakeholders and appropriate agencies of the Commonwealth in order to recommend legislative action to permit the acceptance of cannabis oil products by any hospice or hospice facility licensed pursuant to § 32.1-162.3 of the Code of Virginia, home care organization as defined in § 32.1-162.7 of the Code of Virginia, private provider licensed by the Department of Behavioral Health and Developmental Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2 of the Code of Virginia, or assisted living facility or adult day care center licensed pursuant to § 63.2-1701 of the Code of Virginia. The Board of Pharmacy shall report its findings and recommendations to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by October 1, 2021.