Chapter 34 of Title 54.1 of the Code of Virginia

The Drug Control Act

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Article 1. General Provisions.

§ 54.1-3400. Citation.

This chapter may be cited as "The Drug Control Act."

1970, c. 650, § 54-524.1; 1988, c. 765.

§ 54.1-3401. 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 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed advanced nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

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

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

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

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

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

"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, an advanced practice registered nurse, a 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.

"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, its resin, or any extract containing one or more cannabinoids. "Marijuana" does not include (i) 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; (ii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent; (iii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990; (iv) a hemp product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined in § 3.2-5145.1; or (vi) any substance containing a tetrahydrocannabinol isomer, ester, ether, salt, or salts of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act (§ 54.1-3400 et seq.) pursuant to § 54.1-3443.

"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 advanced practice registered nurse 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.

"Tetrahydrocannabinol" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of this definition, "isomer" means the optical, position, and geometric isomers.

"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.

"Total tetrahydrocannabinol" means the sum, after the application of any necessary conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of tetrahydrocannabinolic acid.

"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.

Code 1950, §§ 54-399, 54-487; 1952, c. 451; 1958, c. 551, § 54-524.2; 1966, c. 193; 1968, c. 582; 1970, c. 650; 1971, Ex. Sess., c. 94; 1972, c. 798; 1975, c. 425; 1976, c. 14; 1977, c. 193; 1978, c. 833; 1979, c. 435; 1980, c. 150; 1988, c. 765; 1991, cc. 519, 524; 1992, cc. 737, 793; 1996, cc. 37, 152, 158, 407, 408; 1997, cc. 20, 677, 806; 1998, c. 470; 1999, cc. 661, 750; 2000, cc. 861, 878, 935; 2003, cc. 509, 639, 995; 2005, cc. 475, 839; 2006, c. 346; 2012, c. 213; 2013, cc. 412, 504, 544, 765; 2014, cc. 674, 719; 2015, cc. 158, 180, 300; 2016, cc. 221, 495; 2017, cc. 115, 429; 2018, cc. 241, 242, 689, 690; 2019, cc. 653, 654; 2020, cc. 831, 1285, 1286; 2021, Sp. Sess. I, c. 110; 2023, cc. 183, 744, 794.

§ 54.1-3401.1. Repealed.

Repealed by Acts 2016, c. 221, cl. 2.

§ 54.1-3402. Repealed.

Repealed by Acts 2003, c. 509.

§ 54.1-3403. Chapter not applicable to economic poisons.

This chapter shall not be construed to apply (i) to poisons used for the control of insects, animal pests, weeds, fungus diseases or other substances sold for use in agricultural, horticultural or related arts and sciences when such substances which are poisons within the meaning of this chapter are sold in original unbroken packages bearing a label having plainly printed upon it the name of the contents and the word POISON and an effective antidote or (ii) to any person, persons, corporations or associations engaged in the business of selling, making, compounding

or manufacturing industrial chemicals for distribution or sale at wholesale or for making, compounding or manufacturing other products.

Code 1950, § 54-403.1; 1958, c. 551; 1970, c. 650, § 54-524.4; 1988, c. 765.

§ 54.1-3404. Inventories of controlled substances required of certain persons; contents and form of record.

A. Except as set forth in subsection G, every person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business. If there are no controlled substances on hand at that time, he shall record this fact as part of the inventory. An inventory taken by use of an oral recording device shall be promptly reduced to writing and maintained in a written, typewritten or printed form. Such inventory shall be made either as of the opening of business or as of the close of business on the inventory date.

B. After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.

C. The record of such drugs received shall in every case show the date of receipt, the name and address of the person from whom received and the kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture, and the date of such production or removal from process of manufacture. The record shall in every case show the proportion of morphine, cocaine, or ecgonine contained in or producible from crude opium or coca leaves received or produced.

D. The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were sold, administered or dispensed, and the kind and quantity of drugs. Any person selling, administering, dispensing or otherwise disposing of such drugs shall make and sign such record at the time of each transaction. The keeping of a record required by or under the federal laws, containing substantially the same information as is specified above, shall constitute compliance with this section, except that every such record shall contain a detailed list of any drugs lost, destroyed or stolen, the kind and quantity of such drugs, and the date of the discovery of such loss, destruction or theft. The form of records shall be prescribed by the Board.

E. Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs.

Within 30 days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.

F. All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded.

G. Each person authorized to conduct chemical analyses using controlled substances in the Department of Forensic Science shall comply with the inventory requirements set forth in subsections A through F; however, the following substances shall not be required to be included in such inventory: (i) controlled substances on hand at the time of the inventory in a quantity of less than one kilogram, other than a hallucinogenic controlled substance listed in Schedule I of this chapter; or (ii) hallucinogenic controlled substances, other than lysergic acid diethylamide, on hand at the time of the inventory in a quantity of less than 20 grams; or (iii) lysergic acid diethylamide on hand at the time of the inventory in a quantity of less than 0.5 grams. Further, no inventory shall be required of known or suspected controlled substances that have been received as evidentiary materials for analyses by the Department of Forensic Science.

1970, c. 650, § 54-524.56; 1972, c. 798; 1978, c. 833; 1979, c. 435; 1980, c. 203; 1982, c. 278; 1988, c. 765; 1998, c. 105; 2004, c. 51; 2005, cc. 868, 881.

§ 54.1-3405. Access to and copies of records; inspections.

Every person required to prepare or obtain, and keep, records, and any carrier maintaining records with respect to any shipment containing any drug, and every person in charge or having custody of such records shall, upon request of an agent designated by the Board, permit such agent at reasonable times to have access to and copy such records.

Any agent designated by the Superintendent of the Department of State Police to conduct drug diversion investigations shall, for the purpose of such investigations, also be permitted access at reasonable times to all such records relevant to a specific investigation and be allowed to inspect and copy such records. However, agents designated by the Superintendent of the Department of State Police to conduct drug diversion investigations shall not copy and remove patient records unless such patient records are relevant to a specific investigation. Any agent designated by the Superintendent of the Department of State Police shall allow the person or carrier maintaining such records, or agent thereof, to examine any copies of records before their removal from the premises. If the agent designated by the Superintendent of State Police copies records on magnetic storage media, he will deliver a duplicate of the magnetic storage media on which the copies are stored to the person or carrier maintaining such records or an agent thereof, prior to removing the copies from the premises. If the original of any record is removed by any agent designated by the Superintendent of State Police, a receipt therefor shall be left with the person or carrier maintaining such records or an agent thereof, and a copy of the removed record shall be provided the person or carrier maintaining such records within a reasonable time thereafter.

For the purposes of verification of such records and of enforcement of this chapter, agents designated by the Board or by the Superintendent are authorized, upon presenting appropriate credentials to the owner, operator, or agent in charge, to enter, at reasonable times, any factory,

warehouse, establishment, or vehicle in which any drug is held, manufactured, compounded, processed, sold, delivered, or otherwise disposed of; and to inspect, within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished material, containers and labeling, including records, files, papers, processes, controls, and facilities, bearing on violation of this chapter; and to inventory and obtain samples of any stock of any drugs.

If a sample of any drug is obtained, the agent making the inspection shall, upon completion of the inspection and before leaving the premises, give to the owner, operator, or agent in charge a receipt describing the sample. No inspection shall extend to financial data, sales data other than shipment data, pricing data, personnel data or research data.

Any information obtained by a designated State Police agent during an inspection under this section which constitutes evidence of a violation of any provision of this chapter shall be reported to the Department of Health Professions upon its discovery.

Any information obtained by an agent designated by the Board during an inspection under this section which constitutes evidence of a violation of Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2 shall be reported to the Department of State Police upon its discovery.

1970, c. 650, § 54-524.57; 1988, cc. 266, 765; 1992, cc. 743, 808.

§ 54.1-3406. Records confidential; disclosure of information about violations of federal law.

A. No agent of the Board or agent designated by the Superintendent of the Department of State Police having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a criminal investigation authorized by the Attorney General or attorney for the Commonwealth or with a prosecution or proceeding in court or before a regulatory board or officer, to which investigation, prosecution or proceeding the person to whom such prescriptions, papers or records relate is a subject or party. This section shall not be construed to prohibit the Board president or his designee and the Director of the Department of Health Professions from discharging their duties as provided in this title.

B. Notwithstanding the provisions of § 54.1-2400.2, the Board shall have the authority to submit to the U.S. Secretary of Health and Human Services information resulting from an inspection or an investigation indicating that a compounding pharmacy or outsourcing facility may be in violation of federal law or regulations with the exception of compounding for office-based administration in accordance with § 54.1-3410.2.

Code 1950, § 54-512; 1970, c. 650; 1983, c. 528, § 54-524.58; 1988, cc. 266, 765; 2015, c. 300.

§ 54.1-3407. Analysis of controlled substances.

A licensed physician or pharmacist may receive controlled substances from or on behalf of a patient for qualitative or quantitative analysis purposes only, without an official order form, if

within twenty-four hours of its receipt the physician or pharmacist mails or delivers the entire sample to a laboratory operated by the Commonwealth and designated by the Board to receive such substances. If the sample is mailed, it shall be sent by registered or certified mail, postage prepaid, with return receipt requested. If personally delivered, a receipt shall be obtained from such laboratory. All receipts or returns shall be kept on file for three years and shall be available for inspection by the Board at any reasonable time.

1972, c. 798, § 54-524.59:1; 1988, c. 765.

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed advanced practice registered nurse pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice. A licensed midwife pursuant to § 54.1-2957.7 shall only obtain, possess, and administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:
1. A nurse, physician assistant, or intern under his direction and supervision;
2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;
3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol;
4. Persons who are employed or engaged at a medical care facility, as defined in § 32.1-3, who have a valid emergency medical services provider certification issued by the Board of Health as a requirement of being employed or engaged at the medical care facility within the scope of such certification, pursuant to an oral or written order or standing protocol to administer drugs and devices at the medical care facility; or
5. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed

practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.
Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.
Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, licensed athletic trainer under contract with a local school division, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a public place, as defined in § 15.2-2820, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen and IV saline for use in emergency situations; subcutaneous lidocaine for wound closure; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of

those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by

the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.
Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.
In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued

competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, a licensed practical nurse, an advanced practice registered nurse, a physician assistant, a doctor of medicine or osteopathic medicine, or a pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely

administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, an advanced practice registered nurse, or a physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered

nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated by the Director of the Department of Corrections or designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers, employees of regional jails, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, other school board employees or individuals contracted by a school board to provide school health services, and firefighters may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, any person may possess and administer naloxone or other opioid antagonist used for overdose reversal, other than naloxone in an injectable formulation with a hypodermic needle or syringe, in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may dispense naloxone, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board

of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Code 1950, § 54-497; 1956, c. 225; 1970, c. 650, § 54-524.65; 1973, c. 468; 1976, cc. 358, 614; 1977, c. 302; 1978, c. 224; 1980, cc. 270, 287; 1983, cc. 456, 528; 1984, cc. 141, 555; 1986, c. 81; 1987, c. 226; 1988, c. 765; 1990, c. 309; 1991, cc. 141, 519, 524, 532; 1992, cc. 610, 760, 793; 1993, cc. 15, 810, 957, 993; 1994, c. 53; 1995, cc. 88, 529; 1996, cc. 152, 158, 183, 406, 408, 490; 1997, cc. 272, 566, 806, 906; 1998, c. 112; 1999, c. 570; 2000, cc. 135, 498, 861, 881, 935; 2003, cc. 465, 497, 515, 794, 995, 1020; 2005, cc. 113, 610, 924; 2006, cc. 75, 432, 686, 858; 2007, cc. 17, 699, 702, 783; 2008, cc. 85, 694; 2009, cc. 48, 110, 506, 813, 840; 2010, cc. 179, 245, 252; 2011, c. 292; 2012, cc. 787, 803, 833, 835; 2013, cc. 114, 132, 183, 191, 252, 267, 328, 336, 359, 617; 2014, cc. 88, 491; 2015, cc. 302, 387, 502, 503, 514, 725, 732, 752; 2016, c. 144; 2017, cc. 3, 55, 107, 168, 174, 182, 294, 304, 713; 2018, cc. 62, 247; 2019, cc. 87, 212, 221, 431; 2020, cc. 39, 302, 459, 460, 556, 560, 853, 860, 861, 924, 927, 1095; 2021, Sp. Sess. I, cc. 181, 200, 201, 508; 2022, cc. 695, 696, 733, 774; 2023, cc. 115, 116, 183, 267, 569, 631, 673, 674, 729.

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If the prescriber is providing expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, then "Expedited Partner Therapy" or "EPT" shall be affixed on the written prescription, in lieu of the contact patient's name and address. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

2000, cc. 135, 861; 2002, c. 411; 2003, c. 639; 2006, c. 195; 2009, cc. 813, 840; 2020, c. 464.

§ 54.1-3408.02. Transmission of prescriptions.

A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions.

B. Any prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription.

C. The requirements of subsection B shall not apply if:

1. The prescriber dispenses the controlled substance that contains an opioid directly to the patient or the patient's agent;

2. The prescription is for an individual who is residing in a hospital, assisted living facility, nursing home, or residential health care facility or is receiving services from a hospice provider or outpatient dialysis facility;

3. The prescriber experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided that the prescriber documents the reason for this exception in the patient's medical record;

4. The prescriber issues a prescription to be dispensed by a pharmacy located on federal property, provided that the prescriber documents the reason for this exception in the patient's medical record;

5. The prescription is issued by a licensed veterinarian for the treatment of an animal;

6. The FDA requires the prescription to contain elements that are not able to be included in an electronic prescription;

7. The prescription is for an opioid under a research protocol;

8. The prescription is issued in accordance with an executive order of the Governor of a declared emergency;

9. The prescription cannot be issued electronically in a timely manner and the patient's condition is at risk, provided that the prescriber documents the reason for this exception in the patient's medical record; or

10. The prescriber has been issued a waiver pursuant to subsection D.

D. The licensing health regulatory board of a prescriber may grant such prescriber, in accordance with regulations adopted by such board, a waiver of the requirements of subsection B, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

2000, c. 878; 2017, cc. 115, 429; 2019, c. 664.

§ 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted.

A. A pharmacist may dispense a therapeutically equivalent drug product for a prescription that is written for a brand-name drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product.

In the case of an oral prescription, the prescriber's oral dispensing instructions regarding substitution shall be followed.

B. Prescribers using prescription blanks printed in compliance with Virginia law in effect on June 30, 2003, having two check boxes and referencing the Virginia Voluntary Formulary, may indicate, until July 1, 2006, that substitution is not authorized by checking the "Dispense as Written" box. If the "Voluntary Formulary Permitted" box is checked on such prescription blanks or if neither box is checked, a pharmacist may dispense a therapeutically equivalent drug product pursuant to such prescriptions.

C. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so inform the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his permanent record and the prescription label, the brand name or, in the case of a therapeutically equivalent drug product, the name of the manufacturer or the distributor. Whenever a pharmacist dispenses a therapeutically equivalent drug product pursuant to a prescription written for a brand-name product, the pharmacist shall label the drug with the name of the therapeutically equivalent drug product followed by the words "generic for" and the brand name of the drug for which the prescription was written.

D. When a pharmacist dispenses a drug product other than the drug product prescribed, the dispensed drug product shall be at a lower retail price than that of the drug product prescribed. Such retail price shall not exceed the usual and customary retail price charged by the pharmacist for the dispensed therapeutically equivalent drug product.

2003, c. 639.

§ 54.1-3408.04. Dispensing of interchangeable biosimilars permitted.

A. A pharmacist may dispense a biosimilar that has been licensed by the U.S. Food and Drug Administration as interchangeable with the prescribed product unless (i) the prescriber indicates such substitute is not authorized by specifying on the prescription "brand medically necessary" or (ii) the patient insists on the dispensing of the prescribed biological product. In the case of an oral prescription, the prescriber's oral dispensing instructions regarding dispensing of an interchangeable biosimilar shall be followed. No pharmacist shall dispense a biosimilar in place of a prescribed biological product unless the biosimilar has been licensed as interchangeable with the prescribed biological product by the U.S. Food and Drug Administration.

B. When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall inform the patient prior to dispensing the interchangeable biosimilar. The pharmacist or his designee shall also indicate, unless otherwise directed by the prescriber, on both the record of dispensing and the prescription label, the brand name or, in the case of an interchangeable biosimilar, the product name and the name of the manufacturer or distributor of the interchangeable biosimilar. Whenever a pharmacist substitutes an interchangeable biosimilar pursuant to a prescription written for a brand-name product, the pharmacist or his designee shall label the drug with the name of the interchangeable biosimilar followed by the words "Substituted for" and the name of the biological product for which the prescription was written. Records of substitutions of interchangeable biosimilars shall be maintained by the pharmacist and the prescriber for a period of not less than two years from the date of dispensing.

C. [Expired]

D. [Expired]

2013, cc. 412, 544.

§ 54.1-3408.05. Use of FDA-approved substance upon publication of final rule.

Except as otherwise provided in this chapter, no person shall be prosecuted under Chapter 7 (§ 18.2-247 et seq.) of Title 18.2 for acting in accordance with § 54.1-3421 or for prescribing, administering, dispensing, or possessing pursuant to a valid prescription issued by a prescriber any substance that has been approved as a prescription drug by the U.S. Food and Drug Administration pursuant to 21 U.S.C. § 360bb and 21 U.S.C. § 355 on or after July 1, 2017, in accordance with any final or interim final order or rule issued pursuant to 21 U.S.C. § 811(j). Such immunity from prosecution for a particular substance shall remain in effect until the earlier of (i) nine months as calculated from the latter of the date of the publication in the Federal Register of the interim final order or rule scheduling such substance or the final order or rule scheduling such substance, provided that a final order or rule is issued within nine months of the interim final order or rule, or (ii) such substance being added to a schedule in Article 5 (§ 54.1-3443 et seq.) pursuant to § 54.1-3443 or by enactment into law.

2017, cc. 416, 432.

§ 54.1-3408.1. Prescription in excess of recommended dosage in certain cases.

In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes.

Nothing in this section shall be construed to grant any person immunity from investigation or disciplinary action based on the prescription, dispensing or administration of an excess dosage in violation of this title.

1988, c. 870, § 54-524.65:1; 1990, c. 681; 1995, c. 277.

§ 54.1-3408.2. Failure to report administration or dispensing of or prescription for controlled substances; report required; penalty.

Any person authorized to prescribe, dispense, or administer controlled substances pursuant to § 54.1-3408 who has reason to suspect that a person has obtained or attempted to obtain a controlled substance or prescription for a controlled substance by fraud or deceit, may report the activity to the local law-enforcement agency for investigation. Any person who, in good faith, makes a report or furnishes information or records to a law-enforcement officer or entity pursuant to this section shall not be liable for civil damages in connection with making such report or furnishing such information or records.

2010, c. 185.

§ 54.1-3408.3. (Effective until January 1, 2024) Certification for use of cannabis products for treatment.

A. As used in this section:

"Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same parts of the same chemovar of cannabis plant.

"Cannabis dispensing facility" means the same as that term is defined in § 54.1-3442.5.

"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include industrial hemp extracts, including isolates and distillates, acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains, except as otherwise provided in Article 4.2 (§ 54.1-3442.5 et seq.), no more than 10 milligrams of tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, handled, or processed in compliance with state or federal law, unless it has been grown and processed in the Commonwealth by a registered industrial hemp processor and acquired and formulated by a pharmaceutical processor.

"Cannabis product" means a product that (i) is formulated with cannabis oil or botanical cannabis; (ii) is produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility; (iii) is registered with the Board; (iv) contains, except as otherwise provided in Article 4.2 (§ 54.1-3442.5 et seq.), no more than 10 milligrams of tetrahydrocannabinol per dose; and (v) is compliant with testing requirements.

"Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home health services, private provider licensed by the Department of Behavioral Health and Developmental Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility licensed pursuant to § 63.2-1701, or adult day care center licensed pursuant to § 63.2-1701.

"Pharmaceutical processor" means the same as that term is defined in § 54.1-3442.5.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or an advanced practice registered nurse jointly licensed by the Board of Medicine and the Board of Nursing.

"Registered agent" means an individual (i) designated by a patient who has been issued a written certification, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and (ii) registered with the Board or listed on the patient's written certification pursuant to subsection G.

"Usable cannabis" means any cannabis plant material, including seeds, but not (i) resin that has been extracted from any part of the cannabis plant, its seeds, or its resin; (ii) the mature stalks, fiber produced from the stalks, or any other compound, manufacture, salt, or derivative, mixture, or preparation of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine, provided that the use of telemedicine includes the delivery of patient care through real-time interactive audio-visual technology. No practitioner may issue a written certification while such practitioner is on the premises of a pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor shall not endorse or promote any practitioner who issues certifications to patients. If a practitioner determines it is consistent with the standard of care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such dispensing. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing. A practitioner who issues written certifications shall not directly or indirectly accept, solicit, or receive anything of value from a pharmaceutical processor, cannabis dispensing facility, or any person associated with a

pharmaceutical processor, cannabis dispensing facility, or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabis products.

C. The written certification shall be on a form provided by the Board of Pharmacy. Such written certification shall contain the name, address, and telephone number of the practitioner; the name and address of the patient issued the written certification; the date on which the written certification was made; and the signature or authentic electronic signature of the practitioner. Such written certification issued pursuant to subsection B shall expire one year after its issuance unless the practitioner provides in such written certification an earlier expiration. A written certification shall not be issued to a patient by more than one practitioner during any given time period.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for the issuance of a certification for the use of cannabis products for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude a practitioner's professional licensing board from sanctioning the practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section (i) shall hold sufficient education and training to exercise appropriate professional judgment in the certification of patients; (ii) shall not offer a discount or any other thing of value to a patient or a patient's parent, guardian, or registered agent that is contingent on or encourages the person's decision to use a particular pharmaceutical processor or cannabis product; (iii) shall not issue a certification to himself or his family members, employees, or coworkers; (iv) shall not provide product samples containing cannabis other than those approved by the U.S. Food and Drug Administration; and (v) shall not accept compensation from a pharmaceutical processor or cannabis dispensing facility. The Board shall not limit the number of patients to whom a practitioner may issue a written certification. The Board may report information to the applicable licensing board on unusual patterns of certifications issued by a practitioner.

F. No patient shall be required to physically present the written certification after the initial dispensing by any pharmaceutical processor or cannabis dispensing facility under each written certification, provided that the pharmaceutical processor or cannabis dispensing facility maintains an electronic copy of the written certification. Pharmaceutical processors and cannabis dispensing facilities shall electronically transmit, on a monthly basis, all new written certifications received by the pharmaceutical processor or cannabis dispensing facility to the Board.

G. A patient, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes of receiving cannabis products pursuant to a valid written certification. Such designated individual shall register with the Board unless the individual's name is listed on the patient's written certification. An individual may, on the basis of medical need and in the discretion of the patient's registered practitioner, be listed on the patient's written certification

upon the patient's request. The Board may set a limit on the number of patients for whom any individual is authorized to act as a registered agent.

H. Upon delivery of a cannabis product by a pharmaceutical processor or cannabis dispensing facility to a designated caregiver facility, any employee or contractor of a designated caregiver facility, who is licensed or registered by a health regulatory board and who is authorized to possess, distribute, or administer medications, may accept delivery of the cannabis product on behalf of a patient or resident for subsequent delivery to the patient or resident and may assist in the administration of the cannabis product to the patient or resident as necessary.

I. Information obtained under the patient certification or agent registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed practitioners or pharmacists, or their agents, for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a patient, (iv) a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a patient, or (v) a registered agent, but only with respect to information related to such patient.

2015, cc. 7, 8; 2017, c. 613; 2018, cc. 246, 809; 2019, cc. 653, 654, 681, 690; 2020, cc. 730, 831, 928, 1278; 2021 Sp. Sess. I, cc. 205, 227, 228; 2022, cc. 259, 391, 392, 642; 2023, cc. 183, 744, 760, 780, 794, 799.

§ 54.1-3408.3. (Effective January 1, 2024) Certification for use of cannabis for treatment

A. As used in this section, "botanical cannabis," "cannabis oil," "cannabis product," and "practitioner" mean the same as those terms are defined in § 4.1-1600.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use in accordance with the provisions of § 4.1-1601.

2015, cc. 7, 8; 2017, c. 613; 2018, cc. 246, 809; 2019, cc. 653, 654, 681, 690; 2020, cc. 730, 831, 928, 1278; 2021 Sp. Sess. I, cc. 205, 227, 228; 2022, cc. 259, 391, 392, 642; 2023, cc. 183, 740, 744, 760, 773, 780, 794, 799.

§ 54.1-3408.5. Epinephrine required in certain public places.

Every public place, as defined in § 15.2-2820, may make epinephrine available for administration. Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice and in accordance with policies and guidelines established by the Department of Health, any employee of a public place, as defined in § 15.2-2820, who is authorized by a prescriber and trained in the administration of epinephrine may possess and

administer epinephrine to a person present in the public place believed in good faith to be having an anaphylactic reaction.

2020, c. 556.

§ 54.1-3409. Professional use by veterinarians.

A veterinarian may not prescribe controlled substances for human use and shall only prescribe, dispense or administer a controlled substance in good faith for use by animals within the course of his professional practice. He may prescribe, on a written prescription or on oral prescription as authorized by § 54.1-3410. He may administer drugs, and he may cause them to be administered by an assistant or orderly under his direction and supervision. Such a prescription shall be dated and signed by the person prescribing on the day when issued, and shall bear the full name and address of the owner of the animal, and the species of the animal for which the drug is prescribed and the full name, address and registry number, under the federal laws of the person prescribing, if he is required by those laws to be so registered.

Code 1950, § 54-498; 1956, c. 225; 1970, c. 650, § 54-524.66; 1983, c. 528; 1988, c. 765.

§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed. If the prescription is for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, the prescription shall state "Expedited Partner Therapy" or "EPT" in lieu of the full name and address of the contact patient.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section. However, if the pharmacist dispenses a Schedule III through VI drug or device for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, the prescription shall state "Expedited Partner Therapy" or "EPT" in lieu of the full name and address of the contact patient.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.

If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy. If the prescription is for a Schedule VI drug or device for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, then labeling the name and address of the contact patient is not required.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

E. A dispenser who receives a non-electronic prescription for a controlled substance containing an opioid is not required to verify that one of the exceptions set forth in § 54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and applicable law.

1970, c. 650, § 54-524.67; 1972, c. 798; 1976, c. 614; 1977, c. 302; 1983, cc. 395, 612; 1988, c. 765; 1996, c. 408; 2003, c. 511; 2017, cc. 115, 429; 2019, c. 664; 2020, c. 464.

§ 54.1-3410.1. Requirements for radiopharmaceuticals.

A. A pharmacist who is authorized by the Board and acting in good faith, may sell and dispense radiopharmaceuticals pursuant to the order of a physician who is authorized by state or federal law to possess and administer radiopharmaceuticals for the treatment or diagnosis of disease.

B. When an authorized nuclear pharmacist dispenses a radioactive medical material, he shall assure that the outer container (shield) of the radiopharmaceutical shall bear the following information:

1. The name and address of the nuclear pharmacy;

2. The name of the prescriber (authorized user);

3. The date of dispensing;

4. The serial number assigned to the radiopharmaceutical order;

5. The standard radiation symbol;

6. The name of the diagnostic procedure;

7. The words "Caution: Radioactive Material";

8. The name of the radionuclide;

9. The amount of radioactivity and the calibration date and time;

10. The expiration date and time;

11. In the case of a diagnostic radiopharmaceutical, the patient's name or the words "Per Physician's Order"; and

12. In the case of a therapeutic radiopharmaceutical, the patient's name.

C. Orders for radiopharmaceuticals, whether written or verbal, shall include at least the following information:

1. The name of the institution or facility and the name of the person transmitting the order;

2. The date that the radiopharmaceutical will be needed and the calibration time;

3. The name or generally recognized and accepted abbreviation of the radiopharmaceutical;

4. The dose or activity of the radiopharmaceutical at the time of calibration; and

5. In the case of a therapeutic radiopharmaceutical or a radiopharmaceutical blood product, the name of the patient shall be obtained prior to dispensing.

2000, c. 861.

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.

Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA; and

2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been

found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product; or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is

difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304, and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

2003, c. 509; 2005, c. 200; 2012, c. 173; 2013, c. 765; 2014, c. 147; 2015, c. 300; 2016, c. 221.

§ 54.1-3411. When prescriptions may be refilled.

Prescriptions may be refilled as follows:

1. A prescription for a drug in Schedule II may not be refilled.

2. A prescription for a drug in Schedules III or IV may not be filled or refilled more than six months after the date on which such prescription was issued and no such prescription may be authorized to be refilled, nor be refilled, more than five times, except that any prescription for such a drug after six months from the date of issue, or after being refilled five times, may be renewed by the prescriber issuing it either in writing, or orally, if promptly reduced to writing and filed by the pharmacist filling it.

3. A prescription in Schedule VI may not be refilled unless authorized by the prescriber either on the face of the original prescription or orally by the prescriber except as provided in subdivision 4. Oral instructions shall be reduced promptly to writing by the pharmacist and filed on or with the original prescription.

4. A prescription for a drug controlled by Schedule VI, including insulin, may be refilled without authorization from the prescriber if reasonable effort has been made to communicate with the

prescriber, and the pharmacist has determined that he is not available and the patient's health would be in imminent danger without the benefits of the drug. Authorization to refill under this subdivision also exists when the pharmacist only has access to the label on a prescription container. The pharmacist shall inform the patient of the prescriber's unavailability and that the refill is being made without his authorization. The pharmacist shall promptly inform the prescriber of such refill. The date and quantity of the refill, the prescriber's unavailability, and the rationale for the refill shall be noted on the reverse side of the prescription.

1970, c. 650, § 54-524.68; 1972, c. 798; 1976, c. 614; 1983, c. 395; 1988, c. 765; 1996, c. 408; 2023, c. 341.

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:

1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;

2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or

3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.

B. The Board shall promulgate regulations to establish a prescription drug donation program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in subdivision A 2, for the purpose of re-dispensing such drugs to indigent patients, either through hospitals or through clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured. Such program shall accept eligible prescription drugs from individuals, including those residing in nursing homes, assisted living facilities, or intermediate care facilities established for individuals with intellectual disability (ICF/IID), licensed hospitals, or any facility operated by the Department of Behavioral Health and Developmental Services. Additionally, such program shall accept eligible prescription drugs from an agent pursuant to a power of attorney, a decedent's personal representative, a legal guardian of an incapacitated person, or a guardian ad litem donated on behalf of the represented individual.

C. Unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, may be donated pursuant to this section unless such donation is prohibited.

D. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient or any other activity undertaken in accordance with a drug distribution program established pursuant to this section.

E. Nothing in this section shall be construed to create any new or additional liability, or to abrogate any liability that may exist, applicable to a pharmaceutical manufacturer for its products separately from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient in accordance with a drug distribution program established pursuant to this section.

F. In the absence of bad faith or gross negligence, no person that donates, accepts, or dispenses unused prescription drugs in accordance with this section and Board regulations shall be subject to criminal or civil liability for matters arising from the donation, acceptance, or dispensing of such unused prescription drugs.

2002, c. 632; 2005, c. 68; 2008, c. 429; 2009, cc. 109, 114; 2018, c. 376.

§ 54.1-3411.2. Prescription drug disposal programs.

A. As used in this section:

"Authorized pharmacy disposal site" means a pharmacy that qualifies as a collection site pursuant to 21 C.F.R § 1317.40.

"Pharmacy drug disposal program" means any voluntary drug disposal program located at or operated in accordance with state and federal law by a pharmacy.

B. A pharmacy may participate in a pharmacy drug disposal program in accordance with state and federal law regarding proper collection, storage, and destruction of prescription drugs, including controlled and noncontrolled substances. A pharmacy that chooses to participate in a pharmacy drug disposal program shall notify the Board, and the Board shall maintain a list of all pharmacies in the Commonwealth that have chosen to participate in a pharmacy drug disposal program on a website maintained by the Board.

C. No person that participates in a pharmacy drug disposal program shall be liable for any theft, robbery, or other criminal act related to its participation in the pharmacy drug disposal program nor shall such person be liable for acts of simple negligence in the collection, storage, or destruction of prescription drugs collected through such pharmacy drug disposal program, provided that the pharmacy practice site is acting in good faith and in accordance with applicable state and federal law and regulations.

D. In order to mitigate the risk of diversion of drugs upon the death of a patient, any hospice licensed by the Department or exempt from licensure pursuant to § 32.1-162.2 shall develop policies and procedures for the disposal of drugs, including opioids, dispensed as part of the hospice plan of care. Such disposal shall be (i) performed in a manner that complies with all state and federal requirements for the safe disposal of drugs by a licensed nurse, physician assistant, or

physician who is employed by or has entered into a contract with the hospice program; (ii) witnessed by a member of the patient's family or a second employee of the hospice program who is licensed by a health regulatory board within the Department of Health Professions; and (iii) documented in the patient's medical record.

2016, c. 95; 2018, c. 95; 2020, c. 739.

§ 54.1-3411.2:1. Guidelines for disposal of unused drugs.

A. The Board of Pharmacy shall develop guidelines for the provision of counseling and information regarding proper disposal of unused dispensed drugs, including information about pharmacy drug disposal programs in which the pharmacy participates pursuant to § 54.1-3411.2, by pharmacists to patients for whom a prescription is dispensed.

B. The Board of Pharmacy shall determine methods to enhance public awareness of proper drug disposal methods, which may include requirements for pharmacies or hospitals or clinics with an on-site pharmacy to provide such information to customers and the public through the provision of informative pamphlets, the posting of signs in public areas of the pharmacy, and the posting of information on public-facing websites.

2017, c. 114; 2020, c. 614.

§ 54.1-3412. Date of dispensing; initials of pharmacist; automated data processing system.

Pursuant to regulations promulgated by the Board, the pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found.

1970, c. 650, § 54-524.69; 1979, c. 388; 1987, c. 198; 1988, c. 765; 2002, c. 411.

§ 54.1-3413. Manufacturing and administering Schedule I drugs.

It shall be lawful for a person to manufacture, and for a practitioner to administer, Schedule I drugs if:

1. The manufacturer and practitioner are expressly authorized to engage in such activities by the Attorney General of the United States, or pursuant to the federal Food, Drug and Cosmetic Act;

2. The manufacturer or dispenser is registered under all appropriate provisions of this chapter;

3. Any Schedule I drug so manufactured is sold or furnished on an official written order to a practitioner or other authorized person only; and

4. The manufacturer and practitioner comply with all other requirements of this chapter.

1970, c. 650, § 54-524.58:1; 1972, c. 798; 1988, c. 765.

§ 54.1-3414. Official orders for Schedule II drugs.

An official written order for any Schedule II drug shall be signed by the purchasing licensee or by his agent. The original shall be presented to the person who supplies the drug or drugs. If such person accepts the order, each party to the transaction shall preserve his copy of the order for two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter. It shall be deemed a compliance with this section if the parties to the transaction have complied with the federal laws respecting the requirements governing the use of order forms. Parties ordering Schedule II drugs electronically shall comply with all requirements of federal law and regulation governing such transactions.

Code 1950, § 54-493; 1970, c. 650, § 54-524.60; 1988, c. 765; 2006, c. 346.

§ 54.1-3415. Distribution of drugs in Schedules II through VI by manufacturers and wholesalers.

A. A permitted manufacturer or wholesaler may distribute Schedule II drugs to any of the following persons, but only on official written orders or pursuant to an electronic order in compliance with federal laws and regulations governing the electronic ordering of Schedule II drugs:

1. To a manufacturer or wholesaler who has been issued permits pursuant to this chapter;

2. To a licensed pharmacist, permitted pharmacy or a licensed practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine;

3. To a person who has been issued a controlled substance registration certificate pursuant to § 54.1-3422, if the certificate of such person authorizes such purchase;

4. On a special written order accompanied by a certificate of exemption, as required by the federal laws, to a person in the employ of the United States government or of any state, territorial, district, county, municipal, or insular government, purchasing, receiving or possessing drugs by reason of his official duties;

5. To a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft when not in port. However, such drugs shall be sold to a master of such ship or person in charge of such aircraft pursuant to a special order form approved by a commissioned medical officer or acting assistant surgeon of the United States Public Health Service; and

6. To a person in a foreign country in compliance with the provisions of the relevant federal laws.

B. A permitted manufacturer or wholesaler may distribute drugs classified in Schedule III through Schedule VI and devices to all persons listed in subsection A of this section without an official written order. However, this section shall not be construed to prohibit the distribution of a Schedule VI drug or device to any person who is otherwise authorized by law to administer, prescribe or dispense such drug or device.

Code 1950, § 54-492; 1970, c. 650; 1972, c. 798, § 54-524.59; 1977, c. 302; 1978, c. 833; 1988, c. 765; 1998, c. 490; 2006, c. 346.

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

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

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

2018, cc. 241, 242.

§ 54.1-3416. No prescription for preparations listed pursuant to Schedule V.

A preparation listed pursuant to Schedule V may be dispensed without a prescription if:

1. The preparation is dispensed only by a pharmacist directly to the person requesting the preparation;

2. The preparation is dispensed only to a person who is at least eighteen years of age;

3. The pharmacist requires the person requesting the preparation to furnish suitable identification including proof of age when appropriate;

4. The pharmacist does not dispense to any one person, or for the use of any one person or animal, any narcotic drug preparation or preparations, when he knows, or can by reasonable diligence ascertain, that such dispensing will provide the person to whom or for whose use, or the owner of the animal for the use of which, such preparation is dispensed, within 48 consecutive hours, with more than 200 milligrams of opium, or more than 270 milligrams of codeine, or more than 130 milligrams of dihydrocodeinone, or more than 65 milligrams of ethylmorphine, or more than 32 5/10 milligrams of diphenoxylate. In dispensing such a narcotic drug preparation, the pharmacist shall exercise professional discretion to ensure that the preparation is being dispensed for medical purposes only.

Any pharmacist shall, at the time of dispensing, make and keep a record showing the date of dispensing, the name and quantity of the preparation, the name and address of the person to whom the preparation is dispensed, and enter his initials thereon. Such records shall be maintained as set forth in § 54.1-3404 and the regulations of the Board.

1970, c. 650, § 54-524.75; 1972, c. 798; 1988, c. 765.

§ 54.1-3417. Disposing of stocks of Schedules II through V drugs.

The owner of any stocks of drugs included in Schedules II through V obtained in compliance with this chapter, upon discontinuance of dealing in such drugs, may dispose of such stocks only on an official written order as follows:

1. A pharmacy or practitioner or an agent or agents of a pharmacy or practitioner under specific written authorization from the owner of such pharmacy or such practitioner, may dispose of such stocks to a manufacturer or wholesaler holding a valid license to deal in such drugs, or to another pharmacy or practitioner.

2. A manufacturer or wholesaler may dispose of such stocks only to a manufacturer or wholesaler holding a valid permit to deal in such drugs.

1970, c. 650, § 54-524.61; 1976, c. 406; 1988, c. 765.

§ 54.1-3418. Sale of aqueous or oleaginous solutions.

A pharmacist, only upon an official written order, may sell to a physician, dentist, or veterinarian, in quantities not exceeding one ounce at any one time, aqueous or oleaginous solutions compounded by the pharmacist, of which the content of narcotic drugs does not exceed a proportion greater than twenty percent of the complete solution, to be used for medical purposes.

Code 1950, § 54-496; 1956, c. 225; 1970, c. 650, § 54-524.62; 1988, c. 765.

§ 54.1-3419. Dispensing of insulin preparations.

Any insulin preparation shall be dispensed only by or under the supervision of a licensed pharmacist.

1984, c. 723, § 54-524.67:3; 1988, c. 765.

§ 54.1-3420. Distribution of certain drugs; written request or confirmation of receipt.

No manufacturer or distributor of controlled substances shall distribute or dispense any substance listed on Schedules II through V to any person, whether a practitioner of the healing arts or some other profession, except with the written request or confirmation of receipt of the practitioner. Such request or confirmation shall be maintained as required by this chapter.

Subject to the foregoing provisions, no person shall be prohibited from distributing controlled substances listed on Schedules II through V for charitable uses or for use in research or investigations.

1984, c. 724, § 54-524.58:2; 1988, c. 765.

§ 54.1-3420.1. Identification required for filling prescriptions.

A. Before dispensing any drug listed on Schedules III through V, a pharmacist may require proof of identity from any patient presenting a prescription or requesting a refill of a prescription.

B. A pharmacist, or his agent, shall require proof of identity at the time of delivery from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription, unless such person is known to the pharmacist or to his agent. If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, and the person is not known to the pharmacist or his agent, the pharmacist or his agent shall either make a photocopy or electronic copy of such person's identification or record the full name and address of such person. The pharmacist shall keep records of the names and addresses or copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one month. For the purposes of this subsection, "proof of identity" means a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address.

C. Whenever any pharmacist permitted to operate in the Commonwealth or nonresident pharmacist registered to conduct business in the Commonwealth delivers a prescription drug order for any drug listed on Schedule II by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

1988, c. 400, § 54-524.67:4; 2010, c. 193; 2011, cc. 262, 318.

§ 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and

2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

B. If a prescription drug order for a Schedule VI controlled substance is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient, the delivery location shall hold a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems. Schedule II through Schedule V controlled substances shall be delivered to an alternate delivery location only if such delivery is authorized by federal law and regulations of the Board.

C. Prescription drug orders dispensed to a patient and delivered to a community services board or behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the facility on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by a community services board or behavioral health authority facility for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

D. Prescription drug orders dispensed to a patient and delivered to a Virginia Department of Health or local health department clinic upon the signed written request of a patient, a patient's legally authorized representative, or a Virginia Department of Health district director or his designee may be stored and retained at the clinic on behalf of the patient for subsequent delivery or administration.

E. Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3 upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the site on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order

retained by the PACE site for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

1998, c. 597; 2002, c. 411; 2010, c. 28; 2015, c. 505.

§ 54.1-3420.3. Prohibition on refusing to fill prescription from telemedicine provider.

A. A pharmacy shall not implement or enforce a policy that prevents a pharmacist from dispensing a prescription solely on the basis of the prescriber's use of a telemedicine platform to provide services.

B. A pharmacist shall not prioritize dispensing a prescription from a prescriber who does not use telemedicine over dispensing a prescription from a prescriber who does use telemedicine solely on the basis of the prescriber's use of a telemedicine platform to provide services.

2023, c. 368.

§ 54.1-3421. New drugs.

A. No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has been approved and the approval has not been withdrawn under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355).

B. This section shall not apply to a drug subject to the federal act intended solely for investigational use and for which a notice of claimed investigational exemption for a new drug has been filed with the U.S. Food and Drug Administration in accordance with 21 C.F.R. Part 312.

1970, c. 650, § 54-524.95; 1988, c. 765; 2000, c. 135.

§ 54.1-3422. Controlled substances registration certificate required in addition to other requirements; exemptions.

A. Every person who manufactures, distributes or dispenses any substance that is controlled in Schedules I through V or who proposes to engage in the manufacture, distribution or dispensing of any such controlled substance except permitted pharmacies, those persons who are licensed pharmacists, those persons who are licensed physician assistants, and those persons who are licensed practitioners of medicine, osteopathy, podiatry, dentistry, optometry, nursing, or veterinary medicine shall obtain annually a controlled substances registration certificate issued by the Board. This registration shall be in addition to other licensing or permitting requirements enumerated in this chapter or otherwise required by law.

B. Registration under this section and under all other applicable registration requirements shall entitle the registrant to possess, manufacture, distribute, dispense, perform laboratory analysis, or conduct research with those substances to the extent authorized by this registration and in conformity with the other provisions of this chapter.

C. The following persons need not register and may possess controlled substances listed on Schedules I through VI:

1. An agent or employee of any holder of a controlled substance registration certificate or of any practitioner listed in subsection A of this section as exempt from the requirement for registration, if such agent or employee is acting in the usual course of his business or employment;

2. A common or contract carrier or warehouseman, or his employee, whose possession is in the usual course of business or employment; or

3. An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a prescriber or in lawful possession of a Schedule V substance.

D. A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

1972, c. 798, § 54-524.47:2; 1988, c. 765; 1996, cc. 408, 468, 496; 1998, c. 490; 2001, cc. 243, 465; 2020, c. 941.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;

4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

C. Practitioners must be registered to conduct research or laboratory analysis with controlled substances in Schedules II through VI or marijuana. Practitioners registered under federal law to conduct research with Schedule I substances, other than marijuana, may conduct research with Schedule I substances within the Commonwealth upon furnishing the evidence of that federal registration.

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II through VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. Controlled substances used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs and biological products used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological products shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs and biological products, written protocols for administering, and training records of those persons administering drugs and biological products on the premises of the shelter.

F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.

G. The Board may register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration. In determining whether the registration shall be issued, the Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration, and (iii) whether the issuance of the registration is consistent with the public interest.

H. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

I. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

1972, c. 798, § 54-524.47:3; 1978, c. 833; 1980, c. 288; 1988, c. 765; 1996, cc. 468, 496; 1998, c. 490; 2009, cc. 149, 169; 2010, c. 28; 2014, c. 148; 2017, cc. 58, 110; 2018, c. 774; 2020, c. 941; 2023, cc. 744, 794.

§ 54.1-3424. Suspension or revocation of registration, license or permit; limitation to particular controlled substance; controlled substances placed under seal; sale of perishables and forfeiture; notification to DEA.

A. A registration to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Board upon a finding that the registrant:

1. Has furnished false or fraudulent material information in an application filed under this chapter;

2. Has been convicted of a felony under any state or federal law relating to any controlled substance;

3. Has had his federal registration to manufacture, distribute or dispense controlled substances suspended or revoked;

4. Has violated or cooperated with others in violating any provision of this chapter or regulations of the Board relating to the manufacture, distribution or dispensing of controlled substances.

B. The Board may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

C. If the Board summarily suspends, suspends, or revokes a registration, license, permit, or certificate, all controlled substances and prescription devices owned or possessed pursuant to the registration, license, permit, or certificate may be placed under seal by the Board or an authorized agent of the Board as of the effective date of the order of summary suspension, suspension, or revocation. The Board or an authorized agent of the board shall perform an inventory of the controlled substances and prescription devices placed under seal. The controlled substances and prescription devices under seal shall remain in a secured manner on the premises at the previously authorized address of the registration, license, permit, or certificate. No person shall access or relocate such controlled substances and prescription devices without authorization from the Board. The registrant, licensee, permittee, or certificate holder shall ensure the controlled substances and prescription devices remain securely under seal at all times with no unauthorized access.

Following the conclusion of all appeals, if any, or the deadline to file an appeal, if none are filed, the controlled substances and prescription devices shall be subject to forfeiture. The Board shall direct the owner to appropriately transfer or dispose of the sealed controlled substances and prescription devices under the supervision of an authorized agent, or the controlled substances and devices shall be forfeited, seized, and destroyed by the Board, the authorized agent of the Board, or any law-enforcement officer. Costs associated with the storage and destruction of the seized substances and devices shall be at the expense of the owner of such.

Prior to forfeiture, the owner of the controlled substances or prescription devices may request permission from the Board to transfer the sealed controlled substances and prescription devices, at the owner's expense and under the supervision of an authorized agent, to an entity authorized to possess or destroy such substances or devices.

D. Controlled substances and prescription devices that have been abandoned and are stored at a location that is not authorized for the storage of such substances and devices shall be considered contraband. The Board, an authorized agent of the Board, or any law-enforcement officer may seize and destroy such substances and devices. Costs associated with the storage and destruction of the seized substances and devices shall be at the expense of the owner of such substances and devices, if known.

E. The Board shall promptly notify the DEA of all orders suspending or revoking registration and all forfeitures of controlled substances.

1972, c. 798, § 54-524.47:4; 1988, c. 765; 1996, cc. 468, 496; 1998, c. 490; 2019, c. 94.

§ 54.1-3425. Repealed.

Repealed by Acts 2009, c. 149, cl. 2, effective March 6, 2009, and c. 169, cl. 2, effective March 23, 2009.

§ 54.1-3426. Regulations for special packaging.

A. The Board shall adopt standards for special packaging consistent with those promulgated pursuant to the federal Poison Prevention Packaging Act of 1970 (15 U.S.C. § 1471 et seq.). The Board may exempt any drug from the requirements of special packaging and shall exempt any drug exempted pursuant to the Poison Prevention Packaging Act of 1970.

B. A prescriber or a purchaser may direct that a drug, which is subject to being dispensed in special packaging, be dispensed in other than special packaging.

1978, c. 833, § 54-524.67:1; 1988, c. 765; 1996, c. 408.

§ 54.1-3427. Dispensing drugs without safety closure container.

When a pharmacist receives the request of any person that a drug or drugs for such person to be dispensed by the pharmacist not be placed in a safety closure container, the pharmacist may dispense such drug or drugs in such nonsafety closure container. The delivering pharmacist shall not be civilly liable simply by reason of dispensing a drug or drugs in such a container if the recipient signs a release covering a period of time or a single delivery, which release provides that the recipient releases the pharmacist from civil liability for not using the safety closure container, unless the pharmacist acted with willful and wanton disregard of safety.

1978, c. 839, § 54-524.67:2; 1988, c. 765.

§ 54.1-3428. Dissemination of information.

The Board may disseminate such information regarding drugs, devices, and cosmetics as the Board deems necessary in the interest of public health and the protection of the consumer against fraud. This section shall not be construed to prohibit the Board from collecting, reporting, and illustrating the results of its investigations.

1970, c. 650, § 54-524.100; 1988, c. 765.

§ 54.1-3429. Revocation of permit issued to manufacturer, wholesaler or distributor.

The Board may revoke a permit issued to a manufacturer, wholesaler or distributor for failure to comply with regulations promulgated pursuant to the provisions of this chapter.

1970, c. 650, § 54-524.46; 1988, c. 765.

§ 54.1-3430. Display of permit; permits nontransferable; renewal.

Permits issued under the provisions of this chapter shall be displayed in a conspicuous place in the factory or other place of business for which issued.

Permits shall not be transferable and shall be renewed annually.

Code 1950, §§ 54-449, 54-450; 1970, c. 650, § 54-524.38; 1976, c. 614, § 54-524.39; 1988, c. 765.

§ 54.1-3431. Admission into evidence of certain certificates of analysis.

In any administrative hearing, a certificate of analysis of a chemist, performed in any laboratory operated by the Department of Forensic Science or authorized by such Department to conduct such analysis, when such certificate is attested by such chemist, shall be admissible as evidence. A copy of such certificate shall be delivered to the parties in interest at least seven days prior to the date fixed for the hearing.

Any certificate of analysis purporting to be signed by any chemist shall be admissible as evidence in such hearing without any proof of the seal or signature or of the official character of the chemist whose name is signed to it.

Code 1950, § 54-524.77; 1970, c. 650; 1972, cc. 741, 798, § 54-524.77:1; 1973, c. 479; 1977, c. 633; 1988, c. 765; 1990, c. 825; 2005, cc. 868, 881.

Article 2. Permitting of Pharmacies.

§ 54.1-3432. Supervision by pharmacist.

Every pharmacy shall be under the personal supervision of a pharmacist on the premises of the pharmacy.

Code 1950, § 54-478; 1958, c. 551; 1970, c. 650, § 54-524.51; 1988, c. 765.

§ 54.1-3433. Certain advertising and signs unlawful.

It shall be unlawful for any place of business which is not a pharmacy as defined in this chapter to advertise or to have upon it or in it as a sign the words, "pharmacy," "pharmacist," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled" or any like words indicating that drugs are compounded or sold or prescriptions filled. Each day during which such advertisement appears or such sign is allowed to remain upon or in such place of business shall constitute a separate offense under this section. Upon consultation with the Department of Historic Resources, the Board may grant an exception from this section for such signage on an historic building that formerly housed a drugstore or pharmacy if that building is individually listed as a Virginia Historic Landmark, a contributing property in a Virginia Historic Landmark District, or determined to be eligible for listing by the Department of Historic Resources, provided that the signage relates to the historic character of the building.

Code 1950, § 54-477; 1970, c. 650, § 54-524.49; 1988, c. 765; 2005, c. 97.

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and

devices on the premises within 15 days of receipt of this notice. At the conclusion of the 15-day period, the Director or his authorized agent, or any law-enforcement officer in coordination with the Director, shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and the Director shall notify the owner of such seizure. The Director, his authorized agent, or the law-enforcement officer may properly dispose of the seized drugs and devices after 60 days from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board or law-enforcement agency shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every pharmacy shall be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Every pharmacy shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

Each day during which a person is in violation of this section shall constitute a separate offense.

1970, c. 650, § 54-524.31; 1972, c. 798; 1976, c. 614; 1977, c. 302; 1980, c. 288; 1983, c. 286; 1986, c. 207; 1988, cc. 445, 765; 1994, c. 299; 1998, c. 470; 2000, c. 135; 2008, c. 320; 2011, c. 610; 2016, c. 221; 2019, c. 94.

§ 54.1-3434.01. Notice of pharmacy closing; change of ownership; penalty.

A. Prior to the closing of a pharmacy for more than one week, the owner shall either (i) post a conspicuous notice at least thirty days prior to the anticipated closing or (ii) mail a notice, at least fourteen days prior to the anticipated closing, to every current pharmacy customer having refill authority. Each notice posted or mailed pursuant to this section shall indicate the date of such closing, if available, and the name of the pharmacy to which prescriptions and other required prescription dispensing records and individual patient records will be transferred unless patients

indicate their preference to the contrary. The Board of Pharmacy shall promulgate regulations providing for a definition of "closing of a pharmacy" and exceptions to the requirements of this section.

B. Upon any change of ownership of a pharmacy, regardless of how such change may be effectuated, the prescription dispensing records and other patient records for at least two years immediately prior to the change of ownership, shall be transferred, in accordance with Board regulations, to the new owner in a manner to ensure the confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records and the continuity of pharmacy services at substantially the same level as that offered by the previous owner.

Refusing to process a request for the prescription dispensing records and other patient records tendered in accordance with law or regulation shall constitute a closing and the requirements of this section shall apply. Such refusal may constitute a violation of § 54.1-111 A 9, depending on the circumstance.

1992, c. 667; 1994, c. 668; 1998, c. 470.

§ 54.1-3434.02. Automated drug dispensing systems.

A. Hospitals licensed pursuant to Title 32.1 or Title 37.2 may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital;

2. The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system and for ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients;

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

4. Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;

5. Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;

6. Filling and stocking of all drugs in automated drug dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into an

automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug dispensing system or the pharmacist-in-charge, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system.

B. Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose packaging, other than those administered orally, may be placed in such a device if approved by the pharmacist-in-charge in consultation with a standing hospital committee comprised of pharmacy, medical, and nursing staff.

C. The pharmacist-in-charge in a pharmacy located within a hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.

D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from automated drug dispensing systems and for reviewing the operation and maintenance of automated drug dispensing systems.

1999, c. 750; 2004, c. 140; 2009, c. 100.

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

2011, c. 124.

§ 54.1-3434.04. Automatic review of certain case decisions.

The Board of Pharmacy shall, in cases in which a monetary fine may be imposed for a violation of the provisions of Article 2 (§ 54.1-3432 et seq.) of the Drug Control Act relating to the practice of pharmacy and the pharmacy subject to the fine is affiliated with a free clinic that receives state or local funds, ascertain the factual basis for its decisions of such cases through informal conference or consultation proceedings in accordance with § 2.2-4019, unless the named party and the Board agree to resolve the matter through a consent order or the named party consents to waive such a conference or proceeding to go directly to a formal hearing.

2014, c. 345.

§ 54.1-3434.05. Permit to act as an outsourcing facility.

A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.

B. Applications for a permit to act as an outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the compounding performed at the location designated on the application. Such application shall be accompanied by a fee determined by the Board in regulation. All permits shall expire annually on a date determined by the Board in regulation. No permit shall be issued or renewed for an outsourcing facility unless the facility can demonstrate compliance with all applicable federal and state laws and regulations governing outsourcing facilities.

C. As a prerequisite to obtaining or renewing a permit from the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for a permit to the Board or (b) no more than two years prior to the date of submission of an application for renewal of a permit to the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. Every outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations except § 54.1-3410.2, to include all applicable guidance documents

and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

E. An outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a permit to operate a pharmacy.

2015, c. 300.

Article 2.1. Registration of Nonresident Pharmacies.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly

authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

F. Pharmacies subject to this section shall comply with the requirements set forth in § 54.1-3408.04 relating to dispensing of an interchangeable biosimilar in the place of a prescribed biological product.

G. Every nonresident pharmacy shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

1990, c. 270; 1994, c. 300; 2000, c. 882; 2005, cc. 115, 637, 678; 2006, c. 397; 2008, cc. 79, 618; 2011, c. 124; 2013, cc. 412, 544, 765; 2016, c. 221.

§ 54.1-3434.2. Permit to be issued.

The Board shall only register nonresident pharmacies that maintain a current unrestricted license, certificate, permit, or registration as a pharmacy in a jurisdiction within the United States, or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States.

Applications for a nonresident pharmacy registration, under this section, shall be made on a form furnished by the Board. The Board may require such information as it deems is necessary to carry out the purpose of the section.

The permit or nonresident pharmacy registration shall be renewed annually on a date determined by the Board in regulation. Renewal is contingent upon the nonresident pharmacy providing documentation of a current inspection report in accordance with subdivision A 3 of § 54.1-3434.1; continuing current, unrestricted licensure in the resident jurisdiction; and continuing certification if required in subdivision A 4 of § 54.1-3434.1.

1990, c. 270; 2005, c. 115; 2008, cc. 79, 320, 618; 2013, c. 765.

§ 54.1-3434.3. Denial, revocation, suspension of registration, summary proceedings.

The Board may deny, revoke, suspend, or take other disciplinary actions against a nonresident pharmacy registration as provided for in § 54.1-3316.

The Board shall immediately suspend, without a hearing, the registration of any nonresident pharmacy upon receipt of documentation by the licensing agency in the jurisdiction where a nonresident pharmacy registered with the Board is located, that the nonresident pharmacy has had its license, certificate, permit, or registration as a pharmacy revoked or suspended by that agency and has not been reinstated, or if the Board has received notification from the licensing agency that the pharmacy in the resident state no longer holds a valid unexpired license, permit, certificate, or registration as a pharmacy. The Board shall provide written notice of the suspension to the nonresident pharmacy at the address of record on file with the Board and to the resident-state licensing agency. The nonresident pharmacy may apply for reinstatement of the registration only after it has been reinstated by and holds a current and unrestricted license, certificate, permit, or registration as a pharmacy from the licensing agency in the jurisdiction where it is located. Such nonresident pharmacy shall be entitled to a hearing not later than the

next regular meeting of the Board after the expiration of 60 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify on its behalf.

The Board may summarily suspend the registration of any nonresident pharmacy without a hearing, simultaneously with the institution of proceedings for a hearing, if it finds that there is a substantial danger to the public health or safety that warrants such action. The Board may meet by telephone conference call when summarily suspending the registration if a good faith effort to assemble a quorum of the Board has failed and, in the judgment of a majority of the members of the Board, the continued dispensing by the nonresident pharmacy constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension. The Board may consider other information concerning possible violations of Virginia law at a hearing, if reasonable notice is given to such nonresident pharmacy of the information.

A nonresident pharmacy with a suspended registration shall not ship, mail, or deliver any Schedule II through VI drugs into the Commonwealth unless reinstated by the Board.

The Board may refer complaints concerning nonresident pharmacies to the regulatory or licensing agency in the jurisdiction where the pharmacy is located. The Board may take other disciplinary action against a nonresident pharmacy in accordance with §§ 54.1-2400 and 54.1-3316 following notice and the opportunity for a hearing.

1990, c. 270; 2005, c. 115; 2007, c. 662; 2019, c. 138.

§ 54.1-3434.4. Prohibited acts.

A. It is unlawful for any person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy or compounding services of an outsourcing facility that has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy or outsourcing facility to obtain controlled substances.

B. Any controlled substance that is ordered or shipped in violation of any provision of this chapter, shall be considered as contraband and may be seized by any law-enforcement officer or any agent of the Board of Pharmacy.

1990, c. 270; 2005, c. 115; 2008, cc. 79, 618; 2015, c. 300.

§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers in any manner Schedule II through VI drugs or devices into the Commonwealth shall be considered a nonresident outsourcing facility and shall be registered with the Board.

B. Applications for registration to act as a non-resident outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who is licensed as a pharmacist in Virginia and who is in full and actual charge of the outsourcing facility, is fully engaged in the compounding performed at the location stated on the application, and is fully responsible for the outsourcing facility's compliance with state and federal law and regulations. Such application shall be accompanied by a fee determined by the Board in regulation. All registrations shall expire annually on a date determined by the Board in regulation.

C. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. A nonresident outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a registration to operate a nonresident pharmacy. The nonresident pharmacy shall comply with all state and federal laws, regulations, and requirements except § 54.1-3410.2.

2015, c. 300.

Article 3. Wholesale Distributors and Medical Equipment Suppliers.

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

A. It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in the Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in the Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a

date determined by the Board in regulation; notify the Board within 30 days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

B. A wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.

C. A wholesale distributor shall be immune from civil liability for giving notice in accordance with subsection B unless the notice was given in bad faith or with malicious intent.

D. The Board shall not impose any disciplinary or enforcement action against any licensee or permit holder solely on the basis of a notice received from a wholesale distributor pursuant to subsection B.

E. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

F. Every wholesale distributor shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

1970, c. 650, § 54-524.44; 1976, c. 614; 1980, c. 288; 1988, c. 765; 1992, c. 737; 2008, c. 320; 2015, c. 299; 2016, c. 221.

§ 54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.

A. Any person located outside the Commonwealth who engages in the wholesale distribution of prescription drugs into the Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on a date determined by the Board in regulation; notify the Board within 30 days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

D. A nonresident wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.

E. A nonresident wholesale distributor shall be immune from civil liability for giving notice in accordance with subsection D unless the notice was given in bad faith or with malicious intent.

F. The Board shall not impose any disciplinary or enforcement action against any licensee or permit holder solely on the basis of a notice received from a nonresident wholesale distributor pursuant to subsection D.

G. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within the Commonwealth.

H. Every nonresident wholesale distributor shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

1994, c. 300; 2008, c. 320; 2015, c. 299; 2016, c. 221.

§ 54.1-3435.02. Certain permitted pharmacies and medical equipment suppliers exempted.

A. A permitted pharmacy may engage in wholesale distributions of small quantities of prescription drugs without being licensed as wholesale distributors when such wholesale distributions are in compliance with federal law as follows: such wholesale distributions of controlled substances do not exceed five percent of the gross annual sales of prescription drugs by the relevant permitted pharmacy or such wholesale distributions of Schedules II through V controlled substances do not exceed five percent of the total dosage units of the Schedule II through V controlled substances dispensed annually by the relevant permitted pharmacy.

B. A permitted medical equipment supplier may engage in wholesale distributions of small quantities of oxygen without being licensed as a wholesale distributor when such wholesale distributions are in compliance with federal law and such distributions do not exceed five percent of the gross annual sales of oxygen by the relevant permitted medical equipment supplier.

2003, c. 509; 2004, c. 854.

§ 54.1-3435.1. Denial, revocation, and suspension of license, permit, or registration of certain entities.

A. The Board may deny, revoke, suspend, or take other disciplinary actions against a wholesale distributor license, nonresident wholesale distributor registration, third-party logistics provider permit, nonresident third-party logistics provider registration, manufacturer permit, nonresident manufacturer permit, or nonresident warehouser registration as provided for in § 54.1-3316 or the following:

1. Any conviction of the applicant, licensee, or registrant under federal or state laws relating to controlled substances, including, but not limited to, drug samples and wholesale or retail prescription drug distribution;

2. Violations of licensing requirements under previously held licenses;

3. Failure to maintain and make available to the Board or to federal regulatory officials those records required to be maintained by wholesale distributors of prescription drugs; or

4. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal Drug Supply Chain Security Act of 2013, Title II of P. L. 113-54, and the requirements of Chapter 21 of the Code of Federal Regulations.

B. Wholesale drug distributors, nonresident wholesale drug distributors, third-party logistics providers, nonresident third-party logistics providers, manufacturers, nonresident manufacturers, and nonresident warehousers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

1992, c. 737; 1994, c. 300; 2007, c. 662; 2016, c. 221; 2018, c. 96.

§ 54.1-3435.2. Permit to act as medical equipment supplier; storage; limitation; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a medical equipment supplier, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a medical equipment supplier in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on a date determined by the Board in regulation; and remit a fee as determined by the Board.

B. Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water and saline for irrigation.

C. Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful order by a prescriber authorized to prescribe such drugs and devices.

D. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs, devices and controlled paraphernalia by medical equipment suppliers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices and controlled paraphernalia, and to protect the public.

1992, c. 737; 1996, c. 408; 1997, c. 677; 2008, c. 320; 2013, c. 504.

§ 54.1-3435.3. Inspection and audit.

Medical equipment suppliers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures.

1992, c. 737; 2007, c. 662.

§ 54.1-3435.3:1. Registration of nonresident medical equipment suppliers; renewal; fee.

A. Any person located outside the Commonwealth other than a nonresident pharmacy registered pursuant to § 54.1-3434.1 that ships, mails, or delivers to a consumer in the Commonwealth any hypodermic syringes or needles, medicinal oxygen, Schedule VI controlled device, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, sterile water and saline for irrigation, or solutions for peritoneal dialysis pursuant to a lawful order of a prescriber shall be registered with the Board as a nonresident medical equipment supplier. Registration as a nonresident medical equipment supplier shall be renewed by March 1 of each year. Applicants for registration or renewal of a registration shall submit a fee specified by the Board in regulations at the time of registration or renewal. A nonresident medical equipment supplier registered in accordance with this section shall notify the Board within 30 days of any substantive change in the information previously submitted to the Board.

B. The nonresident medical equipment supplier shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located, if required by the resident state, and shall furnish proof of such license, permit, or registration upon application for registration or renewal. If the resident state does not require a license, permit, or registration to engage in direct consumer supply of the medical equipment described in subsection A, the applicant shall furnish proof that it meets the minimum statutory and regulatory requirements for medical equipment suppliers in the Commonwealth.

C. Records of distribution of medical equipment described in subsection A into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distribution into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

2016, c. 88.

§ 54.1-3435.4. Permit to act as warehouser; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a warehouser, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a warehouser in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on a date determined by the Board in regulation; and remit a fee as determined by the Board.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by warehousers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. Warehousers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to warehousers' premises and delivery vehicles.

1992, c. 737; 2008, c. 320.

§ 54.1-3435.4:01. Registration to act as a nonresident warehouser; regulations.

A. Any warehouser located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident warehouser shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident warehousers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident warehouser shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located that authorizes the possession and distribution of such prescription drugs and devices and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs and devices distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

2018, c. 96.

§ 54.1-3435.4:1. Permitting of third-party logistics provider; renewal.

A. It shall be unlawful for any person to operate as a third-party logistics provider in the Commonwealth without a valid, unrevoked permit issued by the Board. The third-party logistics provider shall renew such permit annually on a date determined by the Board in regulation and shall notify the Board within 30 days of any substantive change in the information reported on the application form previously submitted.

B. The Board shall adopt such regulations relating to the requirements to operate as a third-party logistics provider, including the storage, handling, and distribution of prescription drugs by third-party logistics providers, as it deems necessary to prevent diversion of prescription drugs and to protect the public.

2016, c. 221.

§ 54.1-3435.4:2. Registration of nonresident third-party logistics provider; renewal.

A. Any third-party logistics provider located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident third-party logistics provider shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident third-party logistics providers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current licensure as a third-party logistics provider with the FDA and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs and devices distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

2018, c. 96.

§ 54.1-3435.5. Repealed.

Repealed by Acts 2007, c. 662, cl. 2.

§ 54.1-3436. Repealed.

Repealed by Acts 1992, c. 737.

§ 54.1-3436.1. Prescription drug price transparency.

A. As used in this section:

"Brand-name drug" means a prescription drug approved under 21 U.S.C. § 355(b) or 42 U.S.C. § 262.

"Generic drug" means a prescription drug approved under 21 U.S.C. § 355(j).

"Nonprofit data services organization" has the same meaning as set forth in § 32.1-23.4.

"Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.

"Wholesale acquisition cost" has the same meaning as set forth in 42 U.S.C. § 1395w-3a(c)(6)(B).

B. To ensure data that is useful, relevant, and not duplicative, the Department of Health may request wholesale distributors to report to the nonprofit organization with which the Department of Health has entered into a contract or agreement pursuant to § 32.1-23.4 the following information on the 25 costliest drugs in the Commonwealth upon a determination by the Department of Health that data received from health carriers, pharmacy benefits managers, and manufacturers is insufficient:

1. The wholesale acquisition cost that the wholesale distributor has negotiated directly with the manufacturer in the last calendar year, related to the 25 costliest drugs dispensed in the Commonwealth;

2. The wholesale acquisition cost that the wholesale distributor has negotiated directly with the manufacturer in the current calendar year for the 25 costliest drugs dispensed in the Commonwealth;

3. Aggregate total rebates, discounts, and price concessions negotiated directly with the manufacturer for the 25 costliest drugs dispensed in the Commonwealth in the last calendar year, for business in the Commonwealth, in total; and

4. Aggregate total discounts, dispensing fees, and other fees negotiated in the last calendar year with pharmacies, for the 25 costliest drugs dispensed in the Commonwealth, in total.

C. A report submitted by a wholesale distributor pursuant to subsection B shall not disclose the identity of a specific wholesale distributor, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any price concession, rebate, or fee provided for a specific prescription drug or class of prescription drugs.

2021, Sp. Sess. I, c. 304.

Article 4. Permitting of Manufacturers.

§ 54.1-3437. Permit to manufacture drugs.

It shall be lawful to manufacture, make, produce, pack, package, repackage, relabel or prepare any drug not controlled by Schedule I after first obtaining the appropriate permit from the Board. Such permits shall be subject to the Board's regulations on sanitation, equipment, and safeguards against diversion, and shall allow the distribution of the drug manufactured, made, produced, packed, packaged, repackaged, relabeled, or prepared to anyone other than the end user without the need to obtain a wholesale distributor permit. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or package no other drugs.

Code 1950, § 54-448; 1958, c. 551; 1970, c. 650, § 54-524.36; 1988, c. 765; 1996, cc. 37, 407; 2016, c. 221.

§ 54.1-3437.1. Limited permit for repackaging drugs.

The Board may issue a limited manufacturing permit for the purpose of repackaging drugs, upon such terms and conditions approved by the Board, to the pharmacy directly operated by the Department of Behavioral Health and Developmental Services and which serves clients of the community services boards.

1997, c. 218; 2009, cc. 813, 840.

§ 54.1-3438. Manufacturing, etc., of drugs or proprietary medicines, to be supervised by pharmacist.

No drugs or proprietary medicines shall be manufactured, made, produced, packed, packaged, repackaged, relabeled or prepared within this Commonwealth, except under the personal and immediate supervision of a pharmacist or such other person as may be approved by the Board of Pharmacy after an investigation and a determination by the Board that they are qualified by scientific or technical training to perform such duties or supervision as may be necessary to protect the public health and safety. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or pack no other drugs. Medicated feeds are hereby defined as products obtained by mixing a commercial feed and a drug.

Code 1950, § 54-447; 1958, c. 551; 1970, c. 650, § 54-524.37; 1976, c. 614; 1988, c. 765; 1996, cc. 37, 407.

§ 54.1-3439. Application for nonrestricted manufacturing permit; fee.

Every person desiring to manufacture any drug or proprietary medicines shall annually apply to the Board for a nonrestricted manufacturing permit. The application shall be accompanied by the required fee. Separate applications shall be made and separate permits issued for each specific place of manufacturing. Each such permit shall expire annually on a date determined by the Board in regulation.

1970, c. 650, § 54-524.40; 1972, c. 798; 1976, c. 614; 1980, c. 288; 1988, c. 765; 1996, cc. 37, 407; 2008, c. 320.

§ 54.1-3440. Persons to whom nonrestricted permit is granted.

No person shall be granted a nonrestricted permit as a manufacturer unless he is of good moral character and properly equipped as to land, buildings, equipment and safeguards against diversion to carry out the functions of a manufacturer with due regard to the protection of the public safety.

1970, c. 650, § 54-524.41; 1976, c. 614; 1988, c. 765.

§ 54.1-3441. Restricted manufacturing permit; application; fee; separate application and permit for each place of manufacturing.

Every person desiring to manufacture a proprietary medicine or to repackage medical gases shall apply to the Board for a restricted manufacturing permit. The application shall be accompanied by the required fee. Separate applications shall be made and separate permits issued for each separate place of manufacturing.

1976, c. 614, § 54-524.41:1; 1980, c. 288; 1988, c. 765; 1996, cc. 37, 407.

§ 54.1-3442. When permit not to be granted; regulations.

No person shall be granted a restricted manufacturing permit as a manufacturer unless such person is properly equipped as to buildings and equipment to carry out the functions of a manufacturer with due regard to the protection of the public health. The Board shall promulgate regulations in order to carry out the provisions of this section.

1976, c. 614, § 54-524.41:2; 1988, c. 765.

§ 54.1-3442.01. Registration of nonresident manufacturer; renewal.

A. Any manufacturer located outside the Commonwealth who ships prescription drugs into the Commonwealth shall be registered with the Board. The nonresident manufacturer shall renew

such registration annually on a date determined by the Board in regulation and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The nonresident manufacturer shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current registration as a manufacturer or repackager with the federal Food and Drug Administration and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

2016, c. 221.

§ 54.1-3442.02. (Effective January 1, 2022) Prescription drug price transparency.

A. As used in this section:

"Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under 42 U.S.C. § 262(k)(3).

"Brand-name drug" means a prescription drug approved under 21 U.S.C. § 355(b) or 42 U.S.C. § 262.

"Generic drug" means a prescription drug approved under 21 U.S.C. § 355(j) or 42 U.S.C. 262(k).

"New prescription drug" means a drug or biological product receiving initial approval under an original new drug application pursuant to 21 U.S.C. § 355(b) or under a biologics license application under 42 U.S.C. § 262.

"Nonprofit data services organization" has the same meaning as set forth in § 32.1-23.4.

"Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.

"Wholesale acquisition cost" has the same meaning as set forth in 42 U.S.C. § 1395w-3a(c)(6)(B).

B. Every manufacturer shall report annually by April 1 to the nonprofit organization with which the Department of Health has entered into a contract or agreement pursuant to § 32.1-23.4, for each (i) brand-name drug and biologic other than a biosimilar with a wholesale acquisition cost of $100 or more for a 30-day supply or a single course of treatment and any increase of 15 percent or more in the wholesale acquisition cost of such brand-name drug or biologic over the preceding calendar year; (ii) biosimilar with an initial wholesale acquisition cost that is not at

least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched; and (iii) generic drug with a price increase that results in an increase in the wholesale acquisition cost of such generic drug that is equal to 200 percent or more during the preceding 12-month period, when the wholesale acquisition cost of such generic drug is equal to or greater than $100, annually adjusted by the Consumer Price Index for All Urban Consumers, for a 30-day supply, with such increase defined as the difference between the wholesale acquisition cost of the generic drug after such increase and the average wholesale acquisition cost of such generic drug during the previous 12 months, the following information:

1. The name of the prescription drug;

2. Whether the drug is a brand name or generic;

3. The effective date of the change in wholesale acquisition cost;

4. Aggregate, company-level research and development costs for the most recent year for which final audit data is available;

5. The name of each of the manufacturer's new prescription drugs approved by the U.S. Food and Drug Administration within the previous three calendar years;

6. The name of each of the manufacturer's prescription drugs that, within the previous three calendar years, became subject to generic competition and for which there is a therapeutically equivalent generic version; and

7. A concise statement regarding the factor or factors that caused the increase in wholesale acquisition cost.

C. A manufacturer's obligations pursuant to this section shall be fully satisfied by the submission to the nonprofit data services organization with which the Department of Health has entered into a contract pursuant to § 32.1-23.3 of information and data that a manufacturer includes in the manufacturer's annual consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure.

2021, Sp. Sess. I, c. 304.

Article 4.1. Expanded Access to Investigational Drugs, Biological Products, and Devices.

§ 54.1-3442.1. Definitions.

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

"Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase I of a clinical trial but has not been approved for general use by the U.S. Food and Drug Administration and remains under investigation in a clinical trial.

"Terminal condition" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical probability, a patient cannot recover and (i) the patient's death is imminent or (ii) the patient is in a persistent vegetative state.

"Treating physician" means a physician who is providing or has previously provided medical treatment or evaluation to and has or previously had an ongoing treatment relationship with the person.

2015, cc. 655, 656.

§ 54.1-3442.2. Eligibility for expanded access to investigational drugs, biological products, and devices; written, informed consent to treatment.

A. A person shall be eligible for expanded access to investigational drugs, biological products, or devices if:

1. He has a terminal condition, attested to by his treating physician and confirmed by a second physician not previously involved in the treatment of the person who has conducted an independent examination of the person;

2. He has, in consultation with his treating physician, considered all other treatment options currently approved by the U.S. Food and Drug Administration and the treating physician has determined that no reasonable opportunity exists for him to participate in an ongoing clinical trial for his terminal condition;

3. The potential benefits of use of the investigational drug, biological product, or device to treat his terminal condition are greater than the potential risks of the use of the investigational drug, biological product, or device to treat his terminal condition;

4. He has received a recommendation from his treating physician for use of an investigational drug, biological product, or device for treatment of his terminal condition; and

5. He or, if he is incapable of making an informed decision, his legally authorized representative has given written informed consent to use of the investigational drug, biological product, or device for treatment of his terminal condition or, if the person is a minor or lacks capacity to provide informed consent, his parent or legal guardian has given written informed consent to the use of the investigational drug, biological product, or device for treatment of his terminal condition.

Documentation indicating that the person meets the criteria for eligibility for expanded access to investigational drugs, biological products, or devices shall be provided by the person's treating physician and shall be included in the person's medical record.

B. Written informed consent to use of an investigational drug, biological product, or device shall include:

1. An explanation of the currently approved products and treatments for the person's terminal condition;

2. A statement that the person has, in consultation with his treating physician, considered all other treatment options currently approved by the U.S. Food and Drug Administration and the treating physician has determined that no reasonable opportunity exists for the person to participate in an ongoing clinical trial for his terminal condition;

3. An explanation of the specific investigational drug, biological product, or device proposed for treatment of the person's terminal condition;

4. A description of possible outcomes resulting from use of the investigational drug, biological product, or device to treat the person's terminal condition, including a statement that new, unanticipated, different, or worse symptoms might result from and death could be hastened by the proposed treatment, based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the person's terminal condition;

5. A statement that the person may be required to pay any costs associated with use of the investigational drug, biological product, or device; and

6. A statement that the person or, if the person is a minor or lacks capacity to provide informed consent, his parent or legal guardian consents to the use of the investigational drug, biological product, or device for treatment of his terminal condition.

2015, cc. 655, 656.

§ 54.1-3442.3. Expanded access to investigational drugs, biological products, or devices; cost; insurance coverage.

A. A manufacturer of an investigational drug, biological product, or device may make such investigational drug, biological product, or device available to a person who meets the criteria set forth in subsection A of § 54.1-3442.2; however, nothing in this article shall require a manufacturer of an investigational drug, biological product, or device to make such investigational drug, biological product, or device available to such person.

B. A manufacturer that makes an investigational drug, biological product, or device available to a person who meets the criteria set forth in subsection A of § 54.1-3442.2 may provide the investigational drug, biological product, or device to the person free of charge or may require the person to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

C. An insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis, a corporation providing individual or group accident and sickness subscription contracts, or a health maintenance organization providing a health care plan for health care services may provide coverage for costs related to treatment of a person's terminal condition with an

investigational drug, biological product, or device; however, nothing in this article shall require an insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis, a corporation providing individual or group accident and sickness subscription contracts, or a health maintenance organization providing a health care plan for health care services to provide coverage for costs related to treatment of a person's terminal condition with an investigational drug, biological product, or device.

2015, cc. 655, 656.

§ 54.1-3442.4. Limitation of liability.

A. Notwithstanding any other provision of law to the contrary, a health care provider as defined in § 8.01-581.1 who recommends an investigational drug, biological product, or device to a person who meets the criteria set forth in subsection A of § 54.1-3442.2 shall be immune from civil liability for any adverse action, condition, or other outcome resulting from the person's use of the investigational drug, biological product, or device.

B. Notwithstanding any other provision of law to the contrary, a manufacturer, distributor, administrator, health care provider as defined in § 8.01-581.1, sponsor, or physician who manufactures, supplies, distributes, administers, prescribes, or recommends an investigational drug, biological product, or device to a person who meets the criteria set forth in § 54.1-3442.2 shall be immune from suit and liability caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescription, recommendation, administration, efficacy, or use of such investigational drug, biological product, or device made available to such person.

C. No claim or cause of action against a manufacturer, distributor, administrator, health care provider as defined in § 8.01-581.1, sponsor, or physician who manufactures, supplies, distributes, administers, prescribes, or recommends an investigational drug, biological product, or device to a person who meets the criteria set forth in § 54.1-3442.2 shall exist in any state court for claims of property, personal injury, or death caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescription, recommendation, administration, efficacy, or use of such investigational drug, biological product, or device made available to such person.

D. No health care provider as defined in § 8.01-581.1 who recommends, prescribes, administers, distributes, or supplies an investigational drug, biological product, or device to a person who meets the criteria set forth in § 54.1-3442.2 shall be deemed to have engaged in unprofessional conduct, or shall be adversely affected in any decision relating to licensure, on such grounds.

E. Nothing in this article shall require a person to violate or act in contravention of any federal or state law as such law relates to the prescribing, dispensing, administration, or use of an investigational drug, biological product, or device.

2015, cc. 655, 656.

Article 4.2. Permitting of Pharmaceutical Processors to Produce and Dispense Cannabis Products.

§ 54.1-3442.5. (Effective until Jan. 1, 2024, pursuant to Acts 2023, cc. 740, 773, cl.2) Definitions.

As used in this article:

"Botanical cannabis,""cannabis oil,""cannabis product," and "usable cannabis" have the same meanings as specified in § 54.1-3408.3.

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis products produced by a pharmaceutical processor to a patient, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.

"Designated caregiver facility" has the same meaning as defined in § 54.1-3408.3.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil, botanical cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis products to a patient pursuant to a written certification, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"Registered agent" has the same meaning as specified in § 54.1-3408.3.

2017, c. 613; 2018, cc. 246, 809; 2019, c. 690; 2020, c. 1278; 2021, Sp. Sess. I, cc. 205, 227, 228; 2022, cc. 259, 391, 392, 642.

§ 54.1-3442.6. (Effective until Jan. 1, 2024, pursuant to Acts 2023, cc. 740, 773, cl.2) Permit to operate pharmaceutical processor or cannabis dispensing facility.

A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor's dispensing area or cannabis dispensing facility. The Board shall establish an application fee and other general requirements for such application.

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and up to five cannabis dispensing facilities for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and cannabis dispensing facility.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and securely dispensing and delivering in person cannabis products to a patient, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) dosage limitations for cannabis oil that provide that each dispensed dose of cannabis oil not exceed 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution of and the transfer of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical processors, between a pharmaceutical processors and a cannabis dispensing facility, and between cannabis dispensing facilities; (xi) an allowance for the sale of devices for administration of dispensed cannabis products and hemp-based CBD products that meet the applicable standards set forth in state and federal law, including the laboratory testing standards set forth in subsection M; (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification; (xiii) a process for acquiring industrial hemp extracts and formulating such extracts into cannabis products; and (xiv) an allowance for the advertising and promotion of the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical processor from the provision of educational material to practitioners who issue written certifications and patients. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis products, (b) the secure disposal of agricultural waste, and (c) a process for registering cannabis oil products.

D. The Board shall require that, after processing and before dispensing any cannabis products, a pharmaceutical processor shall make a sample available from each batch of cannabis product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate botanical cannabis or cannabis oil that fails any quality testing standard except pesticides. Following remediation, all remediated botanical cannabis or cannabis oil shall be subject to laboratory testing and approved upon satisfaction of applicable testing standards, which shall not be more stringent than initial testing prior to remediation. If a batch of botanical cannabis fails retesting after remediation, it shall be considered usable cannabis and may be processed into

cannabis oil. Stability testing shall not be required for any cannabis product with an expiration date assigned by the pharmaceutical processor of six months or less from the date of the cannabis product registration approval. Stability testing required for assignment of an expiration date longer than six months shall be limited to microbial testing, on a pass/fail basis, and potency testing, on a 10 percent deviation basis, of active ingredients.

E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the Board in regulation.

F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis dispensing facility. The pharmaceutical processor shall ensure that security measures are adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have concurrent responsibility for preventing diversion from the dispensing area.

Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation and production areas of the pharmaceutical processor and shall provide such information to the Board. The Board shall direct all communications related to enforcement of requirements related to cultivation and production of cannabis oil products by the pharmaceutical processor to such designated person.

G. The Board shall require the material owners of an applicant for a pharmaceutical processor or cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity. A pharmaceutical processor shall maintain evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

H. In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than two years of experience (i) to perform cultivation-related duties under the supervision of an individual who has received a degree in a field related to the cultivation of plants or a certification recognized by the Board or who has at least two years of experience cultivating plants, (ii) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants, and (iii) to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a pharmacy technician.

I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to five cannabis dispensing facilities for the dispensing of cannabis products that have been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board.

Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

J. No person who has been convicted of a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a pharmaceutical processor or cannabis dispensing facility.

K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

L. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical processor's dispensing area or cannabis dispensing facility.

M. A pharmaceutical processor may acquire industrial hemp extracts grown and processed in Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or processor. A pharmaceutical processor may process and formulate such extracts into an allowable dosage of cannabis product. Industrial hemp extracts acquired and formulated by a pharmaceutical processor are subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall be performed by a laboratory located in Virginia and in compliance with state law governing the testing of cannabis products. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before industrial hemp extracts may be acquired.

N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment. The legislative review provisions of subsections A and B of § 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section. The Board of Pharmacy shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

O. The Board shall register all cannabis products that meet testing, labeling, and packaging standards.

2017, c. 613; 2018, c. 567; 2019, cc. 417, 681, 690; 2020, cc. 831, 928, 944, 1278; 2021 Sp. Sess. I, cc. 205, 227, 228, 550, 551; 2022, cc. 259, 391, 392, 642.

§ 54.1-3442.7. (Effective until Jan. 1, 2024, pursuant to Acts 2023, cc. 740, 773, cl.2) Dispensing cannabis products; report.

A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia as made evident to the Board, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3; (ii) such patient's registered agent; or (iii) if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident or temporarily resides in Virginia as made evident to the Board and is registered with the Board pursuant to § 54.1-3408.3. A companion may accompany a registered patient into a pharmaceutical processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing of cannabis products pursuant to each written certification, a pharmacist or pharmacy technician employed by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or remotely by electronic means, for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view, in person or by audiovisual means, a current photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, registered agent, parent, or legal guardian. Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian, or designated caregiver facility. Prior to any subsequent dispensing of cannabis products pursuant to each written certification, an employee or delivery agent shall view a current photo identification of the patient, registered agent, parent, or legal guardian and the current board registration issued to the patient, registered agent, parent, or legal guardian. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a 90-day supply, as determined by the dispensing pharmacist or certifying practitioner, for any patient during any 90-day period. A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day supply of a cannabis product for any patient during any 90-day period; however, a pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. The Board shall establish in regulation an amount of cannabis oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease. In determining the appropriate amount of a cannabis product to be dispensed to a patient, a pharmaceutical processor or cannabis dispensing facility shall consider all cannabis products dispensed to the patient and adjust the amount dispensed accordingly.

B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis products produced on the premises of a pharmaceutical processor permitted by the Board or cannabis oil that has been formulated with oil from industrial hemp acquired by a pharmaceutical processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

C. The Board shall report annually by December 1 to the Chairmen of the House Committee for Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, including the number of practitioners, patients, registered agents, and parents or legal

guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

D. The concentration of delta-9-tetrahydrocannabinol in any cannabis product on site may be up to 10 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any cannabis product on site is within such range. A pharmaceutical processor producing cannabis products shall establish a stability testing schedule of cannabis products.

2017, c. 613; 2018, cc. 246, 567, 809; 2019, c. 690; 2020, cc. 730, 831, 928, 1278; 2021, Sp. Sess. I, cc. 205, 227, 228; 2022, cc. 259, 391, 392, 642.

§ 54.1-3442.8. (Effective until Jan. 1, 2024, pursuant to Acts 2023, cc. 740, 773, cl.2) Criminal liability; exceptions.

No agent or employee of a pharmaceutical processor or cannabis dispensing facility shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-248 or 18.2-250 for possession or manufacture of marijuana or for possession, manufacture, or distribution of cannabis products, subject to any civil penalty, denied any right or privilege, or subject to any disciplinary action by a professional licensing board if such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing cannabis products in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabis products that are consistent with generally accepted cannabis industry standards in accordance with the provisions of this article and Board regulations.

2017, c. 613; 2020, cc. 764, 1278; 2021, Sp. Sess. I, cc. 227, 228, 550, 551.

Article 5. Standards and Schedules.

§ 54.1-3443. Board to administer article.

A. The Board shall administer this article and may add substances to or deschedule or reschedule all substances enumerated in the schedules in this article pursuant to the procedures of the Administrative Process Act (§ 2.2-4000 et seq.). In making a determination regarding a substance, the Board shall consider the following:

1. The actual or relative potential for abuse;

2. The scientific evidence of its pharmacological effect, if known;

3. The state of current scientific knowledge regarding the substance;

4. The history and current pattern of abuse;

5. The scope, duration, and significance of abuse;

6. The risk to the public health;

7. The potential of the substance to produce psychic or physical dependence; and

8. Whether the substance is an immediate precursor of a substance already controlled under this article.

B. After considering the factors enumerated in subsection A, the Board shall make findings and issue a regulation controlling the substance if it finds the substance has a potential for abuse.

C. If the Board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

D. If the Board, in consultation with the Department of Forensic Science, determines the substance shall be placed into Schedule I or II pursuant to § 54.1-3445 or 54.1-3447, the Board may amend its regulations pursuant to Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall conduct a public hearing. At least 30 days prior to conducting such hearing, it shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. In the notice, the Board shall include a list of all substances it intends to schedule by regulation. The Board shall notify the House Committee for Courts of Justice and the Senate Committee on the Judiciary of any new substance added to Schedule I or II pursuant to this subsection. Any substance added to Schedule I or II pursuant to this subsection shall remain on Schedule I or II for a period of 18 months. Upon expiration of such 18-month period, such substance shall be descheduled unless a general law is enacted adding such substance to Schedule I or II. Nothing in this subsection shall preclude the Board from adding substances to or descheduling or rescheduling all substances enumerated in the schedules pursuant to the provisions of subsections A, B, and E.

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 30 days from publication in the Federal Register of a final or interim final order or rule designating a substance as a controlled substance or rescheduling or descheduling a substance by amending its regulations in accordance with the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. The Board shall include a list of all substances it intends to schedule by regulation in such notice.

F. Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 4.1.

G. The Board shall exempt any nonnarcotic substance from a schedule if such substance may, under the provisions of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) or state law, be lawfully sold over the counter without a prescription.

H. Any tetrahydrocannabinol isomer, ester, ether, salt, or salts of such isomer, ester, or ether scheduled pursuant to this section shall not be included in the definition of marijuana set forth in § 4.1-600, 18.2-247, or 54.1-3401.

1972, c. 798, § 54-524.84:1; 1976, c. 614; 1988, c. 765; 1993, c. 866; 1996, c. 408; 2014, cc. 674, 719; 2017, cc. 416, 432; 2023, cc. 744, 794.

§ 54.1-3444. Controlled substances included by whatever name designated.

The controlled substances listed or to be listed in the schedules in this chapter are included by whatever official, common, usual, chemical, or trade name designated.

1972, c. 798, § 54-524.84:2; 1988, c. 765.

§ 54.1-3445. Placement of substance in Schedule I.

The Board shall place a substance in Schedule I if it finds that the substance:

1. Has high potential for abuse; and

2. Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

1972, c. 798, § 54-524.84:3; 1988, c. 765.

§ 54.1-3446. Schedule I.

The controlled substances listed in this section are included in Schedule I:

1. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine);

1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237);

1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (other name: PEPAP);

1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238);

1-methyl-4-phenyl-4-propionoxypiperidine (other name: MPPP);

2-(4-ethoxybenzyl)-5-nitro-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne);

2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene);

2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl);

3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700);

3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921);

Acetyl fentanyl (other name: desmethyl fentanyl);

Acetylmethadol;

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

Alphameprodine;

Alphamethadol;

Benzethidine;

Betacetylmethadol;

Betameprodine;

Betamethadol;

Betaprodine;

Clonitazene;

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetylbutyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Furethidine;

Hydroxypethidine;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Morpheridine;

MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine);

N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl);

N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (other name: Tetrahydrofuranyl fentanyl);

N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]-N-phenylpropanamide (other name: alpha-methylthiofentanyl);

N-[1-(1-methyl-2-phenylethyl)-4-piperidyl]-N-phenylacetamide (other name: acetyl-alpha-methylfentanyl);

N-{1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl}-N-phenylpropanamide (other name: beta-hydroxythiofentanyl);

N-[1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxyfentanyl);

N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl]propionanilide (other names: 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine, alpha-methylfentanyl);

N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl);

N-(3-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl);

N-[3-methyl-1-(2-hydroxy-2-phenylethyl)4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxy-3-methylfentanyl);

N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylfentanyl);

N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl);

N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl);

N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl);

N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl);

N-(4-fluorophenyl)-N-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluorofentanyl);

N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene);

N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other names: Etazene, Desnitroetonitazene);

N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene);

N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl);

N-phenyl-N-(4-piperidinyl)-propanamide (other name: Norfentanyl);

Noracymethadol;

Norlevorphanol;

Normethadone;

Norpipanone;

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl);

N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide (other name: thiofentanyl);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tilidine;

Trimeperidine;

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole fentanyl);

3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900);

2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methyl acetamide (other name: U-48800);

2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methyl acetamide (other name: U-51754);

N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Ocfentanil);

N-(4-methoxyphenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: 4-methoxybutyrylfentanyl);

N-phenyl-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: Isobutyryl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-cyclopentanecarboxamide (other name: Cyclopentyl fentanyl);

N-phenyl-N-(1-methyl-4-piperidinyl)-propanamide (other name: N-methyl norfentanyl);

N-[2-(dimethylamino)cyclohexyl]-N-methyl-1,3-benzodioxole-5-carboxamide (other names: 3,4-methylenedioxy U-47700 or 3,4-MDO-U-47700);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl);

N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl fentanyl);

N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF-17);

N-[2-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17);

3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700).

2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine;

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine;

Thebacon.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):

Alpha-ethyltryptamine (some trade or other names: Monase; a-ethyl-1H-indole-3-ethanamine; 3-2-aminobutyl] indole; a-ET; AET);

4-Bromo-2,5-dimethoxyphenethylamine (some trade or other names: 2-4-bromo-2,5-dimethoxyphenyl]-1-aminoethane;alpha-desmethyl DOB; 2C-B; Nexus);

3,4-methylenedioxy amphetamine;

5-methoxy-3,4-methylenedioxy amphetamine;

3,4,5-trimethoxy amphetamine;

Alpha-methyltryptamine (other name: AMT);

Bufotenine;

Diethyltryptamine;

Dimethyltryptamine;

4-methyl-2,5-dimethoxyamphetamine;

2,5-dimethoxy-4-ethylamphetamine (DOET);

4-fluoro-N-ethylamphetamine;

2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7);

Ibogaine;

5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT);

Lysergic acid diethylamide;

Mescaline;

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo [b,d] pyran; Synhexyl);

Peyote;

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocyn;

Salvinorin A;

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA);

3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers;

3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);

N-hydroxy-3,4-methylenedioxyamphetamine (some other names: N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);

4-methoxyamphetamine (some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA);

Ethylamine analog of phencyclidine (some other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE);

Pyrrolidine analog of phencyclidine (some other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP);

Thiophene analog of phencyclidine (some other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP);

1-1-(2-thienyl)cyclohexyl]pyrrolidine (other name: TCPy);
3,4-methylenedioxypyrovalerone (other name: MDPV);

4-methylmethcathinone (other names: mephedrone, 4-MMC);

3,4-methylenedioxymethcathinone (other name: methylone);

Naphthylpyrovalerone (other name: naphyrone);

4-fluoromethcathinone (other names: flephedrone, 4-FMC);

4-methoxymethcathinone (other names: methedrone; bk-PMMA);

Ethcathinone (other name: N-ethylcathinone);

3,4-methylenedioxyethcathinone (other name: ethylone);

Beta-keto-N-methyl-3,4-benzodioxolylbutanamine (other name: butylone);

N,N-dimethylcathinone (other name: metamfepramone);

Alpha-pyrrolidinopropiophenone (other name: alpha-PPP);

4-methoxy-alpha-pyrrolidinopropiophenone (other name: MOPPP);

3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (other name: MDPPP);

Alpha-pyrrolidinovalerophenone (other name: alpha-PVP);

6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (other name: MDAI);

3-fluoromethcathinone (other name: 3-FMC);

4-Ethyl-2,5-dimethoxyphenethylamine (other name: 2C-E);

4-Iodo-2,5-dimethoxyphenethylamine (other name: 2C-I);

4-Methylethcathinone (other name: 4-MEC);

4-Ethylmethcathinone (other name: 4-EMC);

N,N-diallyl-5-methoxytryptamine (other name: 5-MeO-DALT);

Beta-keto-methylbenzodioxolylpentanamine (other names: Pentylone, bk-MBDP);

Alpha-methylamino-butyrophenone (other name: Buphedrone);

Alpha-methylamino-valerophenone (other name: Pentedrone);

3,4-Dimethylmethcathinone (other name: 3,4-dmmc);

4-methyl-alpha-pyrrolidinopropiophenone (other name: MPPP);

4-Iodo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 25-I, 25I-NBOMe, 2C-I-NBOMe);

Methoxetamine (other names: MXE, 3-MeO-2-Oxo-PCE);

4-Fluoromethamphetamine (other name: 4-FMA);

4-Fluoroamphetamine (other name: 4-FA);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (other name: 2C-D);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (other name: 2C-C);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-2);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-4);

2-(2,5-Dimethoxyphenyl)ethanamine (other name: 2C-H);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (other name: 2C-N);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (other name: 2C-P);

(2-aminopropyl)benzofuran (other name: APB);

(2-aminopropyl)-2,3-dihydrobenzofuran (other name: APDB);

4-chloro-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-C-NBOMe, 25C-NBOMe, 25C);

4-bromo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-B-NBOMe, 25B-NBOMe, 25B);

Acetoxydimethyltryptamine (other names: AcO-Psilocin, AcO-DMT, Psilacetin);

Benocyclidine (other names: BCP, BTCP);

Alpha-pyrrolidinobutiophenone (other name: alpha-PBP);

3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA);

4-bromomethcathinone (other name: 4-BMC);

4-chloromethcathinone (other name: 4-CMC);

4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25I-NBOH);

Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP);

Alpha-Pyrrolidinoheptiophenone (other name: PV8);

5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT);

Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB);

Beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B);

1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone);

1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP);

1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP);

4-Chloroethcathinone (other name: 4-CEC);

3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone);

1-propionyl lysergic acid diethylamide (other name: 1P-LSD);

(2-Methylaminopropyl)benzofuran (other name: MAPB);

1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);

1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9);

3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: TH-PVP);

4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);

4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25B-NBOH);

4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone);

4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);

4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);

4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT);

4-methyl-alpha-ethylaminopentiophenone;

4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);

5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT);

5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT);

6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD);

6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD);

(N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB);

2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine);

2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine);

2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP);

Alpha-ethylaminohexanophenone (other name: N-ethylhexedrone);

N-ethyl-1-(3-methoxyphenyl)cyclohexylamine (other name: 3-methoxy-PCE);

4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP);

N-ethyl-1,2-diphenylethylamine (other name: Ephenidine);

2,5-dimethoxy-4-chloroamphetamine (other name: DOC);

3,4-methylenedioxy-N-tert-butylcathinone;

Alpha-pyrrolidinoisohexiophenone (other name: alpha-PiHP);

1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP);

4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT);

4-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT);

3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP);

5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT);

1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other names: Eutylone, bk-EBDB);

1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone);

N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA);

1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone);

1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD);

2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone);

(2-ethylaminopropyl)benzofuran (other name: EAPB);

4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH);

2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone);

4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT);

2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, alpha-isobutylaminohexanphenone);

1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA);

N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE);

N-heptyl-3,4-dimethoxyamphetamine (other name: N-heptyl-3,4-DMA);

N-hexyl-3,4-dimethoxyamphetamine (other name: N-hexyl-3,4-DMA);

4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP);

4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone);

N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA);

4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT);

Alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP);

3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8);

4-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone);

1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone);

2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone);

3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone);

3,4-methylenedioxy-alpha-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone);

3,4-methylenedioxy-alpha-isopropylaminobutiophenone (other name: N-isopropyl butylone);

4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone);

4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin);

4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline);

Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV).

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam);

7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam);

Bromazolam;

Clonazolam;

Deschloroetizolam;

Etizolam;

Flualprazolam;

Flubromazepam;

Flubromazolam;

Gamma hydroxybutyric acid (some other names include GHB; gamma hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate);

Mecloqualone;

Methaqualone.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine);

Aminorex (some trade or other names; aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4,5-dihydro-5-phenyl-2-oxazolamine);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, norephedrone), and any plant material from which Cathinone may be derived;

Cis-4-methylaminorex (other name: cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Ethylamphetamine;

Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate);

Fenethylline;

Methcathinone (some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)-propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR 1432);

N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine);

N,N-dimethylamphetamine (other names: N,N-alpha-trimethyl-benzeneethanamine, N,N-alpha-trimethylphenethylamine);

Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (other name: 4-fluoromethylphenidate);

Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate);

4-chloro-N,N-dimethylcathinone;

3,4-methylenedioxy-N-benzylcathinone (other name: BMDP);

4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA).

6. Any substance that contains one or more cannabimimetic agents or that contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of one or more cannabimimetic agents.

a. "Cannabimimetic agents" includes any substance that is within any of the following structural classes:

2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent;

3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent;

3-(1-naphthoyl)pyrrole with substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent;

1-(1-naphthylmethyl)indene with substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent;

3-phenylacetylindole or 3-benzoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent;

3-cyclopropoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the cyclopropyl ring to any extent;

3-adamantoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent;

N-(adamantyl)-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent; and

N-(adamantyl)-indazole-3-carboxamide with substitution at a nitrogen atom of the indazole ring, whether or not further substituted on the indazole ring to any extent, whether or not substituted on the adamantyl ring to any extent.

b. The term "cannabimimetic agents" includes:

5-(1,1-Dimethylheptyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497);

5-(1,1-Dimethylhexyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C6 homolog);

5-(1,1-Dimethyloctyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C8 homolog);

5-(1,1-Dimethylnonyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C9 homolog);

1-pentyl-3-(1-naphthoyl)indole (other names: JWH-018, AM-678);

1-butyl-3-(1-naphthoyl)indole (other name: JWH-073);

1-pentyl-3-(2-methoxyphenylacetyl)indole (other name: JWH-250);

1-hexyl-3-(naphthalen-1-oyl)indole (other name: JWH-019);

1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (other name: JWH-200);

(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tet rahydrobenzo[c]chromen-1-ol (other name: HU-210);

1-pentyl-3-(4-methoxy-1-naphthoyl)indole (other name: JWH-081);

1-pentyl-3-(4-methyl-1-naphthoyl)indole (other name: JWH-122);

1-pentyl-3-(2-chlorophenylacetyl)indole (other name: JWH-203);

1-pentyl-3-(4-ethyl-1-naphthoyl)indole (other name: JWH-210);

1-pentyl-3-(4-chloro-1-naphthoyl)indole (other name: JWH-398);

1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (other name: AM-694);

1-((N-methylpiperidin-2-yl)methyl)-3-(1-naphthoyl)indole (other name: AM-1220);

1-(5-fluoropentyl)-3-(1-naphthoyl)indole (other name: AM-2201);

1-[(N-methylpiperidin-2-yl)methyl]-3-(2-iodobenzoyl)indole (other name: AM-2233);

Pravadoline (4-methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (other name: WIN 48,098);

1-pentyl-3-(4-methoxybenzoyl)indole (other names: RCS-4, SR-19);

1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (other names: RCS-8, SR-18);

1-pentyl-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: UR-144);

1-(5-fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other names: XLR-11, 5-fluoro-UR-144);

N-adamantyl-1-fluoropentylindole-3-carboxamide (other name: STS-135);

N-adamantyl-1-pentylindazole-3-carboxamide (other names: AKB48, APINACA);

1-pentyl-3-(1-adamantoyl)indole (other name: AB-001);

(8-quinolinyl)(1-pentylindol-3-yl)carboxylate (other name: PB-22);

(8-quinolinyl)(1-(5-fluoropentyl)indol-3-yl)carboxylate (other name: 5-fluoro-PB-22);

(8-quinolinyl)(1-cyclohexylmethyl-indol-3-yl)carboxylate (other name: BB-22);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide (other name: AB-FUBINACA);

1-(5-fluoropentyl)-3-(1-naphthoyl)indazole (other name: THJ-2201);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AB-PINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA);

Methyl-2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other name: 5-fluoro-AMB);

1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201);

1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144);

1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl)indole (other name MAM-2201);

N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA);

Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA);

Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA);

Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB);

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other names: FUB-AKB48, 5F-APINACA);

N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);

N-(adamantanyl)-1-(5-chloropentyl) indazole-3-carboxamide (other name: 5-chloro-AKB48);

Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA);

1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006);

Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22);

Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (other name: MMB-CHMICA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-ADB-PINACA);

1-(4-cyanobutyl)-N-(1-methyl-1-phenylethyl)-1H-indazole-3-carboxamide (other name: 4-cyano CUMYL-BUTINACA);

Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro MDMB-PICA, 5F-MDMB-PICA);

Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA);

Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA);
1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA);

Methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA);

Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA);

Methyl 2-[1-(4-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA);

Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB 2201);

Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-BUTINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA, 5-fluoro CUMYL-PINACA, CUMYL-5F-PINACA);

Ethyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5F-EDMB-PINACA, 5-fluoro EDMB-PINACA);

Ethyl-2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3-methylbutanoate (other names: 5-fluoro-EMB-PINACA, 5F-AEB);

Ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA);

Ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA);

Methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA);

Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: MDMB-CHMICA, MMB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-4en-PINACA);

Ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB).

1972, c. 798, § 54-524.84:4; 1973, c. 479; 1976, c. 614; 1977, c. 302; 1979, cc. 387, 435; 1982, c. 505; 1984, cc. 186, 192; 1986, c. 463; 1988, c. 765; 1994, c. 763; 1996, c. 408; 1997, c. 594; 1999, c. 722; 2000, c. 348; 2005, c. 119; 2008, c. 59; 2011, cc. 384, 410; 2012, cc. 762, 816; 2013, cc. 295, 785; 2014, cc. 674, 719; 2015, cc. 726, 757; 2016, cc. 103, 112; 2017, cc. 414, 434; 2018, c. 372; 2019, cc. 85, 653, 654; 2020, cc. 101, 229, 1285, 1286; 2021, Sp. Sess. I, cc. 73, 110; 2022, cc. 114, 115; 2023, cc. 188, 189, 744, 794.

§ 54.1-3447. Placement of substance in Schedule II.

The Board shall place a substance in Schedule II if it finds that:

1. The substance has high potential for abuse;

2. The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and

3. The abuse of the substance may lead to severe psychic or physical dependence.

1972, c. 798, § 54-524.84:5; 1988, c. 765.

§ 54.1-3448. Schedule II.

The controlled substances listed in this section are included in Schedule II:

1. Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxone naltrexone and their respective salts, but including the following:

Raw opium;

Opium extracts;

Opium fluid extracts;

Powdered opium;

Granulated opium;

Tincture of opium;

Codeine;

Dihydroetorphine;

Ethylmorphine;

Etorphine hydrochloride;

Hydrocodone;

Hydromorphone;

Metopon;

Oripavine (3-O-demethylthebaine or 6,7,8,14-tetradehydro-4, 5-alpha-epoxy-6-methoxy-17-methylmorphinan-3-ol);

Morphine;

Noroxymorphone;

Oxycodone;

Oxymorphone;

Thebaine.

Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium.

Opium poppy and poppy straw.

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

Concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid or powder form, which contains the phenanthrene alkaloids of the opium poppy.

2. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Alfentanil;

Alphaprodine;

Anileridine;

Bezitramide;

Bulk dextropropoxyphene (nondosage forms);

Carfentanil;

Dihydrocodeine;

Diphenoxylate;

Fentanyl;

Isomethadone;

Levo-alphacetylmethadol (levo-alpha-acetylmethadol)(levomethadyl acetate)(LAAM);

Levomethorphan;

Levorphanol;

Metazocine;

Methadone;

Methadone — Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

Moramide — Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylicacid;

Pethidine (other name: meperidine);

Pethidine — Intermediate — A, 4-cyano-1-methyl-4-phenylpiperidine;

Pethidine — Intermediate — B, ethyl-4-phenylpiperidine-4-carboxylate;

Pethidine — Intermediate — C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

Phenazocine;

Piminodine;

Racemethorphan;

Racemorphan;

Remifentanil;

Sufentanil;

Tapentadol;

Thiafentanil.

3. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

Amphetamine, its salts, optical isomers, and salts of its optical isomers;

Phenmetrazine and its salts;

Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;

Methylphenidate;

Lisdexamfetamine, its salts, isomers, and salts of its isomers.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Amobarbital;

Glutethimide;

Secobarbital;

Pentobarbital;

Phencyclidine.

5. The following hallucinogenic substances:

Nabilone;

Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances which are:

a. Immediate precursors to amphetamine and methamphetamine:

Phenylacetone.

b. Immediate precursor to phencyclidine:

1-phenylcyclohexylamine;

1-piperidinocyclohexanecarbonitrile (other name: PCC).

c. Immediate precursor to fentanyl:

4-anilino-N-phenethyl-4-piperidine (ANPP).

1972, c. 798, § 54-524.84:6; 1976, c. 614; 1977, c. 302; 1978, c. 833; 1979, c. 387; 1981, c. 30; 1984, c. 192; 1986, c. 463; 1988, cc. 283, 765; 1992, c. 737; 1994, c. 763; 1998, c. 105; 2000, c. 135; 2005, c. 119; 2008, c. 74; 2010, c. 423; 2011, c. 700; 2017, c. 612; 2019, c. 85; 2022, cc. 114, 115.

§ 54.1-3449. Placement of substance in Schedule III.

The Board shall place a substance in Schedule III if it finds that:

1. The substance has a potential for abuse less than the substances listed in Schedules I and II;

2. The substance has currently accepted medical use in treatment in the United States; and

3. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

1972, c. 798, § 54-524.84:7; 1988, c. 765.

§ 54.1-3450. Schedule III.

The controlled substances listed in this section are included in Schedule III:

1. Unless specifically exempted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules;

Any compound, mixture or preparation containing amobarbital, secobarbital, or pentobarbital or any salt of amobarbital, secobarbital, or pentobarbital and one or more other active medicinal ingredients which are not listed in Schedules II through V;

Any suppository dosage form containing amobarbital, secobarbital, or pentobarbital or any salt of amobarbital, secobarbital, or pentobarbital and approved by the Food and Drug Administration for marketing only as a suppository;

Chlorhexadol;

Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355);

Embutramide;

Ketamine, its salts, isomers, and salts of isomers (some other names: [+-] -2-[2-chlorophenyl]-2-[methylamino]-cyclohexanone);

Lysergic acid;

Lysergic acid amide;

Methyprylon;

Perampanel [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl) benxonitrile], including its salts, isomers, and salts of isomers;

Sulfondiethylmethane;

Sulfonethylmethane;

Sulfonmethane; and

Tiletamine-zolazepam combination product or any salt thereof.

2. Nalorphine.

3. Unless specifically excepted or unless listed in another schedule:

a. Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts thereof:

Buprenorphine.

b. Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

Not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

Not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts;

Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

Not more than 50 milligrams of morphine, or any of its salts, per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Benzphetamine;

Chlorphentermine;

Clortermine;

Phendimetrazine.

5. The Board may except by regulation any compound, mixture, or preparation containing any stimulation or depressant substance listed in subsection A from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

Anabolic steroids, including, but not limited to:

3beta,17-dihydroxy-5a-androstane;

3alpha,17beta-dihydroxy-5a-androstane;

5alpha-androstan-3,17-dione;

1-androstenediol (3beta,17beta-dihydroxy-5alpha-androst-1-ene);

1-androstenediol (3alpha,17beta-dihydroxy-5alpha-androst-1-ene);

4-androstenediol (3beta,17beta-dihydroxy-androst-4-ene);

5-androstenediol (3beta,17beta-dihydroxy-androst-5-ene);

1-androstenedione ([5alpha]-androst-1-en-3,17-dione);

4-androstenedione (androst-4-en-3,17-dione);

5-androstenedione (androst-5-en-3,17-dione);

Bolasterone (7alpha,17alpha-dimenthyl-17beta-hydroxyandrost-4-en-3-one);

Boldenone (Dehydrotestosterone)(17beta-hydroxyandrost-1,4,-diene-3-one);

Boldione (androsta-1, 4-diene-3, 17-dione);

Calusterone (7beta,17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one);

Clostebol (4-Chlorotestosterone)(Chlorotestosterone)(4-chloro-17beta-hydr oxyandrost-4-en-3-one);

Dehydrochloromethyltestosterone (4-chloro-17beta-hydroxy-17alpha-methyl-androst-1,4-dien-3-one) ;

Delta1-dihydrotestosterone (1-testosterone) (17beta-hydroxy-5alpha-androst-1-en-3-one);

Desoxymethyltestosterone (madol) (17alpha-methyl-5alpha-androst-2-en-17beta-ol);

Dromostanolone (Drostanolone) (17beta-hydroxy-2alpha-methyl-5alpha-androstan-3- one);

Ethylestrenol (17alpha-ethyl-17beta-hydroxyestr-4-ene);

Fluoxymesterone (9-fluoro-17alpha-methyl-11beta,17beta-dihydroxyandrost-4-en-3- one);

Formyldienolone (Formebolone) (2-formyl-17alpha-methyl-11alpha,17beta-dihydroxyandrost-1,4-di en-3-one);

Furazabol (17alpha-methyl-17beta-hydroxyandrostano[2,3-c]-furazan);

13-beta-ethyl-17alpha-hydroxygon-4-en-3-one;

4-hydroxytestosterone (4,17beta-dihydroxy-androst-4-en-3-one);

4-hydroxy-19-nortestosterone (4,17beta-dihydroxy-estr-4-en-3-one);

Mestanolone (17alpha-methyl-17beta-hydroxy-5-androstan-3-one);

Mesterolone (1alpha-methyl-17beta-hydroxy-[5alpha]-androstan-3-one);

Methandriol (methylandrostenediol) (17alpha-methyl-3beta,17beta-dihydroxyandrost-5-ene);

Methandrostenolone (Methandienone) (Dehydromethyltestosterone) (17alpha-methyl-17beta-hydroxyandrost-1,4-dien-3-one);

Methasterone (2alpha,17alpha-dimethyl-5alpha-androstan-17beta-ol-3-one);

Methenolone (1-methyl-17beta-hydroxy-5alpha-androst-1-en-3-one);

17alpha-methyl-3beta,17beta-dihydroxy-5a-androstane;

17alpha-methyl-3alpha,17beta-dihydroxy-5a-androstane;

17alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene);

17alpha-methyl-4-hydroxynandrolone (17alpha-methyl-4-hydroxy-17beta-hydroxyestr-4-en-3-one);

Methyldienolone (17alpha-methyl-17beta-hydroxyestra-4,9(10)-dien-3-one);

Methyltrienolone (17alpha-methyl-17beta-hydroxyestra-4,9-11-trien-3-one);

17-Methyltestosterone (Methyltestosterone)(17alpha-methyl-17beta-hydroxyandrost-4-en- 3-one);

Mibolerone (7alpha,17alpha-dimethyl-17beta-hydroxyestr-4-en-3-one);

17alpha-methyl-delta1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one)(17-al pha-methyl-1-testosterone);

Nandrolone (19-Nortestosterone)(17beta-hydroxyestr-4-en-3-one);

19-nor-4,9(10)-androstadienedione(estra-4,9(10)-diene-3,17-dion e);

19-nor-4-androstenediol (3beta,17beta-dihydroxyestr-4-ene);

19-nor-4-androstenediol (3alpha,17beta-dihydroxyestr-4-ene);

19-nor-5-androstenediol (3beta,17beta-dihydroxyestr-5-ene);

19-nor-5-androstenediol (3alpha,17beta-dihydroxyestr-5-ene);

19-nor-4-androstenedione (estr-4-en-3,17-dione);

19-nor-5-androstenedione (estr-5-en-3,17-dione);

Norbolethone (13beta,17alpha-diethyl-17beta-hydroxygon-4-en-3-one);

Norclostebol (4-chloro-17beta-hydroxyestr-4-en-3-one);

Norethandrolone (17alpha-ethyl-17beta-hydroxyestr-4-en-3-one);

Normethandrolone (17alpha-methyl-17beta-hydroxyestr-4-en-3-one);

Oxandrolone (17alpha-methyl-17beta-hydroxy-2-oxa-[5alpha]-androstan-3-one);

Oxymesterone (Oxymestrone) (17alpha-methyl-4,17beta-dihydroxyandrost-4-en-3-one);

Oxymetholone (Anasterone) (17alpha-methyl-2-hydroxymethylene-17beta-hydroxy-[5alpha]-androsta n-3-one);

Prostanozol (17beta-hydroxy-5alpha-androstano[3,2-c]pyrazole);

Stanolone (4-Dihydrotestosterone) (Dihydrotestosterone) (17beta-hydroxy-androstan-3-one);

Stanozolol (Androstanazole) (17alpha-methyl-17beta-hydroxy-[5alpha]-androst-2-eno[3,2-c]-py razole);

Stenbolone (17beta-hydroxy-2-methyl-[5alpha]-androst-1-en-3-one);

Testolactone (1-Dehydrotestololactone) (13-hydroxy-3-oxo-13,17-secoandrosta-1 ,4-dien-17-oic acid lactone);

Testosterone (17beta-hydroxandrost-4-en-3-one);

Tetrahydrogestrinone (13beta,17alpha-diethyl-17beta-hydroxygon-4,9,11-trien-3-one);

Trenbolone (Trienbolone) (Trienolone) (17beta-hydroxyestr-4,9,11-trien-3-one); and

Any salt, ester, or ether of a drug or substance described or listed in this paragraph. However, such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the United States Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes any such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subsection.

7. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration.

1972, c. 798, § 54-524.84:8; 1976, c. 614; 1977, c. 302; 1979, c. 387; 1982, c. 505; 1988, cc. 283, 765; 1992, c. 737; 2000, cc. 135, 348; 2003, c. 640; 2005, c. 119; 2006, c. 346; 2007, c. 14; 2010, c. 423; 2013, c. 233; 2014, c. 74; 2015, c. 303.

§ 54.1-3451. Placement of substance in Schedule IV.

The Board shall place a substance in Schedule IV if it finds that:

1. The substance has a low potential for abuse relative to substances in Schedule III;

2. The substance has currently accepted medical use in treatment in the United States; and

3. Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

1972, c. 798, § 54-524.84:9; 1988, c. 765.

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alfaxalone (5[alpha]-pregnan-3[alpha]-ol-11, 20-dione), previously spelled "alphaxalone," including its salts, isomers, and salts of isomers;

Alprazolam;

Barbital;

Brexanolone;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Suvorexant ([(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1, 2, 3-triazol-2-yl) phenyl]methanone), including its salts, isomers, and salts of isomers;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine;

Lorcaserin.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproprex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

Solriamfetol (2-amino-3-phenylpropyl carbamate);

SPA (-)-1-dimethylamino-1,2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit;

2-[(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol, its salts, optical and geometric isomers, and salts of such isomers, including tramadol.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Eluxadoline (including its optical isomers and its salts, isomers, and salts of isomers);

Pentazocine.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

1972, c. 798, § 54-524.84:10; 1976, c. 614; 1977, c. 302; 1978, c. 705; 1979, c. 387; 1982, c. 505; 1986, c. 463; 1988, cc. 283, 765; 1992, c. 737; 1994, c. 763; 1998, c. 105; 1999, c. 605; 2000, c. 135; 2003, c. 640; 2006, c. 346; 2010, c. 423; 2012, c. 540; 2014, c. 74; 2015, c. 303; 2016, c. 499; 2022, cc. 114, 115.

§ 54.1-3453. Placement of substance in Schedule V.

The Board shall place a substance in Schedule V if it finds that:

1. The substance has low potential for abuse relative to the controlled substances listed in Schedule IV;

2. The substance has currently accepted medical use in treatment in the United States; and

3. The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

1972, c. 798, § 54-524.84:11; 1988, c. 765.

§ 54.1-3454. Schedule V.

The controlled substances listed in this section are included in Schedule V:

1. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter and such substances so excepted may be dispensed pursuant to § 54.1-3416.

2. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Pyrovalerone.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB-34714; Briviact);

Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester]-2779;

Gabapentin [1-(aminomethyl)cyclohexaneacetic acid];

Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide];

Lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide];

Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].

1972, c. 798, § 54-524.84:12; 1976, c. 614; 1977, c. 302; 1979, c. 387; 1984, c. 186; 1986, c. 463; 1988, c. 765; 1992, c. 737; 1994, c. 763; 2003, c. 640; 2006, c. 346; 2010, c. 423; 2012, c. 541; 2017, c. 612; 2019, c. 214; 2022, cc. 114, 115.

§ 54.1-3455. Schedule VI.

The following classes of drugs and devices shall be controlled by Schedule VI:

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.

2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.

3. Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend

"Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____." (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

1972, c. 798, § 54-524.84:13; 1976, c. 614; 1977, c. 302; 1988, c. 765; 1999, c. 605.

§ 54.1-3456. Controlled substance analog.

A controlled substance analog shall, to the extent intended for human consumption, be treated, for the purposes of any state law, as a controlled substance in Schedule I or II. A controlled substance analog shall be considered to be listed on the same schedule as the drug or class of drugs which it imitates.

1987, c. 447, § 54-524.84:14; 1988, c. 765; 2014, cc. 674, 719.

§ 54.1-3456.1. Drugs of concern.

The Board may promulgate regulations designating specific drugs and substances, including any controlled substance or other drug or substance where there has been or there is the actual or relative potential for abuse, as drugs of concern. Drugs or substances designated as drugs of concern shall be reported to the Department of Health Professions and shall be subject to reporting requirements for the Prescription Monitoring Program established pursuant to Chapter 25.2 (§ 54.1-2519 et seq.).

2014, c. 664; 2017, c. 181; 2019, c. 214.

Article 6. Misbranded and Adulterated Drugs and Cosmetics.

§ 54.1-3457. Prohibited acts.

The following acts shall be prohibited:

1. The manufacture, sale, delivery, holding, or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded.

2. The adulteration or misbranding of any drug, device, or cosmetic.

3. The receipt in commerce of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

4. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of § 54.1-3421.

5. The dissemination of any false advertisement.

6. The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record.

7. The giving of a false guaranty or undertaking.

8. The removal or disposal of a detained article in violation of § 54.1-3459.

9. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

10. The forging, counterfeiting, simulating, or falsely representing, or without proper authority using of any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act.

11. The using by any person to his own advantage, or revealing, other than to the Board or its authorized representative or to the courts when relevant in any judicial proceeding under this chapter of any information acquired under authority of this chapter concerning any method or process which as a trade secret is entitled to protection.

12. The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under § 54.1-3421, or that such drug complies with the provisions of such section.

13. In the case of a drug distributed or offered for sale in this Commonwealth, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. This subdivision shall not be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

14. Placing or causing to be placed upon any drug or device or container, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by this section or making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the

foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

15. The doing of any act that causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

16. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing, except as provided in § 54.1-3408.03 relating to dispensing of therapeutically equivalent drugs.

17. Dispensing or causing to be dispensed a biosimilar in place of a prescribed biological product or brand of biological product, except as provided in § 54.1-3408.04 related to dispensing of interchangeable biosimilars.

1970, c. 650, § 54-524.85; 1988, c. 765; 2003, c. 639; 2013, cc. 412, 544.

§ 54.1-3458. Violations.

A. Any person who violates any of the provisions of § 54.1-3457 shall be guilty of a Class 2 misdemeanor.

B. No person shall be subject to the penalties of this section for having violated subdivisions 1 and 3 of § 54.1-3457 if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in this Commonwealth from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this chapter.

C. No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section for the dissemination of such false advertisement, unless he has refused, on the request of the Board, to furnish the Board the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in this Commonwealth who caused him to disseminate such advertisement.

1970, c. 650, § 54-524.87; 1988, c. 765.

§ 54.1-3459. Tagging of adulterated or misbranded drugs, devices, or cosmetics; condemnation; destruction; expenses.

A. Whenever a duly authorized agent of the Board finds, or has probable cause to believe, that any drug, device, or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of this chapter or is in violation of § 54.1-3457, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded or in violation of § 54.1-3457 and has been detained. The tag shall also warn all persons not to remove or dispose of such article by sale or otherwise until

permission for removal or disposal is given by an authorized agent or the court. It shall be unlawful for any person to remove or dispose of such detained article by sale or otherwise without permission.

B. When an article is adulterated or misbranded or is in violation of § 54.1-3421, the Board may petition the circuit court in whose jurisdiction the article is detained for condemnation of such article. When an authorized agent finds that an article which has been detained is not adulterated or misbranded, or in violation of § 54.1-3421, he shall remove the tag or other marking.

C. If the court finds that a detained article is adulterated or misbranded, or in violation of § 54.1-3421, such article shall, after entry of the decree, be destroyed at the expense of the claimant, under the supervision of an authorized agent, and all court costs and fees, and storage and other proper expenses, shall be levied against the claimant or his agent. When the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court shall order the article to be properly labeled or processed. The expense of the supervision shall be paid by the claimant. The article shall be returned to the claimant and the bond shall be discharged on the representation to the court by the Board that the article is no longer in violation of this chapter, and that the expenses of such supervision have been paid.

1970, c. 650, § 54-524.88; 1988, c. 765.

§ 54.1-3460. Poisonous or deleterious substance, or color additive.

Any added poisonous or deleterious substance, or any color additive, shall with respect to any particular use or intended use be deemed unsafe with respect to any drug, device, or cosmetic, unless there is a regulation allowing limited use of a quantity of such substance, and the use or intended use of such substance conforms to the terms prescribed by regulation. While such regulations relating to such substance are in effect, a drug or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulations, be considered adulterated.

1970, c. 650, § 54-524.91; 1988, c. 765.

§ 54.1-3461. Adulterated drug or device.

A. A drug or device shall be deemed to be adulterated:

1. If it consists in whole or in part of any filth, putrid or decomposed substance;

2. If it has been produced, prepared, packed, or held under insanitary conditions whereby it has been contaminated with filth, or whereby it has been rendered injurious to health;

3. If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter;

4. If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

5. If it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act or § 54.1-3460; or

6. It is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the federal act or § 54.1-3460.

B. A drug or device shall be deemed to be adulterated if it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination of strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity set forth in such compendium, if the difference in strength, quality, or purity from such standard is plainly stated on its label.

Whenever a drug is recognized in both the United States Pharmacopoeia National Formulary and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia National Formulary unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia National Formulary.

C. A drug or device shall be deemed to be adulterated if it is not subject to the provisions of subsection B of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

D. A drug or device shall be deemed to be adulterated if it is a drug and any substance has been (i) mixed or packed with it so as to reduce its quality or strength or (ii) substituted wholly or in part for it.

Code 1950, § 54-461; 1970, c. 650, § 54-524.92; 1988, c. 765.

§ 54.1-3462. Misbranded drug or device.

A drug or device shall be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.

2. If its package does not bear a label containing the name and place of business of the manufacturer, packer, or distributor. However, all prescription drugs intended for human use and devices shall bear a label containing the name and place of business of the manufacturer of the final dosage form of the drug and, if different, the name and place of business of the packer or

distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Reasonable variations shall be permitted, and exemptions for small packages shall be allowed in accordance with regulations of the Board.

3. If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed with such conspicuousness, as compared with other words, statements, designs or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

4. If it is for use by man and contains any quantity of the narcotic or hypnotic substances alpha-eucaine, barbituric acid, beta-eucaine, bromal, carbromal, chloral, coca, cocaine, codeine, morphine, opium, paraldehyde, or sulfonmethane, or any chemical derivative of such substances, which derivative, after investigation has been found to be and designated as, habit forming, by regulations issued by the Board under this chapter, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning -- May Be Habit Forming."

5. If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name, except the applicable systematic chemical name or the chemical formula, the established name of the drug, and in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subdivision, shall apply only to prescription drugs. Any prescription drug shall have the established name of the drug or ingredient printed on its label prominently and in type at least half as large as that used for any proprietary name or designation for such drug or ingredient. Exemptions may be allowed under regulations of the Board.

As used in this subdivision, the term "established name," with respect to a drug or ingredient, means the applicable official name designated pursuant to § 508 of the federal act, or if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title in such compendium or if neither exists, then the common or usual name, if any, of such drug or of such ingredient. Whenever, an article is recognized in the United States Pharmacopoeia National Formulary and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia National Formulary shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

6. Unless its labeling bears adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. The Board shall promulgate regulations exempting

such drug or device from such requirements when these requirements are not necessary to protect the public health and the articles are also exempted under regulations issued under § 502(f) of the federal act.

7. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed. The method of packing may be modified with the consent of the Board, or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States Pharmacopoeia National Formulary and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia National Formulary with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia National Formulary. However, in the event of inconsistency between the requirements of this subdivision and those of subdivision 5 as to the name by which the drug or its ingredients shall be designated, the requirements of subdivision 5 shall prevail.

8. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling or advertising.

9. If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless it is from a batch for which a certificate or release has been issued pursuant to § 506 of the federal act, and such certificate or release is in effect with respect to such drug.

10. If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative, unless it is from a batch, for which a certificate or release has been issued pursuant to § 507 of the federal act, and such certificate or release is in effect for such drug. This subdivision shall not apply to any drug or class of drugs exempted by regulations promulgated under § 507(c) or (d) of the federal law.

For the purpose of this subdivision the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by microorganisms and which has the capacity to inhibit or destroy microorganisms in dilute solution, including, the chemically synthesized equivalent of any such substance.

11. If it is a color additive, the intended use of which in or on drugs is for coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of the federal act.

12. In the case of any prescription drug distributed or offered for sale in this Commonwealth, unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter a true statement of (i) the established name, as defined in this section, printed prominently and in type at least half as large as that used for any trade or brand name, (ii) the formula showing quantitatively each ingredient of such drug to the extent required for labels under this section, and (iii) such other information in brief summary relating to side effects, contraindications, and effectiveness as are required in regulations issued under the federal act.

13. If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this chapter if such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the Board.

Code 1950, § 54-463; 1958, c. 551; 1970, c. 650, § 54-524.93; 1976, c. 644; 1988, c. 765.

§ 54.1-3463. Exemption of drugs dispensed by filling or refilling prescription.

A. Any drug dispensed by filling or refilling a written or oral prescription of a prescriber shall be exempt from the requirements of § 54.1-3462 except subdivisions 1, 9, and 10, and the packaging requirements of subdivision 7, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.

B. This section shall not be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

1970, c. 650, § 54-524.94; 1988, c. 765; 1996, c. 408.

§ 54.1-3464. Adulterated cosmetics.

A cosmetic shall be deemed to be adulterated:

1. If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement, or under such conditions of use as are customary or usual. This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution -- This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing. For the purpose of this subdivision and subdivision 5, the term "hair dye" shall not include eyelash or eyebrow dyes;

2. If it consists in whole or in part of any filthy, putrid, or decomposed substance;

3. If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

4. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

5. If it is not a hair dye, and it is or it bears or contains a color additive which is unsafe within the meaning of the federal act or § 54.1-3460.

Code 1950, § 54-462; 1970, c. 650, § 54-524.96; 1988, c. 765.

§ 54.1-3465. Misbranded cosmetics.

A cosmetic shall be deemed to be misbranded:

1. If its labeling is false or misleading in any particular;

2. If in package form unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. However, reasonable variations shall be permitted, and exemptions for small packages shall be established by the Board;

3. If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

4. If its container is so made, formed or filled as to be misleading;

5. If it is a color additive, unless its packaging and labeling are in conformity with packaging and labeling requirements applicable to such color additive under the provisions of the federal act. This subdivision shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

A cosmetic which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed, is exempted from the affirmative labeling requirements of this chapter while it is in transit in commerce from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but it is otherwise subject to all applicable provisions of this chapter.

Code 1950, § 54-466; 1970, c. 650, § 54-524.97; 1988, c. 765.

Article 7. Controlled Paraphernalia.

§ 54.1-3466. Possession or distribution of controlled paraphernalia; definition of controlled paraphernalia; evidence; exceptions.

A. For purposes of this chapter, "controlled paraphernalia" means (i) a hypodermic syringe, needle, or other instrument or implement or combination thereof adapted for the administration of controlled dangerous substances by hypodermic injections under circumstances that reasonably indicate an intention to use such controlled paraphernalia for purposes of illegally administering any controlled drug or (ii) gelatin capsules, glassine envelopes, or any other container suitable for the packaging of individual quantities of controlled drugs in sufficient quantity to and under circumstances that reasonably indicate an intention to use any such item for the illegal manufacture, distribution, or dispensing of any such controlled drug. Evidence of such circumstances shall include, but not be limited to, close proximity of any such controlled paraphernalia to any adulterants or equipment commonly used in the illegal manufacture and distribution of controlled drugs including, but not limited to, scales, sieves, strainers, measuring spoons, staples and staplers, or procaine hydrochloride, mannitol, lactose, quinine, or any controlled drug, or any machine, equipment, instrument, implement, device, or combination thereof that is adapted for the production of controlled drugs under circumstances that reasonably indicate an intention to use such item or combination thereof to produce, sell, or dispense any controlled drug in violation of the provisions of this chapter. "Controlled paraphernalia" does not include narcotic testing products used to determine whether a controlled substance contains fentanyl or a fentanyl analog.

B. Except as authorized in this chapter, it is unlawful for any person to possess controlled paraphernalia.

C. Except as authorized in this chapter, it is unlawful for any person to distribute controlled paraphernalia.

D. A violation of this section is a Class 1 misdemeanor.

E. The provisions of this section shall not apply to persons who have acquired possession and control of controlled paraphernalia in accordance with the provisions of this article or to any person who owns or is engaged in breeding or raising livestock, poultry, or other animals to which hypodermic injections are customarily given in the interest of health, safety, or good husbandry; or to hospitals, physicians, pharmacists, dentists, podiatrists, veterinarians, funeral directors and embalmers, persons to whom a permit has been issued, manufacturers, wholesalers, or their authorized agents or employees when in the usual course of their business, if the controlled paraphernalia lawfully obtained continue to be used for the legitimate purposes for which they were obtained.

F. The provisions of this section and of § 18.2-265.3 shall not apply to (i) a person who dispenses naloxone in accordance with the provisions of subsection Y of § 54.1-3408 and who, in conjunction with such dispensing of naloxone, dispenses or distributes hypodermic needles and syringes for injecting such naloxone or (ii) a person who possesses naloxone that has been dispensed in accordance with the provisions of subsection Y of § 54.1-3408 and possesses hypodermic needles and syringes for injecting such naloxone in conjunction with such possession of naloxone.

G. The provisions of this section and of § 18.2-265.3 shall not apply to (i) a person who possesses or distributes controlled paraphernalia on behalf of or for the benefit of a comprehensive harm reduction program established pursuant to § 32.1-45.4 or (ii) a person who possesses controlled paraphernalia obtained from a comprehensive harm reduction program established pursuant to § 32.1-45.4.

1971, Ex. Sess., cc. 210, 245; 1976, c. 614; 1988, c. 765; 2016, c. 229; 2018, c. 97; 2019, c. 215; 2020, c. 839.

§ 54.1-3467. Distribution of hypodermic needles or syringes, gelatin capsules, quinine or any of its salts.

A. Distribution by any method, of any hypodermic needles or syringes, gelatin capsules, quinine or any of its salts, in excess of one-fourth ounce shall be restricted to licensed pharmacists or to others who have received a license or a permit from the Board.

B. Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized by the State Health Commissioner pursuant to a comprehensive harm reduction program established pursuant to § 32.1-45.4 who are acting in accordance with the standards and protocols of such program for the duration of the declared public health emergency.

C. Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized to dispense naloxone in accordance with the provisions of subsection Y of § 54.1-3408 and who, in conjunction with such dispensing of naloxone, dispenses or distributes hypodermic needles and syringes. Nothing in this section shall prohibit the dispensing of hypodermic needles and syringes for the administration of prescribed drugs by prescribers licensed to dispense Schedule VI controlled substances at a nonprofit facility pursuant to § 54.1-3304.1.

D. Notwithstanding the provisions of subsection A, nothing in this section shall prohibit the distribution of hypodermic needles that are designed to be used with a reusable injector pen for the administration of insulin.

1971, Ex. Sess., cc. 210, 245; 1988, c. 765; 2017, c. 183; 2018, c. 97; 2020, cc. 609, 610; 2023, cc. 142, 143.

§ 54.1-3468. Conditions to dispensing device, item, or substance; records.

In dispensing any device, item or substance, the pharmacist or other licensed or permitted person referred to in § 54.1-3467 shall:

1. Require the person requesting such device, item or substance to furnish suitable identification, including proof of age when appropriate;

2. Require the person requesting such item, device or substance to furnish written legitimate purposes for which such item, device or substance is being purchased, except in cases of telephone orders for such item, device or substance from customers of known good standing;

3. At the time of dispensing, make and keep a record showing the date of dispensing, the name and quantity of the device, item or substance, the price at which it was sold, the name and address of the person to whom the device, item or substance was dispensed, the reason for its purchase and enter his initials thereon.

No such devices, substances or items shall be sold or distributed to persons under the age of sixteen years except by a physician for legitimate purposes or upon his prescription. Records shall be maintained pursuant to this chapter and the Board's regulations and shall be made available for inspection to any law-enforcement officer or agent of the Board. Persons violating the provisions of this section shall be guilty of a Class 1 misdemeanor.

1971, Ex. Sess., cc. 210, 245; 1988, c. 765.

§ 54.1-3469. Storage, usage, and disposition of controlled paraphernalia.

Each person, association or corporation which has lawfully obtained possession of any of the controlled paraphernalia mentioned in § 54.1-3467 shall exercise reasonable care in the storage, usage and disposition of such devices or substances to ensure that they are not diverted for reuse for any purposes other than those for which they were lawfully obtained. Any person who permits or causes, directly or indirectly, such controlled paraphernalia to be used for any other purpose than that for which it was lawfully obtained shall be guilty of a Class 1 misdemeanor.

1971, Ex. Sess., cc. 210, 245; 1988, c. 765.

§ 54.1-3470. Obtaining controlled paraphernalia by fraud, etc.

A. No person shall obtain or attempt to obtain any item, device or substance referred to in § 54.1-3467 by fraud, deceit, misrepresentation, or subterfuge or by giving a false name or a false address.

B. No person shall furnish false or fraudulent information in or omit any information from, or willfully make a false statement in obtaining or attempting to obtain any of the instruments or substances referred to in § 54.1-3467.

C. No person shall, for the purpose of obtaining any such instrument or substance, falsely claim to be a manufacturer, wholesaler, pharmacist, practitioner of the healing arts, funeral director, embalmer or veterinarian.

Persons violating the provisions of this section shall be guilty of a Class 1 misdemeanor.

1971, Ex. Sess., cc. 210, 245; 1988, c. 765.

§ 54.1-3471. Issuance of permits to certain persons other than registered pharmacists.

The Board shall, upon written application, on a form furnished by the Board, issue a permit to any person other than a licensed pharmacist who in the usual course of business sells any item referred to in § 54.1-3467 as a wholesale distributor or distributes at retail to any persons who own or breed or raise livestock, poultry, or other animals to which such items, devices or substances are customarily given to or used upon in the interest of health, safety, or good husbandry. This permit shall not authorize the sale or distribution of these items, devices or substances for human use and the permitted person shall exercise reasonable diligence to assure that the items distributed are not for the purpose of human consumption.

1971, Ex. Sess., cc. 210, 245; 1988, c. 765.

§ 54.1-3472. Article inapplicable to certain persons.

The provisions of this article shall not apply to legitimate distribution by or possession of controlled paraphernalia by physicians, dentists, podiatrists, veterinarians, funeral directors and embalmers.

1971, Ex. Sess., cc. 210, 245; 1988, c. 765.