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SENATE BILL NO. 671

Offered January 20, 2022

A BILL to amend and reenact §§ 54.1-3408.3, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to pharmaceutical processors.

Patron—Dunnavant

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3, 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:

"Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same parts of the same chemovar of cannabis plant.

"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include ~~oil from~~ industrial hemp ~~extract~~ *extracts* 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 *grown and processed in the Commonwealth by a registered industrial hemp processor and* acquired and formulated ~~with cannabis plant extract~~ by a pharmaceutical processor.

"Cannabis product" means a product that is (i) produced by a pharmaceutical processor, registered with the Board, and compliant with testing requirements and (ii) composed of cannabis oil or botanical cannabis.

"Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home health services, 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, assisted living facility licensed pursuant to § 63.2-1701, or adult day care center licensed pursuant to § 63.2-1701.

"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.

"Usable cannabis" means any cannabis plant material, including seeds, but not (i) resin that has been extracted from any part of the cannabis plant, its seeds, or its resin; (ii) the mature stalks, fiber produced from the stalks, or any other compound, manufacture, salt, or derivative, mixture, or preparation of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis products 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, provided that the use of telemedicine includes the delivery of patient care through real-time interactive audio-visual technology. If a practitioner determines it is consistent with the standard of care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such dispensing. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.

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 authentic 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 the issuance of a certification for the use of cannabis products 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 not limit the number of patients to whom a practitioner may issue a written certification. The Board may report information to the applicable licensing board on unusual patterns of certifications issued by a practitioner.

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 present 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 products pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number of patients for whom any individual is authorized to act as a registered agent.

H. Upon delivery of *a* cannabis ~~oil~~ *product* by a pharmaceutical processor or cannabis dispensing facility to a designated caregiver facility, any employee or contractor of a designated caregiver facility, who is licensed or registered by a health regulatory board and who is authorized to possess, distribute, or administer medications, may accept delivery of the cannabis ~~oil~~ *product* on behalf of a patient or resident for subsequent delivery to the patient or resident and may assist in the administration of the cannabis ~~oil~~ *product* to the patient or resident as necessary.

I. 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*; and (iv) within 15 days of receipt of an individual registration application, the Board shall review the application for completeness and either accept the application or request additional specific information from the applicant.*

J. 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.

§ 54.1-3442.6. 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'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, including the potency of each botanical cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and securely dispensing and delivering in person cannabis products 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 for cannabis oil that 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 usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical processors, 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 cannabis 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; (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~~ *extracts and formulating such extracts into cannabis products*; 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 products, (b) the secure disposal of agricultural waste, and (c) a process for registering cannabis oil products.

D. The Board shall require that, after processing and before dispensing any cannabis products, a pharmaceutical processor shall make a sample available from each batch of cannabis 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 of cannabis oil is required to achieve a representative cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate *botanical* cannabis ~~oil~~ that fails any quality testing standard. Following remediation, all remediated *botanical* cannabis ~~oil~~ shall be subject to laboratory testing and approved upon satisfaction of testing standards applied to *botanical* cannabis ~~oil~~ generally. If the batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. 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'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. 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'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 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, (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 products that have 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 a felony under the laws of the Commonwealth or 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'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. A pharmaceutical processor may acquire industrial hemp ~~extract~~ *extracts grown and* 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 ~~extract with cannabis plant extract~~ *extracts* into an allowable dosage of cannabis ~~oil~~ *product*. Industrial hemp ~~extract~~ *extracts* acquired *and formulated* by a pharmaceutical processor ~~is~~ *are* 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 *governing the testing of cannabis products*. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before industrial hemp ~~extract~~ *extracts* 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.

O. The Board shall register all cannabis products that meet testing, labeling, and packaging standards.

§ 54.1-3442.7. Dispensing cannabis products; report.

A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis products 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, a pharmacist or pharmacy technician 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, an employee or delivery agent shall view a current photo identification of the patient, registered agent, 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 of a cannabis product, as determined by the dispensing pharmacist or certifying practitioner, for any patient during any 90-day period; however, a pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day supply. In determining the appropriate amount of a cannabis product to be dispensed to a patient, a pharmaceutical processor or cannabis dispensing facility shall consider all cannabis products dispensed to the patient and adjust the amount dispensed accordingly.

B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis products 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 Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, *and shall publish monthly on its website information* including the number of practitioners, patients, registered agents, and parents or legal guardians of patients *in each health service area* who have registered with the Board ~~and~~, the number of written certifications issued pursuant to § 54.1-3408.3, *the number of pending applications for registrations, and the pace at which the Board is approving registrations*.

D. The concentration of delta-9-tetrahydrocannabinol in any cannabis product 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 product on site is within such range. A pharmaceutical processor producing cannabis products shall establish a stability testing schedule of cannabis products.

2. That the Board of Pharmacy shall amend subsection A of 18VAC110-60-280 of the Virginia Administrative Code to permit the use of hydrocarbon-based solvents, and any other generally accepted technology, in the cultivation, extraction, production, or manufacturing process of cannabis products.

3. That the Board of Pharmacy shall amend subsection B of 18VAC110-60-330 of the Virginia Administrative Code to require only the presence of an employee of the pharmaceutical processor to witness destruction and disposal of green waste, extracts, and cannabis oil, as applicable.

4. That the Board of Pharmacy shall permit pharmaceutical processors to engage in wholesale transactions of bulk cannabis oil, botanical cannabis, and usable cannabis, and amend subsection A of 18VAC110-60-251 of the Virginia Administrative Code to remove the requirements that wholesale transactions of bulk cannabis oil, botanical cannabis and usable cannabis from any lot or batch: (i) must have passed the tests required in subsections G and H of 18VAC110-60-300 of the Virginia Administrative Code; and (ii) are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 of the Virginia Administrative Code. The regulations shall state that wholesale cannabis oil, botanical cannabis, and usable cannabis shall be packaged in a tamper-evident container and labeled with: (a) the seller's name and address; (b) the buyer's name and address; (c) the quantity or weight of the cannabis oil, botanical cannabis or usable cannabis in each container; (d) identification of the contents of the container, including a brief description of the type or form of cannabis oil, botanical cannabis, or usable cannabis and the strain name, as appropriate; (e) a unique serial number that will match a cannabis product with the cultivator and manufacturer and lot or batch number to facilitate any warnings or recalls that the Board of Pharmacy or any successor governmental or quasi-governmental body authorized to regulate cannabis or the original pharmaceutical processor deems appropriate; (f) the date of laboratory testing and the name and address of the testing laboratory; (g) the dates of harvest and packaging; and (h) an expiration date.

5. That the Board of Pharmacy shall amend the pharmaceutical processor permit application to include designation of a corporate point of contact who shall receive copies of all communications

sent to the pharmacist in charge or responsible party.

6. That the Board of Pharmacy shall amend subsection C of 18VAC110-60-170 of the Virginia Administrative Code to allow any individual designated by the pharmaceutical processor to serve as a supervisor of cultivation activities, manufacturing activities, and facilities management, and as the responsible party.

7. That the Board of Pharmacy shall amend its regulations to allow pharmaceutical processors to engage in marketing activity, inclusive of product, program, company, and related communications other than those marketing activities that (i) include false or misleading statements; (ii) promote excessive consumption; (iii) depict a person younger than 21 years of age consuming cannabis; (iv) include any image designed or likely to appeal to minors, specifically including cartoons, toys, animals, children, or any other likeness to images, characters, or phrases that are popularly used to advertise to children; (v) depict products or product packaging or labeling that bears reasonable resemblance to any product legally available for consumption as a candy or that promotes cannabis consumption; and (vi) contain any seal, flag, crest, coat of arms, or other insignia that is likely to mislead registered patients or the general public to believe that the cannabis product has been endorsed, made, or used by the Commonwealth of Virginia or any of its representatives except where specifically authorized.

8. That the Board of Pharmacy shall amend subsection B of 18VAC110-60-285 to include the following exceptions: (i) where the total tetrahydrocannabinol (THC) concentration is less than 5 milligrams per dose, the concentration of THC shall be within 0.5 milligrams per dose; (ii) where the total cannabidiol (CBD) concentration is less than 5 milligrams per dose, the concentration of total CBD shall be within 0.5 milligrams per dose; and (iii) the concentration of total THC and CBD in milligrams per single dose for each sample of a brand lot submitted for testing must be within 25 percent of the mean concentration of total THC and CBD in milligrams per single dose for that submitted lot, except that for products with a specific total THC and CBD concentration less than 2 milligrams per single dose, the concentration of each sample for that low concentration cannabinoid shall be within 0.5 milligrams per dose of the mean concentration.

9. That the Board of Pharmacy's initial adoption of regulations necessary to implement the provisions of this act shall be exempt from the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board of Pharmacy shall provide an opportunity for public comment on the regulations prior to adoption of such regulations.

10. That the Board of Pharmacy shall amend and promulgate regulations in accordance with this act by September 1, 2022.