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## SENATE BILL NO. 413

AMENDMENT IN THE NATURE OF A SUBSTITUTE  
(Proposed by the Senate Committee on Education and Health  
on January 18, 2018)

(Patron Prior to Substitute—Senator McDougle)

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 Schedule VI prescription devices.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3401, as it is currently effective and as it shall become effective, of the Code of Virginia is amended and reenacted and the Code of Virginia is amended by adding a section numbered 54.1-3415.1 as follows:

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

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

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

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a

60 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by  
61 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or  
62 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in  
63 expectation of receiving a valid prescription based on observed historical patterns of prescribing and  
64 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as  
65 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the  
66 course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or  
67 chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a  
68 manufacturer's product drugs for the purpose of administration to a patient, when performed by a  
69 practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person  
70 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised  
71 by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of  
72 § 54.1-2901 shall not be considered compounding.

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

78 "Controlled substance analog" means a substance the chemical structure of which is substantially  
79 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a  
80 stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar  
81 to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a  
82 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person  
83 represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous  
84 system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect  
85 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance  
86 analog" does not include (a) any substance for which there is an approved new drug application as  
87 defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally  
88 recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and  
89 Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular  
90 person, any substance for which an exemption is in effect for investigational use for that person under  
91 § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that  
92 substance is pursuant to such exemption; or (c) any substance to the extent not intended for human  
93 consumption before such an exemption takes effect with respect to that substance.

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

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

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

105 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified  
106 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01  
107 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner,  
108 physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis  
109 treatments in a Medicare-certified renal dialysis facility.

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a

controlled substance or marijuana.

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

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

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

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

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

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

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

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

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

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

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

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter 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.**

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

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

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

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

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

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

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

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

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

323 "Board" means the Board of Pharmacy.

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

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

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

340 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a  
341 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by  
342 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or  
343 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in  
344 expectation of receiving a valid prescription based on observed historical patterns of prescribing and  
345 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as  
346 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the  
347 course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or  
348 chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a  
349 manufacturer's product drugs for the purpose of administration to a patient, when performed by a  
350 practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person  
351 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised  
352 by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of  
353 § 54.1-2901 shall not be considered compounding.

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

359 "Controlled substance analog" means a substance the chemical structure of which is substantially  
360 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a  
361 stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar  
362 to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a  
363 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person  
364 represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous  
365 system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect  
366 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance  
367 analog" does not include (a) any substance for which there is an approved new drug application as

defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

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

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability

429 pursuant to 42 U.S.C. § 262(k)(4).

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

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

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

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

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

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

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

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

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

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

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

488 "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to  
489 morphine or being capable of conversion into a drug having such addiction-forming or  
490 addiction-sustaining liability. It does not include, unless specifically designated as controlled under



Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

552 the "Orange Book."

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

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

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

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

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

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

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

574 **§ 54.1-3415.1. Delivery of medical devices on behalf of a medical equipment supplier.**

575 A. A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party  
576 logistics provider, or nonresident third-party logistics provider or registered nonresident manufacturer  
577 or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate  
578 user or consumer on behalf of a medical equipment supplier provided that (i) such delivery occurs at  
579 the direction of a medical equipment supplier that has received a valid order from a prescriber  
580 authorizing the dispensing of such prescription device to the ultimate user or consumer and (ii) the  
581 manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor,  
582 warehouser, nonresident warehouser, third-party logistics provider or nonresident third-party logistics  
583 provider has entered into an agreement with the medical equipment supplier for such delivery.

584 B. A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party  
585 logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer  
586 or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate  
587 user's or consumer's residence to be administered by persons authorized to administer such devices,  
588 provided that (i) such delivery is made on behalf of a medical director of a home health agency,  
589 nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI  
590 prescription device and directs the delivery of such device to the ultimate user's or consumer's residence  
591 and (ii) the medical director on whose behalf such Schedule VI prescription device is being delivered  
592 has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor,  
593 nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or  
594 nonresident third-party logistics provider for such delivery.

595 **2. That the Board of Pharmacy (the Board) shall promulgate regulations to implement the**  
596 **provisions of this act to be effective within 280 days of its enactment. Such regulations shall**  
597 **include provisions governing agreements between a manufacturer, nonresident manufacturer,**  
598 **wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouse, third**  
599 **party logistics provider, or nonresident third-party logistics provider and a medical equipment**  
600 **supplier, home health agency, hospice, pharmacy, nursing home, or assisted living facility for**  
601 **delivery of Schedule VI prescription devices directly to an ultimate user or consumer and such**  
602 **other provisions as the Board may deem appropriate.**