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SENATE BILL NO. 1333

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Finance and Appropriations on February 3, 2021)

(Patron Prior to Substitute—Senator Lucas)

A BILL to amend and reenact §§ 18.2-250.1, 54.1-2519, 54.1-2521, 54.1-2903, 54.1-3408.3, and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia, relating to pharmaceutical processors; cannabis products.

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 54.1-2519, 54.1-2521, 54.1-2903, 54.1-3408.3, and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia are amended and reenacted as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.). The attorney for the Commonwealth or the county, city, or town attorney may prosecute such a case.

Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such person either knowingly or intentionally possessed such marijuana.

Any person who violates this section is subject to a civil penalty of no more than $25. A violation of this section is a civil offense. Any civil penalties collected pursuant to this section shall be deposited into the Drug Offender Assessment and Treatment Fund established pursuant to § 18.2-251.02.

B. Any violation of this section shall be charged by summons. A summons for a violation of this section may be executed by a law-enforcement officer when such violation is observed by such officer. The summons used by a law-enforcement officer pursuant to this section shall be in form the same as the uniform summons for motor vehicle law violations as prescribed pursuant to § 46.2-388. No court costs shall be assessed for violations of this section. A person's criminal history record information as defined in § 9.1-101 shall not include records of any charges or judgments for a violation of this section, and records of such charges or judgments shall not be reported to the Central Criminal Records Exchange. However, if a violation of this section occurs while an individual is operating a commercial motor vehicle as defined in § 46.2-341.4, such violation shall be reported to the Department of Motor Vehicles and shall be included on such individual's driving record.

C. The procedure for appeal and trial of any violation of this section shall be the same as provided by law for misdemeanors; if requested by either party on appeal to the circuit court, trial by jury shall be as provided in Article 4 (§ 19.2-260 et seq.) of Chapter 15 of Title 19.2, and the Commonwealth shall be required to prove its case beyond a reasonable doubt.

D. The provisions of this section shall not apply to members of state, federal, county, city, or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of marijuana is necessary for the performance of their duties.

E. The provisions of this section involving marijuana in the form of cannabis ~~oil~~ *products* as that term is defined in § 54.1-3408.3 shall not apply to any person who possesses such ~~oil~~ *cannabis product* pursuant to a valid written certification issued by a practitioner in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the person's diagnosed condition or disease, (ii) if such person is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease, or (iii) if such person has been designated as a registered agent pursuant to § 54.1-3408.3, the diagnosed condition or disease of his principal or, if the principal is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease.

§ 54.1-2519. Definitions.

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

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug Diversion Unit.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

"Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled substances included in Schedule V for which a prescription is required; naloxone; and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. "Covered substance" also includes cannabis ~~oil~~ *products* dispensed by a pharmaceutical processor in Virginia.

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance to an ultimate user, research subject, or owner of an animal patient by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

"Drug of concern" means any drug or substance, including any controlled substance or other drug or substance, where there has been or there is the potential for abuse and that has been identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

"Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance.

"Recipient" means a person who receives a covered substance from a dispenser and includes the owner of an animal patient.

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including the Board of Dentistry, the Board of Medicine, the Board of Veterinary Medicine, and the Board of Pharmacy.

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.

2. The recipient's date of birth.

3. The covered substance that was dispensed to the recipient.

4. The quantity of the covered substance that was dispensed.

5. The date of the dispensing.

6. The prescriber's identifier number and, in cases in which the covered substance is *a* cannabis ~~oil~~ *product*, the expiration date of the written certification.

7. The dispenser's identifier number.

8. The method of payment for the prescription.

9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

C. Except as provided in subdivision 7 of § 54.1-2522, in cases where the ultimate user of a covered substance is an animal, the dispenser shall report the relevant information required by subsection B for the owner of the animal.

D. The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

§ 54.1-2903. What constitutes practice; advertising in connection with medical practice.

A. Any person shall be regarded as practicing the healing arts who actually engages in such practice as defined in this chapter, or who opens an office for such purpose, or who advertises or announces to the public in any manner a readiness to practice or who uses in connection with his name the words or letters "Doctor," "Dr.," "M.D.," "D.O.," "D.P.M.," "D.C.," "Healer," "N.P.," or any other title, word, letter or designation intending to designate or imply that he is a practitioner of the healing arts or that he is able to heal, cure or relieve those suffering from any injury, deformity or disease.

Signing a birth or death certificate, or signing any statement certifying that the person so signing has rendered professional service to the sick or injured, or signing or issuing a prescription for drugs or other remedial agents, shall be prima facie evidence that the person signing or issuing such writing is

practicing the healing arts within the meaning of this chapter except where persons other than physicians are required to sign birth certificates.

B. No person regulated under this chapter shall use the title "Doctor" or the abbreviation "Dr." in writing or in advertising in connection with his practice unless he simultaneously uses words, initials, an abbreviation or designation, or other language that identifies the type of practice for which he is licensed. No person regulated under this chapter shall include in any advertisement a reference to marijuana, as defined in § 18.2-247, unless such advertisement is for the treatment of addiction or substance abuse. However, nothing in this subsection shall prevent a person from including in any advertisement that such person is registered with the Board of Pharmacy to issue written certifications for the use of cannabis ~~oil~~ *products*, as defined in § 54.1-3408.3.

§ 54.1-3408.3. Certification for use of cannabis products 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 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.

"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.

"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 ~~oil~~ *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 consistent with federal requirements for the prescribing of Schedule II through V controlled substances. *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 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 cannabis ~~oil~~ *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. 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 cannabis ~~oil~~ *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. 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 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~~ *"Botanical cannabis," "cannabis oil," "cannabis product," and "usable cannabis" have* the same ~~meaning~~ *meanings* 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~~ *products* 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.

"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, *botanical cannabis, and usable cannabis,* produces cannabis ~~oil~~ *products,* and dispenses cannabis ~~oil~~ *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.

"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 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) quarterly inspections; (viii) processes for safely and securely dispensing and delivering in person cannabis ~~oil~~ *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~~, which shall~~ *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 and between a pharmaceutical processor and a cannabis dispensing facility; (xi) an allowance for the sale of devices for administration of dispensed *cannabis* products; (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. 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~~ *products*; ~~(b)~~ ~~a maximum number of marijuana plants a pharmaceutical processor may possess at any one time;~~ ~~(c)~~ *(b)* the secure disposal of plant remains; and ~~(d)~~ *(c)* a process for registering cannabis oil products.

D. The Board shall require that, after processing and before dispensing *any* cannabis ~~oil~~ *products*, a pharmaceutical processor shall make a sample available from each ~~homogenized~~ 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. If a sample from a batch of botanical cannabis fails testing requirements, the processor may remediate the batch and submit a sample for retesting. If the batch fails retesting, with the exception of pesticide requirements, it shall be considered usable cannabis and may be processed into cannabis oil. This oil must comply with all applicable testing standards.*

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 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 shall ensure security measures are adequate to protect the cannabis from diversion at all times.

G. The Board shall require 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. 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.

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 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.

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~~ *products* that ~~has~~ *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 (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 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 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.

M. Any person who proposes to use an automated process or procedure during the production of cannabis ~~oil~~ *products* that is not otherwise authorized in law or regulation or at a time when a pharmacist will not be ~~on-site~~ *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. 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.

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 ~~oil~~ *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. Prior to the initial dispensing of each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis 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 cannabis 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 cannabis oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease. *The supply for botanical cannabis products may not exceed four ounces of botanical cannabis per 30-day period. In determining the appropriate supply, the pharmacist shall consider all cannabis products dispensed to the patient and adjust the dispensing accordingly.*

B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis ~~oil that has been cultivated and~~ *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 Courts of Justice and the Senate Committee on the Judiciary 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~~ *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 ~~oil~~ *product* on site is within such range. A pharmaceutical processor producing cannabis ~~oil~~ *products* shall establish a stability testing schedule of cannabis ~~oil~~ *products*.

§ 54.1-3442.8. Criminal liability; exceptions.

No agent or employee of a pharmaceutical processor or cannabis dispensing facility shall be prosecuted under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession, manufacture, or distribution of cannabis ~~oil~~ *products*, subject to any civil

penalty, denied any right or privilege, or subject to any disciplinary action by a professional licensing board if such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing cannabis ~~oil~~ *products* in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabis ~~oil~~ *products that are consistent with generally accepted cannabis industry standards* in accordance with the provisions of this article and Board regulations.

2. That the Board of Pharmacy shall establish testing standards for botanical cannabis and botanical cannabis products consistent with generally accepted cannabis industry standards.

3. That the Board of Pharmacy shall promulgate regulations implementing the provisions of this act including its enactment clauses. The Board's 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 September 1, 2021.

4. That the Board of Pharmacy may assess and collect botanical cannabis regulatory fees from each pharmaceutical processor in an amount sufficient to implement the first, second, and third enactments of this act.

5. That the Board of Pharmacy's acquisition of a commercially available cannabis-specific software product to implement the provisions of this act is exempt from the requirements of the Virginia Public Procurement Act (§ 2.2-4300 et seq. of the Code of Virginia).