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SENATE BILL NO. 591

FLOOR AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by Delegate Freitas on March 2, 2022)

(Patron Prior to Substitute—Senator Hanger)

A BILL to amend and reenact §§ 3.2-4113, 3.2-4118, 4.1-600, 4.1-606, 18.2-247, 18.2-251.1, 19.2-188.1, 54.1-3401, 54.1-3408.3, 54.1-3423, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to marijuana; shape prohibitions; definitions of marijuana and tetrahydrocannabinol.

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-4113, 3.2-4118, 4.1-600, 4.1-606, 18.2-247, 18.2-251.1, 19.2-188.1, 54.1-3401, 54.1-3408.3, 54.1-3423, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 3.2-4113. Production of industrial hemp lawful.

A. It is lawful for a grower, his agent, or a federally licensed hemp producer to grow, a dealer or his agent to deal in, or a processor or his agent to process industrial hemp in the Commonwealth for any lawful purpose. No federally licensed hemp producer or grower or his agent shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-247, 18.2-248, 18.2-248.01, 18.2-248.1, or 18.2-250 for the possession or growing of industrial hemp or any Cannabis sativa with a tetrahydrocannabinol concentration that does not exceed the total delta-9 tetrahydrocannabinol concentration percentage established in federal regulations applicable to negligent violations located at 7 C.F.R. 990.6(b)(3). No dealer or his agent or processor or his agent shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-247, 18.2-248, 18.2-248.01, 18.2-248.1, or 18.2-250 or issued a summons or judgment for the possession, dealing, or processing of industrial hemp. In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2 or the Drug Control Act (§ 54.1-3400 et seq.), it shall not be necessary to negate any exception, excuse, proviso, or exemption contained in this chapter or the Drug Control Act, and the burden of proof of any such exception, excuse, proviso, or exemption shall be on the defendant.

B. Nothing in this chapter shall be construed to authorize any person to violate any federal law or regulation.

C. No person shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-247, 18.2-248, 18.2-248.01, 18.2-248.1, or 18.2-250 for the involuntary growth of industrial hemp through the inadvertent natural spread of seeds or pollen as a result of proximity to a production field, dealership, or process site.

§ 3.2-4118. Forfeiture of industrial hemp grower, dealer, or processor registration; violations.

A. The Commissioner shall deny the application, or suspend or revoke the registration, of any person who, with a culpable mental state greater than negligence, violates any provision of this chapter. The Commissioner shall provide reasonable notice of an informal fact-finding conference pursuant to § 2.2-4019 to any person in connection with the denial, suspension, or revocation of a registration.

B. If a registration is revoked as the result of an informal hearing, the decision may be appealed, and upon appeal an administrative hearing shall be conducted in accordance with the Administrative Process Act (§ 2.2-4000 et seq.). The grower, dealer, or processor may appeal a final order to the circuit court in accordance with the Administrative Process Act.

C. A person issued a registration pursuant to subsection A of § 3.2-4115 who negligently (i) fails to provide a description and geographic data sufficient for locating his production field, dealership, or process site; (ii) grows, deals in, or processes Cannabis sativa with a tetrahydrocannabinol concentration greater than that allowed by federal law; or (iii) produces a Cannabis sativa product shall comply with any corrective action plan established by the Commissioner in accordance with the provisions of subsection E. The Commissioner shall not deem a grower negligent if such grower makes reasonable efforts to grow industrial hemp and grows Cannabis sativa with a tetrahydrocannabinol concentration that does not exceed the total delta-9 tetrahydrocannabinol concentration percentage established in federal regulations applicable to negligent violations located at 7 C.F.R. 990.6(b)(3).

D. A person who grows, deals in, or processes industrial hemp and who negligently fails to register pursuant to subsection A of § 3.2-4115 shall comply with any corrective action plan established by the Commissioner in accordance with the provisions of subsection E.

E. A corrective action plan established by the Commissioner in response to a negligent violation of a provision of this chapter shall identify a reasonable date by which the person who is the subject of the plan shall correct the negligent violation and shall require such person to report periodically for not less than two calendar years to the Commissioner on the person's compliance with the provisions of this

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F. No person who negligently violates the provisions of this chapter three times in a five-year period shall be eligible to grow, deal in, or process industrial hemp for a period of five years beginning on the date of the third violation.

§ 4.1-600. Definitions.

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

"Advertisement" or " advertising" means any written or verbal statement, illustration, or depiction that is calculated to induce sales of retail marijuana, retail marijuana products, marijuana plants, or marijuana seeds, including any written, printed, graphic, digital, electronic, or other material, billboard, sign, or other outdoor display, publication, or radio or television broadcast.

'Authority" means the Virginia Cannabis Control Authority created pursuant to this subtitle.

"Board" means the Board of Directors of the Virginia Cannabis Control Authority.

"Cannabis Control Act" means Subtitle II (§ 4.1-600 et seq.).

"Child-resistant" means, with respect to packaging or a container, (i) specially designed or constructed to be significantly difficult for a typical child under five years of age to open and not to be significantly difficult for a typical adult to open and reseal and (ii) for any product intended for more than a single use or that contains multiple servings, resealable.

"Cultivation" or "cultivate" means the planting, propagation, growing, harvesting, drying, curing, grading, trimming, or other similar processing of marijuana for use or sale. "Cultivation" or "cultivate" does not include manufacturing or testing.

"Edible marijuana product" means a marijuana product intended to be consumed orally, including marijuana intended to be consumed orally or marijuana concentrate intended to be consumed orally.

"Immature plant" means a nonflowering marijuana plant that is no taller than eight inches and no wider than eight inches, is produced from a cutting, clipping, or seedling, and is growing in a container.

"Licensed" means the holding of a valid license granted by the Authority.

"Licensee" means any person to whom a license has been granted by the Authority.
"Manufacturing" or "manufacture" means the production of marijuana products or the blending, infusing, compounding, or other preparation of marijuana and marijuana products, including marijuana extraction or preparation by means of chemical synthesis. "Manufacturing" or "manufacture" does not include cultivation or testing.

"Marijuana" means any part of a plant of the genus Cannabis, whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, its resin, or any extract containing one or more cannabinoids. "Marijuana" does not include (i) the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seed of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis-"Marijuana" does not include (i); (ii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent or (ii); (iii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990 or his agent; or (iv) a hemp product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

"Marijuana concentrate" means marijuana that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product's potency. Resin from granular trichomes from a marijuana plant is a concentrate for purposes of this subtitle.

"Marijuana cultivation facility" means a facility licensed under this subtitle to cultivate, label, and package retail marijuana; to purchase or take possession of marijuana plants and seeds from other marijuana cultivation facilities; to transfer possession of and sell retail marijuana, immature marijuana plants, and marijuana seeds to marijuana wholesalers and retail marijuana stores; to transfer possession of and sell retail marijuana, marijuana plants, and marijuana seeds to other marijuana cultivation facilities; to transfer possession of and sell retail marijuana to marijuana manufacturing facilities; and to sell immature marijuana plants and marijuana seeds to consumers for the purpose of cultivating marijuana at home for personal use.

"Marijuana establishment" means a marijuana cultivation facility, a marijuana testing facility, a marijuana manufacturing facility, a marijuana wholesaler, or a retail marijuana store.

"Marijuana manufacturing facility" means a facility licensed under this subtitle to manufacture, label, and package retail marijuana and retail marijuana products; to purchase or take possession of retail marijuana from a marijuana cultivation facility or another marijuana manufacturing facility; and to transfer possession of and sell retail marijuana and retail marijuana products to marijuana wholesalers, retail marijuana stores, or other marijuana manufacturing facilities.

"Marijuana paraphernalia" means all equipment, products, and materials of any kind that are either designed for use or are intended for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, strength testing, analyzing, packaging, repackaging, storing, containing, concealing, ingesting, inhaling, or otherwise introducing into the human body marijuana.

"Marijuana products" means (i) products that are composed of marijuana and other ingredients and are intended for use or consumption, ointments, and tinctures or (ii) marijuana concentrate.

"Marijuana testing facility" means a facility licensed under this subtitle to develop, research, or test marijuana, marijuana products, and other substances.

"Marijuana wholesaler" means a facility licensed under this subtitle to purchase or take possession of retail marijuana, retail marijuana products, immature marijuana plants, and marijuana seeds from a marijuana cultivation facility, a marijuana manufacturing facility, or another marijuana wholesaler and to transfer possession and sell or resell retail marijuana, retail marijuana products, immature marijuana plants, and marijuana seeds to a marijuana cultivation facility, marijuana manufacturing facility, retail marijuana store, or another marijuana wholesaler.

"Non-retail marijuana" means marijuana that is not cultivated, manufactured, or sold by a licensed marijuana establishment.

"Non-retail marijuana products" means marijuana products that are not manufactured and sold by a licensed marijuana establishment.

"Place or premises" means the real estate, together with any buildings or other improvements thereon, designated in the application for a license as the place at which the cultivation, manufacture, sale, or testing of retail marijuana or retail marijuana products shall be performed, except that portion of any such building or other improvement actually and exclusively used as a private residence.

"Public place" means any place, building, or conveyance to which the public has, or is permitted to have, access, including restaurants, soda fountains, hotel dining areas, lobbies and corridors of hotels, and any park, place of public resort or amusement, highway, street, lane, or sidewalk adjoining any highway, street, or lane.

"Residence" means any building or part of a building or structure where a person resides, but does not include any part of a building that is not actually and exclusively used as a private residence, nor any part of a hotel or club other than a private guest room thereof.

"Retail marijuana" means marijuana that is cultivated, manufactured, or sold by a licensed marijuana establishment.

"Retail marijuana products" means marijuana products that are manufactured and sold by a licensed marijuana establishment.

"Retail marijuana store" means a facility licensed under this subtitle to purchase or take possession of retail marijuana, retail marijuana products, immature marijuana plants, or marijuana seeds from a marijuana cultivation facility, marijuana manufacturing facility, or marijuana wholesaler and to sell retail marijuana, retail marijuana products, immature marijuana plants, or marijuana seeds to consumers.

"Sale" and "sell" includes soliciting or receiving an order for; keeping, offering, or exposing for sale; peddling, exchanging, or bartering; or delivering otherwise than gratuitously, by any means, retail marijuana or retail marijuana products.

"Special agent" means an employee of the Virginia Cannabis Control Authority whom the Board has designated as a law-enforcement officer pursuant to this subtitle.

"Testing" or "test" means the research and analysis of marijuana, marijuana products, or other substances for contaminants, safety, or potency. "Testing" or "test" does not include cultivation or manufacturing.

"Tetrahydrocannabinol" or "THC" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, or salts of isomers.

§ 4.1-606. Regulations of the Board.

A. The Board may promulgate reasonable regulations, not inconsistent with this subtitle or the general laws of the Commonwealth, that it deems necessary to carry out the provisions of this subtitle and to prevent the illegal cultivation, manufacture, sale, and testing of marijuana and marijuana products. The Board may amend or repeal such regulations. Such regulations shall be promulgated, amended, or repealed in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) and shall have the effect of law.

- B. The Board shall promulgate regulations that:
- 1. Govern the outdoor cultivation of marijuana by a marijuana cultivation facility licensee, including security requirements to include lighting, physical security, and alarm requirements, provided that such requirements do not prohibit the cultivation of marijuana outdoors or in a greenhouse;
 - 2. Establish requirements for securely transporting marijuana between marijuana establishments;
 - 3. Establish sanitary standards for retail marijuana product preparation;
- 4. Establish a testing program for retail marijuana and retail marijuana products pursuant to Chapter 14 (§ 4.1-1400 et seq.);

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5. Establish an application process for licensure as a marijuana establishment pursuant to this subtitle in a way that, when possible, prevents disparate impacts on historically disadvantaged communities;

6. Establish requirements for health and safety warning labels to be placed on retail marijuana and retail marijuana products to be sold or offered for sale by a licensee to a consumer in accordance with

the provisions of this subtitle;

- 7. Establish a maximum tetrahydrocannabinol level for retail marijuana products, which shall not exceed (i) five milligrams per serving for edible marijuana products and where practicable an equivalent amount for other marijuana products or (ii) 50 milligrams per package for edible marijuana products and where practicable an equivalent amount for other marijuana products. Such regulations may include other product and dispensing limitations on tetrahydrocannabinol;
- 8. Establish requirements for the form, content, and retention of all records and accounts by all licensees;
- 9. Provide alternative methods for licensees to maintain and store business records that are subject to Board inspection, including methods for Board-approved electronic and offsite storage;
- 10. Establish (i) criteria by which to evaluate new licensees based on the density of retail marijuana stores in the community and (ii) metrics that have similarly shown an association with negative community-level health outcomes or health disparities. In promulgating such regulations, the Board shall coordinate with the Cannabis Public Health Advisory Council established pursuant to § 4.1-603;
- 11. Require retail licensees to file an appeal from any hearing decision rendered by a hearing officer within 30 days of the date the notice of the decision is sent. The notice shall be sent to the licensee at the address on record with the Board by certified mail, return receipt requested, and by regular mail;
- 12. Prescribe the schedule of proration for refunded license fees to licensees who qualify pursuant to subsection C of § 4.1-1002;
- 13. Establish criteria by which to evaluate social equity license applicants, which shall be an applicant who has lived or been domiciled for at least 12 months in the Commonwealth and is either (i) an applicant with at least 66 percent ownership by a person or persons who have been convicted of or adjudicated delinquent for any misdemeanor violation of § 18.2-248.1, former § 18.2-250.1, or subsection A of § 18.2-265.3 as it relates to marijuana; (ii) an applicant with at least 66 percent ownership by a person or persons who is the parent, child, sibling, or spouse of a person who has been convicted of or adjudicated delinquent for any misdemeanor violation of § 18.2-248.1, former § 18.2-250.1, or subsection A of § 18.2-265.3 as it relates to marijuana; (iii) an applicant with at least 66 percent ownership by a person or persons who have resided for at least three of the past five years in a jurisdiction that is determined by the Board after utilizing census tract data made available by the United States Census Bureau to have been disproportionately policed for marijuana crimes; (iv) an applicant with at least 66 percent ownership by a person or persons who have resided for at least three of the last five years in a jurisdiction determined by the Board after utilizing census tract data made available by the United States Census Bureau to be economically distressed; or (v) an applicant with at least 66 percent ownership by a person or persons who graduated from a historically black college or university located in the Commonwealth:
- 14. For the purposes of establishing criteria by which to evaluate social equity license applicants, establish standards by which to determine (i) which jurisdictions have been disproportionately policed for marijuana crimes and (ii) which jurisdictions are economically distressed;
- 15. Establish standards and requirements for (i) any preference in the licensing process for qualified social equity applicants, (ii) what percentage of application or license fees are waived for a qualified social equity applicant, and (iii) a low-interest business loan program for qualified social equity applicants;
- 16. Establish guidelines, in addition to requirements set forth in this subtitle, for the personal cultivation of marijuana that promote personal and public safety, including child protection, and discourage personal cultivation practices that create a nuisance, including a nuisance caused by odor;
- 17. Establish reasonable time, place, and manner restrictions on outdoor advertising of retail marijuana or retail marijuana products, not inconsistent with the provisions of this chapter, so that such advertising displaces the illicit market and notifies the public of the location of marijuana establishments. Such regulations shall be promulgated in accordance with § 4.1-1404;
- 18. Establish restrictions on the number of licenses that a person may be granted to operate a marijuana establishment in single locality or region; and
- 19. Establish restrictions on pharmaceutical processors and industrial hemp processors that have been granted a license in more than one license category pursuant to subsection C of § 4.1-805 that ensure all licensees have an equal and meaningful opportunity to participate in the market. Such regulations may limit the amount of products cultivated or manufactured by the pharmaceutical processor or industrial hemp processor that such processor may offer for sale in its retail marijuana stores; and
- 20. Prohibit the production and sale of retail marijuana and retail marijuana products that depict or are in the shape of a human, animal, or vehicle.

- 1. Limit the number of licenses issued by type or class to operate a marijuana establishment; however, the number of licenses issued shall not exceed the following limits:
 - a. Retail marijuana stores, 400;
 - b. Marijuana wholesalers, 25;

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- c. Marijuana manufacturing facilities, 60; and
- d. Marijuana cultivation facilities, 450.
- In determining the number of licenses issued pursuant to this subdivision, the Board shall not consider any license granted pursuant to subsection C of § 4.1-805 to (i) a pharmaceutical processor that has been issued a permit by the Board of Pharmacy pursuant to Article 4.2 (§ 54.1-3442.5 et seq.) of the Drug Control Act or (ii) an industrial hemp processor registered with the Commissioner of Agriculture and Consumer Services pursuant to Chapter 41.1 (§ 3.2-4112 et seq.) of Title 3.2.
- 2. Prescribe any requirements deemed appropriate for the administration of taxes under §§ 4.1-1003 and 4.1-1004, including method of filing a return, information required on a return, and form of payment.
- 3. Limit the allowable square footage of a retail marijuana store, which shall not exceed 1,500 square feet.
- 4. Allow certain persons to be granted or have interest in a license in more than one of the following license categories: marijuana cultivation facility license, marijuana manufacturing facility license, marijuana wholesaler license, or retail marijuana store license. Such regulations shall be drawn narrowly to limit vertical integration to small businesses and ensure that all licensees have an equal and meaningful opportunity to participate in the market.
- D. Board regulations shall be uniform in their application, except those relating to hours of sale for licensees.
 - E. Courts shall take judicial notice of Board regulations.
- F. The Board shall consult with the Cannabis Public Health Advisory Council in promulgating any regulations relating to public health, including regulations promulgated pursuant to subdivision B 3, 4, 6, 7, 10, or 16, and shall not promulgate any such regulation that has not been approved by a majority of the members of the Cannabis Public Health Advisory Council.
- G. With regard to regulations governing licensees that have been issued a permit by the Board of Pharmacy to operate as a pharmaceutical processor or cannabis dispensing facility pursuant to Article 4.2 (§ 54.1-3442.5 et seq.) of the Drug Control Act, the Board shall make reasonable efforts (i) to align such regulations with any applicable regulations promulgated by the Board of Pharmacy that establish health, safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities and (ii) to deem in compliance with applicable regulations promulgated pursuant to this subtitle such pharmaceutical processors and cannabis dispensing facilities that have been found to be in compliance with regulations promulgated by the Board of Pharmacy that mirror or are more extensive in scope than similar regulations promulgated pursuant to this subtitle.
- H. The Board's power to regulate shall be broadly construed. § 18.2-247. Use of terms "controlled substances," "marijuana," "Schedules I, II, III, IV, V, and VI," "imitation controlled substance" and "counterfeit controlled substance" in Title 18.2.
- A. Wherever the terms As used in this title, "controlled substances" substance" and "Schedules I, II, III, IV, V, and VI" are used in Title 18.2, such terms refer to mean the same as those terms as they are used or defined in the Drug Control Act (§ 54.1-3400 et seq.).
- B. The term When used in this article, "imitation controlled substance" when used in this article means (i) a counterfeit controlled substance or (ii) a pill, capsule, tablet, or substance in any form whatsoever which that is not a controlled substance subject to abuse, and:
- 1. Which by overall dosage unit appearance, including color, shape, size, marking, and packaging or by representations made, would cause the likelihood that such a pill, capsule, tablet, or substance in any other form whatsoever will be mistaken for a controlled substance unless such substance was introduced into commerce prior to the initial introduction into commerce of the controlled substance which that it is alleged to imitate; or
- 2. Which by express or implied representations purports to act like a controlled substance as a stimulant or depressant of the central nervous system and which is not commonly used or recognized for use in that particular formulation for any purpose other than for such stimulant or depressant effect, unless marketed, promoted, or sold as permitted by the U.S. Food and Drug Administration.
- C. In determining whether a pill, capsule, tablet, or substance in any other form whatsoever, is an "imitation controlled substance," there shall be considered, in addition to all other relevant factors, comparisons with accepted methods of marketing for legitimate nonprescription drugs for medicinal purposes rather than for drug abuse or any similar nonmedicinal use, including consideration of the packaging of the drug and its appearance in overall finished dosage form, promotional materials or

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representations, oral or written, concerning the drug, and the methods of distribution of the drug and where and how it is sold to the public.

D. The term "marijuana" when As used in this article:

"Counterfeit controlled substance" means a controlled substance that, without authorization, bears, is packaged in a container or wrapper that bears, or is otherwise labeled to bear the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof of a drug manufacturer, processor, packer, or distributor other than the manufacturer, processor, packer, or distributor that did in fact so manufacture, process, pack, or distribute such drug.

"Marijuana" means any part of a plant of the genus Cannabis, whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, its resin, or any extract containing one or more cannabinoids. "Marijuana" does not include (i) the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seed of such plant, unless such stalks, fiber, oil or cake is combined with other parts of plants of the genus Cannabis-Marijuana does not include (i); (ii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent; (ii) (iii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990; or (iii) or (iv) a hemp product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

"Tetrahydrocannabinol" or "THC" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, or salts of isomers.

- E. The term "counterfeit controlled substance" means a controlled substance that, without authorization, bears, is packaged in a container or wrapper that bears, or is otherwise labeled to bear, the trademark, trade name, or other identifying mark, imprint or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the manufacturer, processor, packer, or distributor who did in fact so manufacture, process, pack or distribute such drug.
- F. The Department of Forensic Science shall determine the proper methods for detecting the concentration of delta-9 tetrahydrocannabinol (THC) tetrahydrocannabinol in substances for the purposes of this title, Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1, and §§ § 54.1-3401 and 54.1-3446. The testing methodology shall use post-decarboxylation testing or other equivalent method and shall consider the potential conversion of delta-9 tetrahydrocannibinol tetrahydrocannabinolic acid (THC-A) into THC. The test result shall include the total available THC derived from the sum of the THC and THC-A content.

§ 18.2-251.1. Possession or distribution of marijuana for medical purposes permitted.

- A. No person shall be prosecuted under § 18.2-250 or § 18.2-250.1 for the possession of marijuana or tetrahydrocannabinol when that possession occurs pursuant to a valid prescription issued by a medical doctor in the course of his professional practice for treatment of cancer or glaucoma.
- B. No medical doctor shall be prosecuted under § 18.2-248 or § 18.2-248.1 for dispensing or distributing marijuana or tetrahydrocannabinol for medical purposes when such action occurs in the course of his professional practice for treatment of cancer or glaucoma.
- C. No pharmacist shall be prosecuted under §§ 18.2-248 to 18.2-248.1 for dispensing or distributing marijuana or tetrahydrocannabinol to any person who holds a valid prescription of a medical doctor for such substance issued in the course of such doctor's professional practice for treatment of cancer or glaucoma.

§ 19.2-188.1. Testimony regarding identification of controlled substances.

- A. In any preliminary hearing on a violation of Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1, Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2, or subdivision 6 of § 53.1-203, any law-enforcement officer shall be permitted to testify as to the results of field tests that have been approved by the Department of Forensic Science pursuant to regulations adopted in accordance with the Administrative Process Act (§ 2.2-4000 et seq.), regarding whether or not any substance the identity of which is at issue in such hearing is a controlled substance, imitation controlled substance, or marijuana, as defined in § 4.1-600 or 18.2-247.
- B. In any trial for a violation of § 4.1-1105.1, any law-enforcement officer shall be permitted to testify as to the results of any marijuana field test approved as accurate and reliable by the Department of Forensic Science pursuant to regulations adopted in accordance with the Administrative Process Act (§ 2.2-4000 et seq.), regarding whether or not any plant material, the identity of which is at issue, is marijuana provided the defendant has been given written notice of his right to request a full chemical analysis. Such notice shall be on a form approved by the Supreme Court and shall be provided to the defendant prior to trial.

In any case in which the person accused of a violation of § 4.1-1105.1, or the attorney of record for the accused, desires a full chemical analysis of the alleged plant material, he may, by motion prior to trial before the court in which the charge is pending, request such a chemical analysis. Upon such

motion, the court shall order that the analysis be performed by the Department of Forensic Science in accordance with the provisions of § 18.2-247 and shall prescribe in its order the method of custody, transfer, and return of evidence submitted for chemical analysis.

§ 54.1-3401. 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 by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised

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by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of \$54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship, including delivery of a Schedule VI prescription device to an ultimate user or consumer on behalf of a medical equipment supplier by a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider at the direction of a medical equipment supplier in accordance with § 54.1-3415.1.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject 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. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether

by brand or therapeutically equivalent drug product name.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 C.F.R. Part 1300.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its

containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, its resin, or any extract containing one or more cannabinoids. Marijuana does not include (i) the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis-Marijuana does not include (i); (ii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent, (iii); (iii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990, or (iii); or (iv) a hemp product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for

peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as

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amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

'Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.
"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning — may be habit-forming," or a drug intended for injection.

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"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Tetrahydrocannabinol" or "THC" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, or salts of isomers.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of (i) selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer and (ii) delivering Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means (i) distribution of prescription drugs to persons other than consumers or patients and (ii) delivery of Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 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 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 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.

"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.

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"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 cannabis oil 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 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 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.

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.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

- A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:
- 1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;
 - 2. Compliance with applicable state and local law;

- 3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;
- 4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;
- 5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
- 6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and
 - 7. Any other factors relevant to and consistent with the public health and safety.
- B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.
- C. Practitioners must be registered to conduct research or laboratory analysis with controlled substances in Schedules II through VI, tetrahydrocannabinol, or marijuana. Practitioners registered under federal law to conduct research with Schedule I substances, other than tetrahydrocannabinol marijuana, may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence of that federal registration.
- D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A of this section in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.
- E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II through VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. Controlled substances used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs and biological products used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological products shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance

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with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs and biological products, written protocols for administering, and training records of those persons administering drugs and biological products on the premises of the shelter.

- F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.
- G. The Board may register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration. In determining whether the registration shall be issued, the Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration, and (iii) whether the issuance of the registration is consistent with the public interest.
- H. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.
- I. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

§ 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 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; 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 cannabis oil that fails any quality testing standard. Following remediation, all remediated cannabis oil shall be subject to laboratory testing and approved upon satisfaction of testing standards applied to cannabis oil generally. 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

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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 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 into an allowable dosage of cannabis oil. Industrial hemp extract 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 industrial hemp extract 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

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

D. The concentration of delta-9 tetrahydrocannabinol tetrahydrocannabinol in any cannabis product on site may be up to 10 percent greater than or less than the level of delta-9 tetrahydrocannabinol 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 provisions of this act amending §§ 54.1-3408.3, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia shall become effective when the Virginia Cannabis Control Authority provides written notice to the Division of Legislative Services that persons are allowed to apply for, obtain, and fully utilize a license from the Virginia Cannabis Control Authority to sell retail marijuana, retail marijuana products, immature marijuana plants, and marijuana seeds to the public.

- 3. That, notwithstanding any other provision of law, if an act of assembly is passed by the 2022 Session of the General Assembly that establishes a regulatory and licensing structure for the retail sale of marijuana and marijuana products to persons 21 years of age or older, such regulatory and licensing requirements that pertain only to retail marijuana or retail marijuana products shall not apply to industrial hemp extract that (i) is processed by an industrial hemp processor that is registered with the Commissioner of Agriculture and Consumer Services pursuant to Chapter 41.1 (§ 3.2-4112 et seq.) of Title 3.2 and is operating in compliance with all laws and regulations governing such processors and manufacturers of edible hemp products operating in accordance with Article 6 (§ 3.2-5145.6 et seq.) of Chapter 51 of Title 3.2; (ii) does not contain a total tetrahydrocannabinol concentration that exceeds 0.3 percent at the time such industrial hemp extract is offered for sale at retail and does not contain more than 0.25 milligram of tetrahydrocannabinol per serving or more than one milligram per package; and (iii) is tested, labeled, packaged, and advertised in accordance with any applicable provisions of such act of assembly or regulations promulgated thereto.
- 4. That the provisions of this act may result in a net increase in periods of imprisonment or commitment. Pursuant to § 30-19.1:4 of the Code of Virginia, the estimated amount of the necessary appropriation cannot be determined for periods of imprisonment in state adult correctional facilities; therefore, Chapter 552 of the Acts of Assembly of 2021, Special Session I, requires the Virginia Criminal Sentencing Commission to assign a minimum fiscal impact of \$50,000. Pursuant to \$ 30-19.1:4 of the Code of Virginia, the estimated amount of the necessary appropriation cannot be determined for periods of commitment to the custody of the Department of Juvenile Justice.
- 5. That the provisions of this act shall not become effective unless an appropriation effectuating the purposes of this act is included in a general appropriation act passed in 2022 by the General Assembly that becomes law.