20105207D

SENATE BILL NO. 976

Offered January 15, 2020

A BILL to amend and reenact §§ 18.2-250.1, 18.2-251.1:1, 22.1-277, 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-2903, 54.1-3320, 54.1-3408.3, and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia, relating to Board of Pharmacy; pharmaceutical processors; processing and dispensing cannabis oil.

Patron—Marsden

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 18.2-251.1:1, 22.1-277, 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-2903, 54.1-3320, 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.).

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 guilty of a misdemeanor and shall be confined in jail not more than 30 days and fined not more than $500, either or both; any person, upon a second or subsequent conviction of a violation of this section, is guilty of a Class 1 misdemeanor.

B. 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.

C. In any prosecution under this section involving marijuana in the form of ~~cannabidiol oil or THC-A~~ *cannabis* oil as those terms are defined in § 54.1-3408.3, it shall be an affirmative defense that the individual possessed such oil 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 individual's diagnosed condition or disease, (ii) if such individual 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 individual 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. If the individual files the valid written certification with the court at least 10 days prior to trial and causes a copy of such written certification to be delivered to the attorney for the Commonwealth, such written certification shall be prima facie evidence that such oil was possessed pursuant to a valid written certification.

§ 18.2-251.1:1. Possession or distribution of ~~cannabidiol oil or THC-A~~ *cannabis* oil; public schools.

No school nurse employed by a local school board, person employed by a local health department who is assigned to the public school pursuant to an agreement between the local health department and the school board, or other person employed by or contracted with a local school board to deliver health-related services shall be prosecuted under § 18.2-248, 18.2-248.1, 18.2-250, 18.2-250.1, or 18.2-255 for the possession or distribution of ~~cannabidiol oil or THC-A~~ *cannabis* oil for storing, dispensing, or administering ~~cannabidiol oil or THC-A~~ *cannabis* oil, in accordance with a policy adopted by the local school board, to a student who has been issued a valid written certification for the use of ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with subsection B of § 54.1-3408.3.

§ 22.1-277. Suspensions and expulsions of students generally.

A. Students may be suspended or expelled from attendance at school for sufficient cause; however, in no cases may sufficient cause for suspensions include only instances of truancy.

B. Except as provided in subsection C or § 22.1-277.07 or 22.1-277.08, no student in preschool through grade three shall be suspended for more than three school days or expelled from attendance at school, unless (i) the offense involves physical harm or credible threat of physical harm to others or (ii)

the local school board or the division superintendent or his designee finds that aggravating circumstances exist, as defined by the Department.

C. Any student for whom the division superintendent of the school division in which such student is enrolled has received a report pursuant to § 16.1-305.1 of an adjudication of delinquency or a conviction for an offense listed in subsection G of § 16.1-260 may be suspended or expelled from school attendance pursuant to this article.

D. The authority provided in § 22.1-276.2 for teachers to remove students from their classes in certain instances of disruptive behavior shall not be interpreted to affect the operation of § 22.1-277.04, 22.1-277.05, or 22.1-277.06.

E. Notwithstanding the provisions of § 22.1-277.08, no school board shall be required to suspend or expel any student who holds a valid written certification for the use of ~~cannabidiol oil or THC-A~~ *cannabis* oil issued by a practitioner in accordance with subsection B of § 54.1-3408.3 for the possession or use of such oil in accordance with the student's individualized health plan and in compliance with a policy adopted by the school board.

§ 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 ~~cannabidiol oil or THC-A~~ *cannabis* oil 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 ~~cannabidiol oil or THC-A~~ *cannabis* oil, 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.

§ 54.1-2522.1. (Effective until July 1, 2022) Requirements of prescribers.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. A prescriber registered with the Prescription Monitoring Program or a person to whom he has delegated authority to access information in the possession of the Prescription Monitoring Program pursuant to § 54.1-2523.2 shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. A prescriber shall not be required to meet the provisions of subsection B if:

1. The opioid is prescribed to a patient currently receiving hospice or palliative care;

2. The opioid is prescribed to a patient during an inpatient hospital admission or at discharge;

3. The opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy;

4. The Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or

5. The prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record.

D. Prior to issuing a written certification for the use of ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 54.1-2522.1. (Effective July 1, 2022) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis or cancer treatments.

D. Prior to issuing a written certification for the use of ~~cannabidiol oil or THC-A~~ *cannabis* oil in

accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 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 ~~cannabidiol oil or THC-A~~ *cannabis* oil, as defined in § 54.1-3408.3.

§ 54.1-3320. Acts restricted to pharmacists.

A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:

1. The review of a prescription, in conformance with this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;

2. The receipt of an oral prescription from a practitioner or his authorized agent;

3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;

4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;

5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy, resolution of any drug therapy problem, or the substitution of any drug prescribed;

6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;

7. The supervision of pharmacy interns and pharmacy technicians; and

8. Any other activity required by regulation to be performed by a pharmacist.

B. A pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A or the Drug Control Act (§ 54.1-3400 et seq.) for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

C. A registered pharmacy technician, working under the direct supervision of a qualified nuclear pharmacist, as defined by regulations of the Board, may accept oral prescriptions for diagnostic, nonpatient specific radiopharmaceuticals in accordance with subsection C of § 54.1-3410.1.

D. Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more pharmacy technicians than allowed by Board regulations. *The pharmacist-to-pharmacist-technician supervision ratio for pharmaceutical processors, as defined in § 54.1-3442.5, shall not exceed one pharmacist to eight pharmacist technicians.*

§ 54.1-3408.3. Certification for use of ~~cannabidiol oil or THC-A~~ *cannabis* oil for treatment.

A. As used in this section:

~~"Cannabidiol oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol per dose but not more than five percent tetrahydrocannabinol. "Cannabidiol oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.~~

"Cannabis oil" means any formulation of processed Cannabis plant extract or a dilution of the resin of the Cannabis plant that contains no more than 10 milligrams of 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.

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

"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

~~"THC-A oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of tetrahydrocannabinol acid per dose but not more than five percent tetrahydrocannabinol.~~

B. A practitioner in the course of his professional practice may issue a written certification for the use of ~~cannabidiol oil or THC-A~~ *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.*

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing ~~cannabidiol oil or THC-A~~ *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. The Board shall, in consultation with the Board of Medicine, set a limit on the number of patients to whom a practitioner may issue a written certification.

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

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

§ 54.1-3442.5. Definitions.

As used in this article:

"~~Cannabidiol~~*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~~ *§ 54.1-3442.6* and (ii) cultivates Cannabis plants intended only for the production of ~~cannabidiol oil or THC-A~~ *cannabis* oil, produces ~~cannabidiol oil or THC-A~~ *cannabis* oil, and dispenses ~~cannabidiol oil or THC-A~~ *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. *"Pharmaceutical processor" includes any off-site dispensing locations established pursuant to § 54.1-3442.6.*

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

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

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

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

A. No person shall operate a pharmaceutical processor 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. 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 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.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. 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 inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing ~~cannabidiol oil and THC-A~~ *cannabis* oil, producing ~~cannabidiol oil and THC-A~~ *cannabis* oil, and dispensing and delivering in person ~~cannabidiol oil and THC-A~~ *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) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; (xi) a process for registering a ~~cannabidiol oil and THC-A~~ *cannabis* oil product; ~~(xii) dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol; and (xiii)~~ *(xii)* a process for the wholesale distribution of and the transfer of ~~cannabidiol oil and THC-A~~ *cannabis* oil products between pharmaceutical processors*; (xiii) an allowance for the sale of devices for administration of dispensed products; (xiv) an allowance for the use and distribution of inert product samples for patient demonstration without the need for a written certification; (xv) operation of off-site dispensing locations; and (xvi) the secure transportation of cannabis oil between the premises at which a pharmaceutical processor processes such cannabis oil and any off-site dispensing locations established by the pharmaceutical processor*.

D. The Board shall require that after processing and before dispensing cannabidiol oil and THC-A oil, a pharmaceutical processor shall make a homogenized sample available from each batch of product for testing at an independent laboratory meeting board requirements. The independent laboratory shall (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The amount of sample required for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory specific procedures. A minimum sample volume of 0.5 percent of the batch mass of usable cannabis is required in order to achieve a representative sample for analysis.

E. The Board shall adopt regulations allowing for the dispensing of unprocessed cannabis flower in the same manner as cannabis oil. Such regulations shall establish testing and labeling standards and set the maximum allowed cannabis flower that may be dispensed in a 90-day period.

~~D.~~ *F.* Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor. *However, a licensed pharmacist shall only be required on the premises of the pharmaceutical processor during dispensing hours and during the production of cannabis oil. A pharmacist in charge of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation and extraction and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access.*

~~E.~~ *G.* The Board shall require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity.

~~F.~~ *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 off-site dispensing locations for the dispensing of cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each off-site dispensing location shall be (i) located within the same health service area as the pharmaceutical processor, (ii) operate under the supervision and control of the pharmaceutical processor, and (iii) comply with all regulations of the Board related to health, safety, and security for pharmaceutical processors. The pharmaceutical processor shall submit the address of each off-site dispensing location on the permit issued to the pharmaceutical processor and shall not be required to obtain a separate permit.

~~G.~~ *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.

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

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

A. A pharmaceutical processor shall dispense or deliver ~~cannabidiol oil or THC-A~~ *cannabis* oil only in person to (i) a patient who ~~is a Virginia resident,~~ 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 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 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 shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of ~~cannabidiol oil or THC-A~~ *cannabis* oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

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

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors 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 tetrahydrocannabinol in any ~~THC-A~~ *cannabis* oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor shall ensure that such concentration in any ~~THC-A~~ *cannabis* onsite is within such range and shall establish a stability testing schedule of ~~THC-A~~ *cannabis* oil.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor 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 ~~cannabidiol oil or THC-A~~ *cannabis* oil, it shall be an affirmative defense that such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with the provisions of this article and Board regulations. If such agent or employee files a copy of the permit issued to the pharmaceutical processor pursuant to § 54.1-3442.6 with the court at

least 10 days prior to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the purposes of producing ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with the provisions of this article and Board regulations or (b) ~~such cannabidiol oil or THC-A~~ *cannabis* oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.