HOUSE BILL NO. 2775

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Agriculture, Chesapeake and Natural Resources on _____)

(Patron Prior to Substitute—Delegate Convirs-Fowler)

A BILL to amend and reenact §§ 3.2-4112, 3.2-4113, 3.2-4116, 3.2-4118, 3.2-4123, 3.2-4126, 3.2-5145.1, 3.2-5145.2:1, 3.2-5145.4, 4.1-600, 18.2-247, and 54.1-3401 of the Code of Virginia, relating to tetrahydrocannabinol; industrial hemp; regulated hemp products.

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-4112, 3.2-4113, 3.2-4116, 3.2-4118, 3.2-4123, 3.2-4126, 3.2-5145.1, 3.2-5145.2:1, 3.2-5145.4 , 4.1-600, 18.2-247, and 54.1-3401 of the Code of Virginia are amended and reenacted as follows:

§ 3.2-4112. Definitions.

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

"Cannabis sativa product" means a product made from any part of the plant Cannabis sativa with a concentration of tetrahydrocannabinol that is greater than that allowed by federal law.

"Edible hemp product" means any hemp product that is or includes an industrial hemp extract, as defined in § 3.2-5145.1, and that is intended to be consumed orally.

"Federally licensed hemp producer" means a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990.

"Grow" means to plant, cultivate, or harvest a plant or crop.

"Grower" means any person registered pursuant to subsection A of § 3.2-4115 to grow industrial hemp.

"Handle" means to temporarily possess industrial hemp grown in compliance with state or federal law that (i) has not been processed and (ii) was not grown by and will not be processed by the person temporarily possessing it.

"Handler" means any person who is registered pursuant to subsection A of § 3.2-4115 to handle industrial hemp. "Handler" does not include a retail establishment that sells or offers for sale a hemp product.

"Handler's storage site" means the location at which a handler stores or intends to store the industrial hemp he handles.

"Hemp product" means a product, including any raw materials from industrial hemp that are used for or added to a food or beverage, that (i) contains industrial hemp and has completed all stages of processing

needed for the product and (ii) when offered for retail sale ~~(a)~~ contains a total *delta-9* tetrahydrocannabinol concentration of no greater than 0.3 percent ~~and (b) contains either no more than two milligrams of total tetrahydrocannabinol per package or an amount of cannabidiol that is no less than 25 times greater than the amount of total tetrahydrocannabinol per package~~.

"Hemp product intended for smoking" means any hemp product intended to be consumed by inhalation.

"Industrial hemp" means any part of the plant Cannabis sativa, including seeds thereof, whether growing or not, with a concentration of tetrahydrocannabinol that is no greater than that allowed by federal law. "Industrial hemp" includes an industrial hemp extract that has not completed all stages of processing needed to convert the extract into a hemp product.

"Process" means to convert industrial hemp into a hemp product.

"Processor" means a person registered pursuant to subsection A of § 3.2-4115 to process industrial hemp.

"Process site" means the location at which a processor processes or intends to process industrial hemp.

"Production field" means the land or area on which a grower or a federally licensed hemp producer is growing or intends to grow industrial hemp.

"Regulated hemp product" means a hemp product intended for smoking or an edible hemp product.

"Tetrahydrocannabinol" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of this definition, "isomer" means the optical, position, and geometric isomers.

"Topical hemp product" means a hemp product that (i) is intended to be rubbed, poured, sprinkled, or sprayed on or otherwise applied to the human body or any part thereof and (ii) is not intended to be consumed orally or by inhalation.

~~"Total tetrahydrocannabinol" means the sum, after the application of any necessary conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of tetrahydrocannabinolic acid.~~

§ 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 handler or his agent to handle, 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 handler 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, handling, 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 article 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 article 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, handler's storage site, or process site.

§ 3.2-4116. Registration conditions.

A. A person who is not a federally licensed hemp producer shall obtain a registration pursuant to subsection A of § 3.2-4115 prior to growing, handling, or processing any industrial hemp in the Commonwealth.

B. A person issued a registration pursuant to subsection A of § 3.2-4115 shall:

1. Maintain records that reflect compliance with this article;

2. Retain all industrial hemp growing, handling, or processing records for at least three years;

3. Allow his production field, handler's storage site, or process site to be inspected by and at the discretion of the Commissioner or his designee, the Department of State Police, or the chief law-enforcement officer of the locality in which the production field, or handler's storage site, or process site exists;

4. Allow the Commissioner or his designee to monitor and test the grower's, handler's, or processor's

industrial hemp for compliance with tetrahydrocannabinol levels and for other appropriate purposes established pursuant to § 3.2-4114, at the cost of the grower, handler, or processor; and

5. If required by the Commissioner, destroy, at the cost of the grower, handler, or processor and in a manner approved of and verified by the Commissioner, any Cannabis sativa that the grower grows, the handler handles, or the processor processes that has been tested and, following any re-sampling and retesting as authorized pursuant to the provisions of § 3.2-4114.2, is found to have a concentration of tetrahydrocannabinol that is greater than that allowed by federal law, or any Cannabis sativa product that the processor produces.

C. A processor shall not sell industrial hemp or a substance containing an industrial hemp extract, as defined in § 3.2-5145.1, to a person if the processor knows or has reason to know that such person will use the industrial hemp or substance containing an industrial hemp extract in a substance that ~~(i)~~ contains a total *delta-9* tetrahydrocannabinol concentration that is greater than 0.3 percent ~~or (ii) contains more than two milligrams of total tetrahydrocannabinol per package and does not contain an amount of cannibidiol that is at least 25 times greater than the amount of total tetrahydrocannabinol per package~~.

§ 3.2-4118. Forfeiture of industrial hemp grower, handler, 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 article. 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, handler, 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 § 3.2-4115 who negligently (i) fails to provide a description and geographic data sufficient for locating his production field, handler's storage site, or process site; (ii) grows, handles, 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, handles, or processes industrial hemp and who negligently fails to register pursuant to § 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 article 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 article.

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

§ 3.2-4123. Product packaging, labeling, and testing.

A. No person shall offer for sale or sell at retail a regulated hemp product unless the product is:

1. Contained in child-resistant packaging, as defined in § 4.1-600, if the product contains tetrahydrocannabinol;

2. Equipped with a label that states, in English and in a font no less than 1/16 of an inch, (i) all ingredients contained in the substance; (ii) the amount of such substance that constitutes a single serving; (iii) the total percentage and milligrams of all tetrahydrocannabinols included in the substance and the total number of milligrams of all tetrahydrocannabinols that are contained in each serving; and (iv) if the substance contains tetrahydrocannabinol, that the product may not be sold to persons younger than 21 years of age; and

3. Accompanied by a certificate of analysis, produced by an independent laboratory that is accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization by a third-party accrediting body, that states the total *delta-9* tetrahydrocannabinol concentration of the substance or the total *delta-9* tetrahydrocannabinol concentration of the batch from which the substance originates. The certificate of accreditation to standard ISO/IEC 17025 issued by the third-party accrediting body to the independent laboratory shall be available for review at the location at which the regulated hemp product is offered for sale or sold.

This subsection shall not (i) apply to products that are approved for marketing by the U.S. Food and Drug Administration and scheduled in the Drug Control Act (§ 54.1-3400 et seq.) or (ii) be construed to prohibit any conduct permitted under Article 4.2 (§ 54.1-3442.5 et seq.) of Chapter 34 of Title 54.1.

B. No person shall offer for sale or sell a regulated hemp product that depicts or is in the shape of a human, animal, vehicle, or fruit.

C. No person shall offer for sale or sell a regulated hemp product that, without authorization, bears, is packaged in a container or wrapper that bears, or is otherwise labeled to bear the trademark, trade name, famous mark as defined in 15 U.S.C. § 1125, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor of a product intended for human consumption other than the manufacturer, processor, packer, or distributor that did in fact so manufacture, process, pack, or distribute such substance.

§ 3.2-4126. Civil penalties.

A. The Commissioner may, in accordance with the Administrative Process Act (§ 2.2-4000 et seq.), deny the application for a regulated hemp product retail facility registration or suspend or revoke the regulated hemp product retail facility registration of any person that violates a provision of this article.

B. Any person that (i) offers for sale or sells at retail a regulated hemp product without first obtaining a registration to do so from the Commissioner in accordance with § 3.2-4122, (ii) continues to offer for sale or sell at retail a regulated hemp product after revocation or suspension of such registration, (iii) offers for sale or sells at retail a substance intended for human consumption, orally or by inhalation, that ~~(a)~~ contains a total *delta-9* tetrahydrocannabinol concentration that is greater than 0.3 percent ~~or (b) contains more than two milligrams of total tetrahydrocannabinol per package and does not contain an amount of cannabidiol that is at least 25 times greater than the amount of total tetrahydrocannabinol per package~~, (iv) offers for sale or sells at retail a regulated hemp product in violation of § 3.2-4123, or (v) offers for sale or sells at retail a substance intended for human consumption, orally or by inhalation, that is advertised or labeled as containing an industrial hemp-derived cannabinoid without a regulated hemp product retail facility registration is, in addition to any other penalties provided, subject to a civil penalty not to exceed $10,000 for each day a violation occurs. Such penalty shall be collected by the Commissioner and the proceeds shall be payable to the State Treasurer for remittance to the Department.

§ 3.2-5145.1. Definitions.

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

"Food" means any article that is intended for human consumption and introduction into commerce, whether the article is simple, mixed, or compound, and all substances or ingredients used in the preparation thereof. "Food" does not mean drug as defined in § 54.1-3401.

"Industrial hemp" means a Cannabis sativa plant that has a concentration of tetrahydrocannabinol that is no greater than that allowed by federal law.

"Industrial hemp extract" means an extract (i) of industrial hemp, (ii) that is intended for human consumption, and (iii) ~~except as otherwise provided in subsection M of § 54.1-3442.6,~~ when offered for retail sale, that ~~(a)~~ contains a total *delta-9* tetrahydrocannabinol concentration that is no greater than 0.3 percent ~~and (b) contains either no more than two milligrams of total tetrahydrocannabinol per package or an amount of cannabidiol that is no less than 25 times greater than the amount of total tetrahydrocannabinol per package~~. "Industrial hemp extract" is not a hemp seed-derived ingredient that is approved by the U.S. Food and Drug Administration or is the subject of a generally recognized as safe notice for which the U.S. Food and Drug Administration had no questions.

"Tetrahydrocannabinol" means the same as that term is defined in § 3.2-4112.

~~"Total tetrahydrocannabinol" means the same as that term is defined in § 3.2-4112~~[LilyJones1]~~.~~

§ 3.2-5145.2:1. Sellers or manufacturers of industrial hemp extract; penalties.

A. Any person who manufactures, sells, or offers for sale an industrial hemp extract or food containing an industrial hemp extract shall be subject to the requirements of this chapter and regulations adopted pursuant to this chapter.

B. Any person who (i) manufactures, sells, or offers for sale an industrial hemp extract or food containing an industrial hemp extract without first obtaining a permit to do so from the Commissioner pursuant to § 3.2-5100, unless exempt from a permit pursuant to subdivision C 6 of § 3.2-5130; (ii) continues to manufacture, sell, or offer for sale an industrial hemp extract or food containing an industrial hemp extract after revocation or suspension of such permit; (iii) fails to disclose on a form prescribed by the Commissioner that he intends to manufacture, sell, or offer for sale a substance intended to be consumed orally that contains an industrial hemp-derived cannabinoid; (iv) sells or offers for sale at retail a food that ~~(a)~~ contains a total *delta-9* tetrahydrocannabinol concentration that is greater than 0.3 percent ~~or (b) contains more than two milligrams of total tetrahydrocannabinol per package and does not contain an amount of cannabidiol that is at~~

~~least~~ ~~25~~ ~~times~~ ~~greater~~ ~~than~~ ~~the~~ ~~amount~~ ~~of~~ ~~total~~ ~~tetrahydrocannabinol~~ ~~per~~ ~~package~~; (v) manufactures, offers for sale, or sells in violation of this chapter or a regulation adopted pursuant to this chapter a substance intended to be consumed orally that is advertised or labeled as containing an industrial hemp-derived cannabinoid; or (vi) otherwise violates any provision of this chapter or a regulation adopted pursuant to this chapter, in addition to any other penalties provided, is subject to a civil penalty not to exceed $10,000 for each day a violation occurs. Such penalty shall be collected by the Commissioner and the proceeds shall be payable to the State Treasurer for remittance to the Department.

C. Any person who (i) manufactures, sells, or offers for sale an industrial hemp extract or food containing an industrial hemp extract without first obtaining a permit to do so from the Commissioner pursuant to § 3.2-5100, unless exempt from a permit pursuant to subdivision C 6 of § 3.2-5130; (ii) continues to manufacture, sell, or offer for sale an industrial hemp extract or food containing an industrial hemp extract after revocation or suspension of such permit; (iii) fails to disclose on a form prescribed by the Commissioner that he intends to manufacture, sell, or offer for sale a substance intended to be consumed orally that contains an industrial hemp-derived cannabinoid; (iv) manufactures, offers for sale, or sells in violation of this chapter or a regulation adopted pursuant to this chapter a substance intended to be consumed orally that is advertised or labeled as containing an industrial hemp-derived cannabinoid; or (v) otherwise violates any provision of this chapter or a regulation adopted pursuant to this chapter, in addition to any other penalties provided, is guilty of a Class 1 misdemeanor. Each day in which a violation occurs shall constitute a separate offense.

D. The Commissioner may, in accordance with the Administrative Process Act (§ 2.2-4000 et seq.), deny, suspend, or revoke a permit issued pursuant to § 3.2-5100 if the permitted entity is found to have violated subdivision A 69, 70, 71, 72, 73, or 74 of § 59.1-200 by a court of competent jurisdiction.

E. This section shall not apply to products that are (i) approved for marketing by the U.S. Food and Drug Administration and scheduled in the Drug Control Act (§ 54.1-3400 et seq.) or (ii) dispensed pursuant to Article 4.2 (§ 54.1-3442.5 et seq.) of Chapter 34 of Title 54.1.

§ 3.2-5145.4. Industrial hemp extract requirements.

A. An industrial hemp extract shall (i) be produced from industrial hemp grown in compliance with applicable law and (ii) when offered for retail sale, ~~(a)~~ contain a total *delta-9* tetrahydrocannabinol concentration of no greater than 0.3 percent ~~and~~ ~~(b)~~ ~~contain~~ ~~either~~ ~~no~~ ~~more~~ ~~than~~ ~~two~~ ~~milligrams~~ ~~of~~ ~~total~~ ~~tetrahydrocannabinol~~ ~~per~~ ~~package~~ ~~or~~ ~~an~~ ~~amount~~ ~~of~~ ~~cannabidiol~~ ~~that~~ ~~is~~ ~~no~~ ~~less~~ ~~than~~ ~~25~~ ~~times~~ ~~greater~~ ~~than~~ ~~the~~

~~amount of total tetrahydrocannabinol per package~~.

B. In addition to the requirements of this chapter, an industrial hemp extract or food containing an industrial hemp extract shall comply with regulations adopted by the Board pursuant to § 3.2-5145.5.

§ 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; (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) 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; (iv) a hemp product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined in § 3.2-5145.1; or (vi) any substance containing a tetrahydrocannabinol isomer, ester, ether, salt, or salts of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act (§ 54.1-3400 et seq.) pursuant to § 54.1-3443.

"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" means the same as that term is defined in § 3.2-4112.

~~"Total tetrahydrocannabinol" means the same as that term is defined in § 3.2-4112.~~

§ 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 "controlled substances" and "Schedules I, II, III, IV, V, and VI" are used in Title 18.2, such terms refer to those terms as they are used or defined in the Drug Control Act (§ 54.1-3400 et seq.).

B. The term "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 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 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 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 used in this article 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; (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) 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; (iv) a hemp product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined in § 3.2-5145.1; or (vi) any substance containing a tetrahydrocannabinol isomer, ester, ether, salt or salts of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act (§ 54.1-3400 et seq.) pursuant to § 54.1-3443.

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 term "tetrahydrocannabinol" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of this definition, "isomer" means the optical, position, and geometric isomers.

~~G. The term "total tetrahydrocannabinol" means the sum, after the application of any necessary conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of tetrahydrocannabinolic acid.~~

~~H.~~ *G.* The Department of Forensic Science shall determine the proper methods for detecting the concentration of tetrahydrocannabinol in substances for the purposes of this title, Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1, and § 54.1-3401. The testing methodology shall use post-decarboxylation testing or other equivalent method and shall consider the potential conversion of tetrahydrocannabinolic acid into tetrahydrocannabinol.

§ 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. "Agent" 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" does 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 by such practitioner or a licensed advanced practice registered nurse 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. "Controlled substance" does 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, an advanced practice registered nurse, a 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" does 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" includes only 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; Schedules 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. "Manufacture" 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; (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) 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; (iv) a hemp product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined in § 3.2-5145.1; or (vi) any substance containing a tetrahydrocannabinol isomer, ester, ether, salt, or salts of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act (§ 54.1-3400 et seq.) pursuant to § 54.1-3443.

"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; or (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 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 Board.

"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. "Opiate" 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). "Opiate" 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 advanced practice registered nurse 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, "proprietary medicine" does 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.

"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. "Radiopharmaceutical" 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).

"Remote dispensing system" means a profile-driven automated drug dispensing system that performs operations or activities relative to the storage, packaging, labeling, or dispensing of medications employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient, authorized agent

of the patient, or person licensed to administer drugs, and collects, controls, and maintains all information online. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 and Board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

"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" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of this definition, "isomer" means the optical, position, and geometric 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.

~~"Total tetrahydrocannabinol" means the sum, after the application of any necessary conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of tetrahydrocannabinolic acid.~~

"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 do 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 have the same meanings as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.