2021 SESSION

INTRODUCED

	20105524D
1	HOUSE BILL NO. 1566
2 3	Offered January 14, 2020
3	A BILL to amend and reenact §§ 3.2-4112 and 54.1-3401, as it is currently effective and as it shall
4	become effective, of the Code of Virginia, relating to industrial hemp concentration of THC.
5	Patrons—Keam, Freitas and Edmunds
6	
7	Referred to Committee on Agriculture, Chesapeake and Natural Resources
8 9	Be it enacted by the General Assembly of Virginia:
9 10	1. That §§ 3.2-4112 and 54.1-3401, as it is currently effective and as it shall become effective, of
11	the Code of Virginia are amended and reenacted as follows:
12	§ 3.2-4112. Definitions.
13	As used in this chapter, unless the context requires a different meaning:
14	"Cannabis sativa product" means a product made from any part of the plant Cannabis sativa,
15	including seeds thereof and any derivative, extract, cannabinoid, isomer, acid, salt, or salt of an isomer,
16 17	whether growing or not, with a concentration of tetrahydrocannabinol that is greater than that allowed by federal law.
18	"Deal" means to buy industrial hemp grown in compliance with state or federal law and to sell such
19	industrial hemp to a person who (i) processes industrial hemp in compliance with state or federal law or
20	(ii) sells industrial hemp to a person who processes industrial hemp in compliance with state or federal
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22 23	"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
23 24	industrial hemp for personal use or retail sale in Virginia.
25	"Dealership" means the location at which a dealer stores or intends to store the industrial hemp in
26	which he deals.
27	"Grow" means to plant, cultivate, or harvest a plant or crop.
28 29	"Grower" means any person registered pursuant to subsection A of § 3.2-4115 to grow industrial
²⁹ 30	"Hemp product" means any finished product that is otherwise lawful and, including raw materials of
31	any part of the plant Cannabis sativa, whether growing or not, that contains industrial hemp, including
32	rope, building materials, automobile parts, animal bedding, animal feed, cosmetics, oil containing an
33	industrial hemp extract, or food or food additives for human consumption.
34	"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
35 36	concentration of tetrahydrocannabinol that is no greater than that allowed by federal law <i>or one percent</i> ,
37	whichever is greater.
38	"Process" means to convert industrial hemp into a hemp product.
39	"Processor" means a person registered pursuant to subsection A of § 3.2-4115 to process industrial
40 41	hemp. "Process site" means the location at which a processor processor or intends to process industrial
41	"Process site" means the location at which a processor processes or intends to process industrial hemp.
43	"Production field" means the land or area on which a grower is growing or intends to grow industrial
44	hemp.
45	§ 54.1-3401. (Effective until July 1, 2020) Definitions.
46 47	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,
48	ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his
49	authorized agent and under his direction or (ii) the patient or research subject at the direction and in the
50	presence of the practitioner.
51 52	"Advertisement" means all representations disseminated in any manner or by any means, other than
52 53	by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.
55 54	"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer,
55	distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or
56	employee of the carrier or warehouseman.
57 58	"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 operations or activities, other than compounding or administration, relating to pharmacy services, 61 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 analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic 66 arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human 67 68 beings.

69 "Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no 70 71 clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency 72 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) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns 80 or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a 81 partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more 82 83 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 84 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 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or 93 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in 94 95 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 96 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the 97 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 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person 102 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. 103 104

105 "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 106 107 108 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 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person 114 115 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 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance 117 analog" does not include (a) any substance for which there is an approved new drug application as 118 defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally 119 recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and 120

121 Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular 122 person, any substance for which an exemption is in effect for investigational use for that person under 123 § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that 124 substance is pursuant to such exemption; or (c) any substance to the extent not intended for human 125 consumption before such an exemption takes effect with respect to that substance.

126 "DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor 127 agency.

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

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

139 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.

146 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the 147 lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or 148 compounding necessary to prepare the substance for that delivery. However, dispensing shall not include 149 the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites 150 operated by such practitioner or that practitioner's medical practice for the purpose of administration of 151 such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For 152 practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a 153 practitioner to patients to take with them away from the practitioner's place of practice.

154 "Dispenser" means a practitioner who dispenses.

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

156 "Distributor" means a person who distributes.

157 "Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia 158 National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to 159 any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or 160 prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect 161 the structure or any function of the body of man or animals; (iv) articles or substances intended for use 162 as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" 163 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, whetherby brand or therapeutically equivalent drug product name.

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

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

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

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include anysuch 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.

180 "Interchangeable" means a biosimilar that meets safety standards for determining interchangeability **181** pursuant to 42 U.S.C. § 262(k)(4). HB1566

"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.

187 "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.

194 "Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a195 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 product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3204 one percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or 205 206 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.

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 including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and 217 any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, 218 derivative, or preparation thereof which is chemically equivalent or identical with any of these 219 220 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.

"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.

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.

"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.

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

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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.

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

249 "Original package" means the unbroken container or wrapping in which any drug or medicine is
250 enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor
251 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.

256 "Person" means both the plural and singular, as the case demands, and includes an individual,257 partnership, corporation, association, governmental agency, trust, or other institution or entity.

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

263 "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.

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

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

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

279 "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, 281 282 original package which does not contain any controlled substance or marijuana as defined in this chapter 283 and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general 284 public by or under the authority of the manufacturer or primary distributor, under a trademark, trade 285 name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of 286 this chapter and applicable federal law. However, this definition shall not include a drug that is only 287 advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, 288 a drug that may be dispensed only upon prescription or the label of which bears substantially the 289 statement "Warning — may be habit-forming," or a drug intended for injection.

290 "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei 291 with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or 292 radionuclide generator that is intended to be used in the preparation of any such substance, but does not 293 include drugs such as carbon-containing compounds or potassium-containing salts that include trace 294 quantities of naturally occurring radionuclides. The term also includes any biological product that is 295 labeled with a radionuclide or intended solely to be labeled with a radionuclide.

296 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C.
297 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food
298 and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to
299 42 U.S.C. § 262(k).

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

302 "Therapeutically equivalent drug products" means drug products that contain the same active
 303 ingredients and are identical in strength or concentration, dosage form, and route of administration and
 304 that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration

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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.

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"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 prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1. No person shall be 316 317 subject to any state or local tax by reason of this definition.

"Wholesale distribution" means (i) distribution of prescription drugs to persons other than consumers 318 or patients and (ii) delivery of Schedule VI prescription devices to the ultimate user or consumer 319 320 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 shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses 325 326 or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning. § 54.1-3401. (Effective July 1, 2020) Definitions. 327 328 329

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, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of 346 347 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 has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency 356 357 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 compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a 360 finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that 361 362 are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) 363 the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns 364 or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a 365 366 partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more

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367 of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation
368 of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the
369 voting stock of which is actively traded on any securities exchange or in any over-the-counter market;
370 (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned
371 subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a
372 corporation's charter.

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

375 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a 376 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by 377 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or 378 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in 379 expectation of receiving a valid prescription based on observed historical patterns of prescribing and 380 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as 381 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the 382 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 383 384 manufacturer's product drugs for the purpose of administration to a patient, when performed by a 385 practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person 386 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person 387 supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to 388 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.

394 "Controlled substance analog" means a substance the chemical structure of which is substantially 395 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a 396 stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar 397 to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a 398 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person 399 represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous 400 system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect 401 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance 402 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 403 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 404 405 406 person, any substance for which an exemption is in effect for investigational use for that person under 407 § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that 408 substance is pursuant to such exemption; or (c) any substance to the extent not intended for human 409 consumption before such an exemption takes effect with respect to that substance.

410 "DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor 411 agency.

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

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

421 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified
422 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§

423 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician
424 assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a
425 Medicare-certified renal dialysis facility.

426 "Dialysis solution" means either the commercially available, unopened, sterile solutions whose427 purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal

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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 such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For 435 practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a 436 437 practitioner to patients to take with them away from the practitioner's place of practice.

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"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.

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.

"Electronic prescription" means a written prescription that is generated on an electronic application 450 451 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.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any 457 458 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 controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture. 462

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

465 "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 466 467 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 include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the 483 484 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 (i) industrial hemp, as defined in § 3.2-4112, that is 485 possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent, or (ii) a hemp 486 487 product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3488 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.

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490 "Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to 491 the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and 492 needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with 493 no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for **494** peritoneal dialysis, and sterile water or saline for irrigation.

495 "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction 496 from substances of vegetable origin, or independently by means of chemical synthesis, or by a 497 combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, **498** or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof 499 which is chemically equivalent or identical with any of the substances referred to in clause (i), but not 500 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, 501 derivative, or preparation thereof which is chemically equivalent or identical with any of these 502 503 substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine. 504

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a 505 506 new animal drug, the composition of which is such that such drug is not generally recognized, among 507 experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, 508 as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, 509 except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior 510 to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as 511 amended, and if at such time its labeling contained the same representations concerning the conditions 512 of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new 513 animal drug, the composition of which is such that such drug, as a result of investigations to determine 514 its safety and effectiveness for use under such conditions, has become so recognized, but which has not, 515 otherwise than in such investigations, been used to a material extent or for a material time under such 516 conditions.

517 "Nuclear medicine technologist" means an individual who holds a current certification with the 518 American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification 519 Board.

520 "Official compendium" means the official United States Pharmacopoeia National Formulary, official 521 Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

522 "Official written order" means an order written on a form provided for that purpose by the U.S. Drug 523 Enforcement Administration, under any laws of the United States making provision therefor, if such 524 order forms are authorized and required by federal law, and if no such order form is provided then on 525 an official form provided for that purpose by the Board of Pharmacy.

526 "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to 527 morphine or being capable of conversion into a drug having such addiction-forming or 528 addiction-sustaining liability. It does not include, unless specifically designated as controlled under 529 Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts 530 (dextromethorphan). It does include its racemic and levorotatory forms.

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

532 "Original package" means the unbroken container or wrapping in which any drug or medicine is 533 enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor 534 for use in the delivery or display of such article.

535 "Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is 536 currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and 537 that complies with all applicable requirements of federal and state law, including the Federal Food, 538 Drug, and Cosmetic Act.

539 "Person" means both the plural and singular, as the case demands, and includes an individual, 540 partnership, corporation, association, governmental agency, trust, or other institution or entity.

541 "Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application 542 for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in 543 a manner complying with the laws and regulations for the practice of pharmacy and the sale and 544 dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy 545 and the pharmacy's personnel as required by § 54.1-3432. 546

"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, 547 548 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, 549 or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and 550

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 pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of 560 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)). 561

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

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, 564 original package which does not contain any controlled substance or marijuana as defined in this chapter 565 566 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 567 name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of 568 569 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 statement "Warning — may be habit-forming," or a drug intended for injection. "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei 572

573 with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or 574 575 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 576 577 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).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any 583 **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 that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration 587 pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent 588 edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as 589 590 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 or patients and (ii) delivery of Schedule VI prescription devices to the ultimate user or consumer 602 603 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.

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

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