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HOUSE BILL NO. 1566

Offered January 14, 2020

A *BILL to amend and reenact §§ 3.2-4112 and 54.1-3401, as it is currently effective and as it shall become effective, of the Code of Virginia, relating to industrial hemp concentration of THC.*

Patrons—Keam, Freitas and Edmunds

Referred to Committee on Agriculture, Chesapeake and Natural Resources

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-4112 and 54.1-3401, as it is currently effective and as it shall become effective, 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*, including seeds thereof and any derivative, extract, cannabinoid, isomer, acid, salt, or salt of an isomer, whether growing or not, with a concentration of tetrahydrocannabinol that is greater than that allowed by federal law.

"Deal" means to buy industrial hemp grown in compliance with state or federal law and to sell such industrial hemp to a person who (i) processes industrial hemp in compliance with state or federal law or (ii) sells industrial hemp to a person who processes industrial hemp in compliance with state or federal law.

"Dealer" means any person who is registered pursuant to subsection A of § 3.2-4115 to deal in industrial hemp. "Dealer" does not include (i) a grower, (ii) a processor, or (iii) any person who buys industrial hemp for personal use or retail sale in Virginia.

"Dealership" means the location at which a dealer stores or intends to store the industrial hemp in which he deals.

"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.

"Hemp product" means any finished product ~~that is otherwise lawful and~~, including raw materials of any part of the plant *Cannabis sativa*, whether growing or not, that contains industrial hemp, including rope, building materials, automobile parts, animal bedding, animal feed, cosmetics, oil containing an industrial hemp extract, or food or food additives for human consumption.

"Industrial hemp" means any part of the plant *Cannabis sativa*, including seeds thereof and any derivative, extract, cannabinoid, isomer, acid, salt, or salt of an isomer, whether growing or not, with a concentration of tetrahydrocannabinol that is no greater than that allowed by federal law *or one percent, whichever is greater.*

"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 is growing or intends to grow industrial hemp.

§ 54.1-3401. (Effective until July 1, 2020) Definitions.

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

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

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

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

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

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

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

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

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

74 "Board" means the Board of Pharmacy.

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

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

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

91 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a
92 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by
93 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or
94 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in
95 expectation of receiving a valid prescription based on observed historical patterns of prescribing and
96 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as
97 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the
98 course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or
99 chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a
100 manufacturer's product drugs for the purpose of administration to a patient, when performed by a
101 practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person
102 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person
103 supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to
104 subdivision A 4 of § 54.1-2901 shall not be considered compounding.

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

110 "Controlled substance analog" means a substance the chemical structure of which is substantially
111 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a
112 stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar
113 to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a
114 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person
115 represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous
116 system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect
117 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance
118 analog" does not include (a) any substance for which there is an approved new drug application as
119 defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally
120 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, warehouse, nonresident warehouse, third-party logistics provider, or nonresident third-party logistics provider at the direction of a medical equipment supplier in accordance with § 54.1-3415.1.

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic 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).

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

187 "Labeling" means all labels and other written, printed, or graphic matter on an article or any of its
188 containers or wrappers, or accompanying such article.

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

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

196 "Marijuana" means any part of a plant of the genus *Cannabis* whether growing or not, its seeds, or
197 its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its
198 seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids
199 unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana
200 include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the
201 seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the
202 genus *Cannabis*. Marijuana shall not include (i) industrial hemp, as defined in § 3.2-4112, that is
203 possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent, or (ii) a hemp
204 product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3
205 one percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or
206 processed in compliance with state or federal law.

207 "Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to
208 the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and
209 needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with
210 no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for
211 peritoneal dialysis, and sterile water or saline for irrigation.

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

222 "New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a
223 new animal drug, the composition of which is such that such drug is not generally recognized, among
224 experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs,
225 as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling,
226 except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior
227 to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as
228 amended, and if at such time its labeling contained the same representations concerning the conditions
229 of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new
230 animal drug, the composition of which is such that such drug, as a result of investigations to determine
231 its safety and effectiveness for use under such conditions, has become so recognized, but which has not,
232 otherwise than in such investigations, been used to a material extent or for a material time under such
233 conditions.

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

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

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

243 "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to

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

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

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

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

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

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

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

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

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

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

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

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

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

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

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

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

"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

305 pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent
306 edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as
307 the "Orange Book."

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

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

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

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

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

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

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

329 **§ 54.1-3401. (Effective July 1, 2020) Definitions.**

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

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

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

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

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

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

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

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

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

358 "Board" means the Board of Pharmacy.

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

363 "Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i)
364 the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns
365 or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a
366 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 nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

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

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

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

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

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

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

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal

428 dialysis, or commercially available solutions whose purpose is to be used in the performance of
429 hemodialysis not to include any solutions administered to the patient intravenously.

430 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the
431 lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or
432 compounding necessary to prepare the substance for that delivery. However, dispensing shall not include
433 the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites
434 operated by such practitioner or that practitioner's medical practice for the purpose of administration of
435 such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For
436 practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a
437 practitioner to patients to take with them away from the practitioner's place of practice.

438 "Dispenser" means a practitioner who dispenses.

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

440 "Distributor" means a person who distributes.

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

448 "Drug product" means a specific drug in dosage form from a known source of manufacture, whether
449 by brand or therapeutically equivalent drug product name.

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

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

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

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

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

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

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

470 "Labeling" means all labels and other written, printed, or graphic matter on an article or any of its
471 containers or wrappers, or accompanying such article.

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

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

479 "Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or
480 its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its
481 seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids
482 unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana
483 include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the
484 seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the
485 genus Cannabis. Marijuana shall not include (i) industrial hemp, as defined in § 3.2-4112, that is
486 possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent, or (ii) a hemp
487 product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3
488 one percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or
489 processed in compliance with state or federal law.

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

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

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

551 administer, or conduct research with respect to a controlled substance in the course of professional
552 practice or research in the Commonwealth.

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

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

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

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

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

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

579 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C.
580 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food
581 and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to
582 42 U.S.C. § 262(k).

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

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

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

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

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

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

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

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

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