	18104352D
1	SENATE BILL NO. 413
2	Offered January 10, 2018
3	Prefiled January 9, 2018
4 5	A BILL to amend and reenact § 54.1-3401, as it is currently effective and as it shall become effective, and to amend the Code of Virginia by adding a section numbered 54.1-3415.1, relating to delivery of
6	Schedule VI prescription devices.
<b>7</b>	
	Patrons—McDougle and Vogel
8	
9	Referred to Committee on Education and Health
10 11	Be it enacted by the General Assembly of Virginia:
12	1. That § 54.1-3401, as it is currently effective and as it shall become effective, of the Code of
13	Virginia is amended and reenacted and the Code of Virginia is amended by adding a section
14	numbered 54.1-3415.1 as follows:
15	§ 54.1-3401. (Effective until July 1, 2020) Definitions.
16 17	As used in this chapter, unless the context requires a different meaning:
17 18	"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
19	authorized agent and under his direction or (ii) the patient or research subject by (i) a practitioner or by his
20	presence of the practitioner.
21	"Advertisement" means all representations disseminated in any manner or by any means, other than
22	by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the
23 24	purchase of drugs or devices. "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer,
2 <del>7</del> 25	distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or
26	employee of the carrier or warehouseman.
27	"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related
28	to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.
29 30	"Animal" means any nonhuman animate being endowed with the power of voluntary action. "Automated drug dispensing system" means a mechanical or electronic system that performs
31	operations or activities, other than compounding or administration, relating to pharmacy services,
32	including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of
33	all transaction information, to provide security and accountability for such drugs.
34	"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood
35 36	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
37	arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human
38	beings.
39	"Biosimilar" means a biological product that is highly similar to a specific reference biological
40 41	product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that
42	has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency
43	of the product.
44	"Board" means the Board of Pharmacy.
45	"Bulk drug substance" means any substance that is represented for use, and that, when used in the
46 47	compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that
48	are used in the synthesis of such substances.
49	"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i)
50	the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns
51 52	or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a
52 53	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
53 54	of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the
55	voting stock of which is actively traded on any securities exchange or in any over-the-counter market;
56	(iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned
57	subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a
58	corporation's charter.

59 "Co-licensed partner" means a person who, with at least one other person, has the right to engage in60 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 61 62 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by 63 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or 64 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in 65 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 66 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the 67 68 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 69 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 70 71 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person 72 73 supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to 74 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.

80 "Controlled substance analog" means a substance the chemical structure of which is substantially 81 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 82 83 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 84 85 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 86 87 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance 88 analog" does not include (a) any substance for which there is an approved new drug application as 89 defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally 90 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 91 92 person, any substance for which an exemption is in effect for investigational use for that person under 93 § 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 94 95 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.

98 "Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by
99 this chapter, whether or not there exists an agency relationship, including delivery of a Schedule VI
100 prescription device to an ultimate consumer on behalf of a medical equipment supplier by a
101 manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor,
102 warehouser, or third-party logistics provider at the direction of a medical equipment supplier in
103 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.

107 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified
 108 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.

116 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the 117 lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or 118 compounding necessary to prepare the substance for that delivery. However, dispensing shall not include 119 the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites 120 operated by such practitioner or that practitioner's medical practice for the purpose of administration of

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121 such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For 122 practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a 123 practitioner to patients to take with them away from the practitioner's place of practice.

124 "Dispenser" means a practitioner who dispenses.

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

126 "Distributor" means a person who distributes.

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127 "Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia 128 National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to 129 any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or 130 prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect 131 the structure or any function of the body of man or animals; (iv) articles or substances intended for use 132 as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" 133 does not include devices or their components, parts, or accessories.

134 "Drug product" means a specific drug in dosage form from a known source of manufacture, whether 135

by brand or therapeutically equivalent drug product name. "Electronic transmission prescription" means any prescription, other than an oral or written 136 137 prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly 138 to a pharmacy without interception or intervention from a third party from a practitioner authorized to 139 prescribe or from one pharmacy to another pharmacy.

140 "Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an 141 electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy 142 form.

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

144 "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. 145

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by 146 147 regulation designates as being the principal compound commonly used or produced primarily for use, 148 and which is an immediate chemical intermediary used or likely to be used in the manufacture of a 149 controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

150 "Interchangeable" means a biosimilar that meets safety standards for determining interchangeability 151 pursuant to  $42^{\circ}$  U.S.C. § 262(k)(4).

152 "Label" means a display of written, printed, or graphic matter upon the immediate container of any 153 article. A requirement made by or under authority of this chapter that any word, statement, or other 154 information appear on the label shall not be considered to be complied with unless such word, 155 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. 156

157 "Labeling" means all labels and other written, printed, or graphic matter on an article or any of its 158 containers or wrappers, or accompanying such article.

159 "Manufacture" means the production, preparation, propagation, conversion, or processing of any item 160 regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or 161 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 162 163 container. This term does not include compounding.

164 "Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a 165 repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or 166 167 its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids 168 unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana 169 include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the 170 171 seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the 172 genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, 173 cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

174 "Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to 175 the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and 176 needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with 177 no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for 178 peritoneal dialysis, and sterile water or saline for irrigation.

179 "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 180 combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, 181

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182 or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof 183 which is chemically equivalent or identical with any of the substances referred to in clause (i), but not 184 including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and 185 any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, 186 derivative, or preparation thereof which is chemically equivalent or identical with any of these 187 substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain 188 cocaine or ecgonine.

189 "New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a 190 new animal drug, the composition of which is such that such drug is not generally recognized, among 191 experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, 192 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 193 194 to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as 195 amended, and if at such time its labeling contained the same representations concerning the conditions 196 of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new 197 animal drug, the composition of which is such that such drug, as a result of investigations to determine 198 its safety and effectiveness for use under such conditions, has become so recognized, but which has not, 199 otherwise than in such investigations, been used to a material extent or for a material time under such 200 conditions.

201 "Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification 202 203 Board.

204 "Official compendium" means the official United States Pharmacopoeia National Formulary, official 205 Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

206 '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 207 208 order forms are authorized and required by federal law, and if no such order form is provided then on 209 an official form provided for that purpose by the Board of Pharmacy.

210 "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to 211 morphine or being capable of conversion into a drug having such addiction-forming or 212 addiction-sustaining liability. It does not include, unless specifically designated as controlled under 213 Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts 214 (dextromethorphan). It does include its racemic and levorotatory forms. 215

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

216 "Original package" means the unbroken container or wrapping in which any drug or medicine is 217 enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor 218 for use in the delivery or display of such article.

219 "Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is 220 currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and 221 that complies with all applicable requirements of federal and state law, including the Federal Food, 222 Drug, and Cosmetic Act.

223 "Person" means both the plural and singular, as the case demands, and includes an individual, 224 partnership, corporation, association, governmental agency, trust, or other institution or entity.

225 "Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application 226 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. 227 228 229

231 "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 232 optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, 233 234 or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and 235 administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth. 236

237 "Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue 238 a prescription.

239 "Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word 240 of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed 241 physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such 242 drugs or medical supplies.

243 "Prescription drug" means any drug required by federal law or regulation to be dispensed only

244 pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of 245 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

246 "Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a 247 controlled substance or marijuana.

248 "Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, 249 original package which does not contain any controlled substance or marijuana as defined in this chapter 250 and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general 251 public by or under the authority of the manufacturer or primary distributor, under a trademark, trade 252 name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of 253 this chapter and applicable federal law. However, this definition shall not include a drug that is only 254 advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, 255 a drug that may be dispensed only upon prescription or the label of which bears substantially the 256 statement "Warning — may be habit-forming," or a drug intended for injection.

257 "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei 258 with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or 259 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 260 quantities of naturally occurring radionuclides. The term also includes any biological product that is 261 labeled with a radionuclide or intended solely to be labeled with a radionuclide. 262

263 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. 264 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food 265 and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 266 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any 267 268 person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active 269 270 ingredients and are identical in strength or concentration, dosage form, and route of administration and 271 that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent 272 edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as 273 274 the "Orange Book."

275 "Third-party logistics provider" means a person that provides or coordinates warehousing of or other 276 logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale 277 distributor, or dispenser of the drug or device but does not take ownership of the product or have 278 responsibility for directing the sale or disposition of the product.

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

280 "Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party 281 logistics provider, engaged in the business of (i) selling or otherwise distributing prescription drugs or 282 devices to any person who is not the ultimate user or consumer and (ii) delivering Schedule VI 283 prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1. No person shall be 284 subject to any state or local tax by reason of this definition.

285 "Wholesale distribution" means (i) distribution of prescription drugs to persons other than consumers 286 or patients and (ii) delivering Schedule VI prescription devices to the ultimate user or consumer 287 pursuant to § 54.1-3415.1 subject to the exemptions set forth in the federal Drug Supply Chain Security 288 Act.

289 "Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed 290 partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

291 The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter 292 shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses 293 or lenses for the eyes.

294 The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be 295 defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning. 296

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

297

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

298 "Administer" means the direct application of a controlled substance, whether by injection, inhalation, 299 ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his 300 authorized agent and under his direction or (ii) the patient or research subject at the direction and in the 301 presence of the practitioner.

302 "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 303 304 purchase of drugs or devices.

305 "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, 306 distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or 307 employee of the carrier or warehouseman.

308 "Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related 309 to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

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

311 "Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, 312 313 including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of 314 all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or 315 316 317 analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic 318 arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human 319 beings.

320 "Biosimilar" means a biological product that is highly similar to a specific reference biological 321 product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that 322 323 has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product. 324 325

"Board" means the Board of Pharmacy.

326 "Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that 327 328 329 are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) 330 the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns 331 332 or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more 333 334 of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation 335 of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the 336 voting stock of which is actively traded on any securities exchange or in any over-the-counter market; 337 (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned 338 subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a 339 corporation's charter.

340 'Co-licensed partner" means a person who, with at least one other person, has the right to engage in 341 the manufacturing or marketing of a prescription drug, consistent with state and federal law.

342 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a 343 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by 344 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or 345 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 346 347 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as 348 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the 349 course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or 350 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 351 practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person 352 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person 353 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. 354 355

356 "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of 357 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 358 359 substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory 360 authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially 361 362 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a 363 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 364 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person 365 366 represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous

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367 system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect 368 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance 369 analog" does not include (a) any substance for which there is an approved new drug application as 370 defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally 371 recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and 372 Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular 373 person, any substance for which an exemption is in effect for investigational use for that person under 374 § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that 375 substance is pursuant to such exemption; or (c) any substance to the extent not intended for human 376 consumption before such an exemption takes effect with respect to that substance.

377 "DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor 378 agency.

379 "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 380 381 prescription device to an ultimate consumer on behalf of a medical equipment supplier by a 382 manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, 383 warehouser, or third-party logistics provider at the direction of a medical equipment supplier in 384 accordance with § 54.1-3415.1.

385 "Device" means instruments, apparatus, and contrivances, including their components, parts, and 386 accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in 387 man or animals or to affect the structure or any function of the body of man or animals.

388 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified 389 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 390 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician 391 assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a 392 Medicare-certified renal dialysis facility.

393 "Dialysis solution" means either the commercially available, unopened, sterile solutions whose 394 purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal 395 dialysis, or commercially available solutions whose purpose is to be used in the performance of 396 hemodialysis not to include any solutions administered to the patient intravenously.

397 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the 398 lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or 399 compounding necessary to prepare the substance for that delivery. However, dispensing shall not include 400 the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites 401 operated by such practitioner or that practitioner's medical practice for the purpose of administration of 402 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 403 **404** practitioner to patients to take with them away from the practitioner's place of practice.

- 405 "Dispenser" means a practitioner who dispenses.
- "Distribute" means to deliver other than by administering or dispensing a controlled substance. 406
- 407 "Distributor" means a person who distributes.

408 "Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia 409 National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to 410 any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or 411 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 412 413 as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" 414 does not include devices or their components, parts, or accessories.

415 "Drug product" means a specific drug in dosage form from a known source of manufacture, whether 416 by brand or therapeutically equivalent drug product name.

417 "Electronic prescription" means a written prescription that is generated on an electronic application 418 and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be 419 transmitted in accordance with 21 C.F.R. Part 1300.

420 "Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an 421 electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy 422 form. 423

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

424 "Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any 425 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 426 427 regulation designates as being the principal compound commonly used or produced primarily for use, 428 and which is an immediate chemical intermediary used or likely to be used in the manufacture of a429 controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

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

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

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

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

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

446 "Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or 447 its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its 448 seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids 449 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 450 seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the 451 452 genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, 453 cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

"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.

459 "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction 460 from substances of vegetable origin, or independently by means of chemical synthesis, or by a 461 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 462 463 which is chemically equivalent or identical with any of the substances referred to in clause (i), but not 464 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, 465 derivative, or preparation thereof which is chemically equivalent or identical with any of these 466 467 substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain 468 cocaine or ecgonine.

469 "New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a 470 new animal drug, the composition of which is such that such drug is not generally recognized, among 471 experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, 472 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 473 474 to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as 475 amended, and if at such time its labeling contained the same representations concerning the conditions 476 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 477 478 its safety and effectiveness for use under such conditions, has become so recognized, but which has not, 479 otherwise than in such investigations, been used to a material extent or for a material time under such 480 conditions.

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

484 "Official compendium" means the official United States Pharmacopoeia National Formulary, official485 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.

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490 "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to 491 morphine or being capable of conversion into a drug having such addiction-forming or 492 addiction-sustaining liability. It does not include, unless specifically designated as controlled under 493 Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts 494 (dextromethorphan). It does include its racemic and levorotatory forms.

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

496 "Original package" means the unbroken container or wrapping in which any drug or medicine is 497 enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor 498 for use in the delivery or display of such article.

499 "Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is 500 currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and 501 that complies with all applicable requirements of federal and state law, including the Federal Food, 502 Drug, and Cosmetic Act.

503 "Person" means both the plural and singular, as the case demands, and includes an individual, 504 partnership, corporation, association, governmental agency, trust, or other institution or entity.

505 "Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application 506 for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in 507 a manner complying with the laws and regulations for the practice of pharmacy and the sale and 508 dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy 509 and the pharmacy's personnel as required by § 54.1-3432. 510

"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, 511 512 licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified 513 optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, 514 or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and 515 administer, or conduct research with respect to a controlled substance in the course of professional 516 practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue 517 518 a prescription.

519 "Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word 520 of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed 521 physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such 522 drugs or medical supplies.

523 "Prescription drug" means any drug required by federal law or regulation to be dispensed only 524 pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of 525 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 526 527 controlled substance or marijuana.

528 "Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, 529 original package which does not contain any controlled substance or marijuana as defined in this chapter 530 and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general 531 public by or under the authority of the manufacturer or primary distributor, under a trademark, trade 532 name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of 533 this chapter and applicable federal law. However, this definition shall not include a drug that is only 534 advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, 535 a drug that may be dispensed only upon prescription or the label of which bears substantially the 536 statement "Warning — may be habit-forming," or a drug intended for injection.

537 "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei 538 with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or 539 radionuclide generator that is intended to be used in the preparation of any such substance, but does not 540 include drugs such as carbon-containing compounds or potassium-containing salts that include trace 541 quantities of naturally occurring radionuclides. The term also includes any biological product that is 542 labeled with a radionuclide or intended solely to be labeled with a radionuclide.

543 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. 544 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food 545 and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k). 546

547 "Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any 548 person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active 549 550 ingredients and are identical in strength or concentration, dosage form, and route of administration and

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that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration 551 pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent 552 553 edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as 554 the "Orange Book."

555 "Third-party logistics provider" means a person that provides or coordinates warehousing of or other 556 logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale 557 distributor, or dispenser of the drug or device but does not take ownership of the product or have 558 responsibility for directing the sale or disposition of the product. 559

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

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party 560 logistics provider, engaged in the business of (i) selling or otherwise distributing prescription drugs or 561 devices to any person who is not the ultimate user or consumer and (ii) delivering Schedule VI 562 563 prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1. No person shall be subject to any state or local tax by reason of this definition. 564

'Wholesale distribution" means (i) distribution of prescription drugs to persons other than consumers 565 566 or patients and (ii) delivering Schedule VI prescription devices to the ultimate user or consumer 567 pursuant to § 54.1-3415.1, subject to the exemptions set forth in the federal Drug Supply Chain 568 Security Act.

569 "Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed 570 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 571 572 shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses 573 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. 574 575 § 54.1-3415.1. Delivery of medical devices on behalf of a medical equipment supplier. 576

577 A permitted manufacturer, wholesale distributor, warehouser, or third-party logistics provider or 578 registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI 579 prescription devices directly to an ultimate consumer on behalf of a medical equipment supplier, home 580 health agency, hospice, pharmacy, nursing home, or assisted living facility, provided that (i) such 581 delivery occurs at the direction of a medical equipment supplier, home health agency, hospice, 582 pharmacy, nursing home, or assisted living facility that has received a valid order for such prescription 583 device for the patient from a prescriber and (ii) the manufacturer, nonresident manufacturer, wholesale **584** distributor, nonresident wholesale distributor, warehouser, or third-party logistics provider has entered 585 into an agreement with the medical equipment supplier, home health agency, hospice, pharmacy, nursing 586 home, or assisted living facility for such delivery.

587 2. That the Board of Pharmacy (Board) shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulations shall include 588 589 provisions governing agreements between a manufacturer, nonresident manufacturer, wholesale 590 distributor, nonresident wholesale distributor, warehouser, or third-party logistics provider and a 591 medical equipment supplier, home health agency, hospice, pharmacy, nursing home, or assisted 592 living facility for delivery of Schedule VI prescription devices directly to an ultimate user or 593 patient and such other provisions as the Board may deem appropriate.