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SENATE BILL NO. 1306

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Agriculture, Conservation and Natural Resources
on January 19, 2017)

(Patron Prior to Substitute—Senator Vogel)

A BILL to amend and reenact §§ 3.2-4112, 3.2-4115, 3.2-4116, 3.2-4117, 3.2-4120, and 54.1-3401 of the Code of Virginia, relating to industrial hemp licensure.

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-4112, 3.2-4115, 3.2-4116, 3.2-4117, 3.2-4120, and 54.1-3401 of the Code of Virginia are amended and reenacted as follows:

§ 3.2-4112. Definitions.

As used in this chapter:

"Grower" means any person licensed pursuant to § 3.2-4115 or 3.2-4117 to grow industrial hemp as part of the industrial hemp research program for any lawful purpose.

"Hemp products" means all products made from industrial hemp, including cloth, cordage, fiber, food, fuel, paint, paper, particleboard, plastics, seed, seed meal and seed oil for consumption, and seed for cultivation.

"Industrial hemp" means all parts and varieties of the plant *Cannabis sativa*, cultivated or possessed by a licensed grower, whether growing or not, that contain a concentration of THC that is no greater than that allowed by federal law. Industrial hemp as defined and applied in this chapter is excluded from the definition of marijuana as found in § 54.1-3401.

"Industrial hemp research program" means the research program established pursuant to § 3.2-4120.

"Seed research" means research conducted to develop or re-create better varieties of industrial hemp, particularly for the purposes of seed production.

"Tetrahydrocannabinol" or "THC" means the natural or synthetic equivalents of the substances contained in the plant, or in the resinous extractives, of the genus *Cannabis*, or any synthetic substances, compounds, salts, or derivatives of the plant or chemicals and their isomers with similar chemical structure and pharmacological activity.

§ 3.2-4115. Issuance of industrial hemp research licenses.

A. The Commissioner shall establish an agricultural pilot program and a program of licensure to allow a person to grow industrial hemp in the Commonwealth in a controlled fashion solely and exclusively as part of the industrial hemp research program study the growth, cultivation, and marketing of industrial hemp that shall be open to application by citizens of the Commonwealth and institutions of higher education. The Commissioner shall aid license holders in an expedient manner by pursuing any permits, waivers, or contracts required to facilitate the importation or purchase of certified industrial hemp seed. License holders shall bear the financial burden of purchasing certified industrial hemp seed.

This form of licensure shall only be allowed subject to a grant of necessary permissions, waivers, or other form of valid legal status by the U.S. Drug Enforcement Administration or other appropriate federal agency pursuant to applicable federal laws relating to industrial hemp.

B. Any person seeking to grow industrial hemp as part of the industrial hemp research program shall apply to the Commissioner for a license on a form provided by the Commissioner. At a minimum, the application shall include:

1. The name and mailing address of the applicant;

2. The legal description and geographic data sufficient for locating the production fields to be used to grow industrial hemp. A license shall authorize industrial hemp propagation only on the land areas specified in the license;

3. A signed statement indicating whether the applicant has ever been convicted of a felony. A person with a prior felony drug conviction within 10 years of applying for a license under this section shall not be eligible for the license;

4. Written consent allowing the sheriff's office, police department, or Department of State Police, if a license is ultimately issued to the applicant, to enter the premises on which the industrial hemp is grown to conduct physical inspections of industrial hemp planted and grown by the applicant and to ensure compliance with the requirements of this chapter. No more than two physical inspections shall be conducted under this subdivision per year, unless a valid search warrant for an inspection has been issued by a court of competent jurisdiction. All testing for THC levels shall be performed as provided in subsection K J;

5. Documentation If the application is for participation in the industrial hemp research program, documentation of an agreement between a public institution of higher education and the applicant that states that the applicant, if licensed pursuant to this section, will be a participant in the industrial

60 hemp research program managed by that ~~public~~ institution of higher education;

61 6. Any other information required by the Commissioner; and

62 7. The payment of a nonrefundable application fee, in an amount set by the Commissioner.

63 C. The Commissioner shall require a state and national fingerprint-based criminal history background
64 check by the Department of State Police on any person applying for licensure. The Department of State
65 Police may charge a fee, as established by the Department of State Police, to be paid by the applicant
66 for the actual cost of processing the background check. A copy of the results of the background check
67 shall be sent to the Commissioner.

68 D. All *industrial hemp research program* license applications shall be processed as follows:

69 1. Upon receipt of a license application, the Commissioner shall forward a copy of the application to
70 the Department of State Police, which shall initiate its review thereof;

71 2. The Department of State Police shall, within ~~60~~ 30 days, perform the required state and national
72 criminal history background check of the applicant; approve the application, if it is determined that the
73 requirements relating to prior criminal convictions have been met; and return all applications to the
74 Commissioner together with its findings and a copy of the state and national criminal history
75 background check; and

76 3. The Commissioner shall review all license applications returned from the Department of State
77 Police. If the Commissioner determines that all requirements have been met and that a license should be
78 granted to the applicant, taking into consideration any prior convictions of the applicant, the
79 Commissioner shall approve the application for issuance of a license.

80 E. ~~The Commissioner may approve licenses for only those selected growers whose demonstration~~
81 ~~plots will, in the discretion of the Commissioner, advance the goals of the industrial hemp research~~
82 ~~program to the furthest extent possible based on location, soil type, growing conditions, varieties of~~
83 ~~industrial hemp and their suitability for particular hemp products, and other relevant factors. The~~
84 ~~location and acreage of each demonstration plot to be grown by a license holder, as well as the total~~
85 ~~number of plots to be grown by a license holder, shall be determined at the discretion of the~~
86 ~~Commissioner.~~

87 F. An industrial hemp research program grower license shall not be subject to a minimum acreage.

88 G. ~~F.~~ Each *industrial hemp research program* license shall be valid for a period of ~~one year~~ two
89 years from the date of issuance and may be renewed in successive years. Each annual renewal shall
90 require the payment of a license renewal fee.

91 H. ~~G.~~ The Commissioner shall establish the fee amounts, *not to exceed \$100*, required for license
92 applications and license renewals allowed under this section. All application and license renewal fees
93 collected by the Commissioner shall be deposited in the State Treasury.

94 I. ~~H.~~ A copy or appropriate electronic record of each license issued by the Commissioner under this
95 section shall be forwarded immediately to the chief law-enforcement officer of each county or city
96 where the industrial hemp is licensed to be planted, grown, and harvested.

97 J. ~~I.~~ All records, data, and information filed in support of a license application shall be considered
98 proprietary and excluded from the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et
99 seq.).

100 K. ~~J.~~ The Commissioner shall be responsible for monitoring the industrial hemp grown by any
101 *industrial hemp research program* license holder and ~~shall~~ may provide for random testing of the
102 industrial hemp for compliance with THC levels and for other appropriate purposes established pursuant
103 to § 3.2-4114 at the cost of the license holder.

104 **§ 3.2-4116. Industrial hemp grower license conditions.**

105 A. A person shall obtain an industrial hemp grower license pursuant to § 3.2-4115 *or* 3.2-4117 prior
106 to planting or growing any industrial hemp in the Commonwealth.

107 B. A person granted an industrial hemp grower license pursuant to § 3.2-4115 *or* 3.2-4117 shall:

108 1. Maintain records that reflect compliance with this chapter and with all other state laws regulating
109 the planting and cultivation of industrial hemp;

110 2. Retain all industrial hemp production records for at least three years; *and*

111 3. Allow industrial hemp crops, throughout sowing, growing, and harvesting, to be inspected by and
112 at the discretion of the Commissioner or his designee, the Department of State Police, or the chief
113 law-enforcement officer of the locality; *and*.

114 4. ~~Maintain a current written agreement with a public institution of higher education that states that~~
115 ~~the grower is a participant in the industrial hemp research program managed by that public institution of~~
116 ~~higher education.~~ C. *Processed and unprocessed industrial hemp from the industrial hemp research*
117 *program may be sold within and outside of the Commonwealth as part of marketing research.*

118 **§ 3.2-4117. Additional industrial hemp licenses.**

119 A. The Board may adopt regulations as necessary to license persons to grow industrial hemp in the
120 Commonwealth for any lawful purpose.

121 B. Notwithstanding the provisions of §§ 3.2-4115 and 3.2-4116, the Commissioner shall establish a

program of licensure and renewal, including the establishment of any fees not to exceed \$250 \$100, to allow a person to grow industrial hemp in the Commonwealth for any lawful purpose. ~~Valid applications shall be granted licensure within 90 days of receipt of the application. All application and license renewal fees collected by the Commissioner shall be deposited in the State Treasury.~~ The Commissioner shall accept license applications throughout the year. Licenses shall be valid for ~~four~~ five years from the date of the issuance of the license. *Any hemp under cultivation at the time of license expiration may remain under cultivation until its harvest. Such license applications shall be processed as followed:*

1. *The Commissioner shall issue an industrial hemp grower's license to every qualified applicant within 60 days of receipt of a completed application. If the Commissioner should fail to either approve the license or deny it for permitted cause within 60 days of receipt, the applicant shall be deemed licensed for one year from the sixty-first day following receipt of the application by the Commissioner.*

2. *A licensed grower of industrial hemp shall notify the Commissioner through a website or paper form provided for that purpose of each specific location where industrial hemp is to be grown at least seven days prior to the commencement of cultivation. A grower who fails to notify the Commissioner of the location of industrial hemp under cultivation shall assume all risk for the eradication of the undisclosed hemp and be subject to a fine of \$100.*

3. *The Commissioner shall immediately revoke a grower's license upon conviction of a drug felony.*

4. *The Commissioner shall accept in lieu of a completed application and state criminal history background check proof that the applicant has received a federal license for the cultivation of industrial hemp if, in the determination of the Commissioner, the requirements for the approval of such license are substantially similar to or more stringent than those imposed under Virginia law. License applications processed under this provision shall be dispositioned within 21 days of receipt by the Commissioner.*

5. *All records, data, and information filed in support of a license application shall be deemed confidential and not subject to the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.).*

§ 3.2-4120. Industrial hemp research program with institutions of higher learning.

A. ~~To the extent that adequate funds are available for the program, the Commissioner shall undertake research of industrial hemp production through the establishment and oversight of an industrial hemp research program to be directly managed by public institutions of higher education. This research program shall consist primarily of demonstration plots planted and cultivated in Virginia by selected growers. The growers shall be licensed pursuant to subsection A of § 3.2-4115 prior to planting any industrial hemp.~~

B. As part of the industrial hemp research program directly managed by public institutions of higher education, the Commissioner may:

1. Oversee and analyze the growth of industrial hemp by licensed growers, for agronomy research and analysis of required soils, growing conditions, and harvest methods relating to the production of various varieties of industrial hemp that may be suitable for various commercial hemp products;

2. Conduct seed research on various types of industrial hemp that are best suited to be grown in Virginia, including seed availability, creation of Virginia hybrid types, and in-the-ground variety trials and seed production, and may establish a program to recognize certain industrial hemp seeds as being Virginia varieties of hemp seed;

3. Study the economic feasibility of developing an industrial hemp market in various types of industrial hemp that can be grown in the Commonwealth;

4. Report on the estimated value-added benefits, including environmental benefits, to Virginia businesses of an industrial hemp market of Virginia-grown industrial hemp varieties;

5. Study the agronomy research being conducted worldwide relating to industrial hemp varieties, production, and use;

6. Research and promote on the world market industrial hemp and hemp seed that can be grown on farms in the Commonwealth;

7. Promote research into the development of industrial hemp and commercial markets for Virginia industrial hemp and hemp products;

8. Study the feasibility of attracting federal or private funding for the Virginia industrial hemp research program; and

9. Study the use of industrial hemp in new energy technologies, including electricity generation, biofuels, or other forms of energy resources; the growth of industrial hemp on reclaimed mine sites; the use of hemp seed oil in the production of fuels; and the production costs, environmental issues, and costs and benefits involved with the use of industrial hemp for energy.

C. B. The research activities outlined in subsection B A shall not:

1. Subject the industrial hemp research program to any criminal liability under the controlled substances laws of the Commonwealth. This exemption from criminal liability is a limited exemption that shall be strictly construed and that shall not apply to any activities of the industrial hemp research

183 program that are not authorized; or

184 2. Alter, amend, or repeal by implication any provision of this Code relating to controlled substances.

185 ~~D. C.~~ The Commissioner shall pursue any permits or waivers from the U.S. Drug Enforcement
186 Administration or appropriate federal agency that are necessary for the advancement of the industrial
187 hemp research program.

188 ~~E. D.~~ The Commissioner shall notify the Superintendent of State Police and all local
189 law-enforcement agencies of the duration, size, and location of all industrial hemp demonstration plots.

190 ~~F. E.~~ The Commissioner is permitted to cooperatively seek funds from public and private sources to
191 implement the industrial hemp research program.

192 ~~G. F.~~ By November 1, 2015, and annually thereafter, the Commissioner shall report on the status and
193 progress of the industrial hemp research program to the Governor and to the General Assembly.

194 **§ 54.1-3401. Definitions.**

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

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

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

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

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

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

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

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

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

223 "Board" means the Board of Pharmacy.

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

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

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

240 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a
241 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by
242 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or
243 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in
244 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 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.

"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 transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"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.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"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, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include 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 shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115 or 3.2-4117.

"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 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. 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

429 advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic,
430 a drug that may be dispensed only upon prescription or the label of which bears substantially the
431 statement "Warning — may be habit-forming," or a drug intended for injection.

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

438 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C.
439 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food
440 and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to
441 42 U.S.C. § 262(k).

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

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

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

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

455 "Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party
456 logistics provider, engaged in the business of selling or otherwise distributing prescription drugs or
457 devices to any person who is not the ultimate user or consumer. No person shall be subject to any state
458 or local tax by reason of this definition.

459 "Wholesale distribution" means distribution of prescription drugs to persons other than consumers or
460 patients, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

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

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

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