DRUG LAWS FOR PRACTITIONERS¹



COMMONWEALTH OF VIRGINIA

Department of Health Professions

January 1, 2024

¹ This document contains selected portions of relevant statutory law and is provided as a courtesy to the public. It is not comprehensive. Practitioners should review <u>all</u> applicable laws posted on the Legislative Information Site, available at https://law.lis.virginia.gov/.

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Selected Drug Laws for Practitioners from the Code of Virginia

SELECTED SECTIONS FROM CHAPTER 33. PHARMACY.

§ 54.1-3300. Definitions.

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

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed advanced practice registered nurse working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"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 delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) the initiating of treatment with or dispensing or administering of certain drugs, devices, or controlled paraphernalia in accordance with the provisions of § 54.1-3303.1.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ <u>54.1-3400</u> 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; 1999, cc. 895, 1011; 2001, c. 317; 2002, c. 411; 2013, c. 192; 2018, c. 776; 2020, cc. 102, 237, 731; 2021, Sp. Sess. I, c. 214; 2023, c. 183.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working in accordance with the provisions of § 54.1-2951.1; or (iv) any licensed advanced practice registered nurse working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes for patients who meet the criteria set forth in the collaborative agreement. However, no person licensed to practice medicine, osteopathy, or podiatry, or licensed as an advanced practice registered nurse or physician assistant, shall be required to participate in a collaborative agreement

with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

- B. A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.
- C. Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.
- D. Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

E. Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

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1999, cc. <u>895</u>, <u>1011</u>; 2013, c. <u>192</u>; 2018, c. <u>776</u>; 2020, cc. <u>46</u>, <u>232</u>, <u>731</u>; 2023, c. <u>183</u>.
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§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

- 1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;
- 2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § <u>54.1-3401</u>, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § <u>54.1-3303</u> or from causing drugs to be administered or dispensed pursuant to §§ <u>32.1-42.1</u> and <u>54.1-3408</u>, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary

Medicine, (iii) the quantity dispensed is no more than a seven-day supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;

- 3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;
- 4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ <u>54.1-3400</u> et seq.) of this title;
- 5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;
- 6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;
- 7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;
- 8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;
- 9. Interfere with any licensed advanced practice registered nurse with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe;
- 10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient.

The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

- 11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or
- 12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.

Code 1950, § 54-481; 1966, c. 171; 1968, c. 582, § 54-524.53; 1970, c. 650, § 54-524.54; 1972, c. 798; 1988, cc. 765, 904; 1989, c. 510; 1998, c. 101; 1999, cc. 745, 750; 2000, c. 924; 2001, c. 465; 2002, cc. 666, 707, 740; 2003, c. 794; 2008, c. 674; 2009, cc. 101, 353, 761; 2012, c. 213; 2014, c. 147; 2018, cc. 100, 776; 2023, c. 183.

§ 54.1-3302. Restrictions on practitioners of the healing arts.

A practitioner of the healing arts shall not sell or dispense controlled substances except as provided in §§ 54.1-2914 and 54.1-3304.1. Such exceptions shall extend only to his own patients unless he is licensed to practice pharmacy.

(Code 1950, § 54-481; 1966, c. 171; 1968, c. 582, § 54-524.53; 1970, c. 650; 1972, c. 798; 1988, c. 765; 1989, c. 510.)

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, a licensed advanced practice registered nurse pursuant to § <u>54.1-2957.01</u>, a licensed certified midwife pursuant to § <u>54.1-2957.04</u>, a licensed physician assistant pursuant to § <u>54.1-2952.1</u>, or a TPA-certified optometrist pursuant to Article 5 (§ <u>54.1-3222</u> et seq.) of Chapter 32.

B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship. If a practitioner is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, then a bona fide practitioner-patient relationship shall not be required.

A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient via telemedicine if such prescribing is in compliance with federal requirements for the practice of telemedicine and, in the case of the prescribing of a Schedule II through V controlled substance, the prescriber maintains a practice at a physical location in the Commonwealth or is able to make appropriate referral of patients to a licensed practitioner located in the Commonwealth in order to ensure an in-person examination of the patient when required by the standard of care.

A prescriber may establish a bona fide practitioner-patient relationship for the purpose of prescribing Schedule II through VI controlled substances by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations; (h) the establishment of a bona fide practitioner-patient relationship via telemedicine is consistent with the standard of care, and the standard of care does not require an in-person examination for the purpose of diagnosis; and (i) the establishment of a bona fide practitioner patient relationship via telemedicine is consistent with federal law and regulations and any waiver thereof. Nothing in this paragraph shall apply to (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

C. A prescription shall only be issued for a medicinal or therapeutic purpose in the usual course of treatment or for authorized research. A prescription not issued in the usual course of treatment or

for authorized research is not a valid prescription. A practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than for medicinal or therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

D. No prescription shall be filled unless a bona fide practitioner-patient-pharmacist relationship exists. A bona fide practitioner-patient-pharmacist relationship shall exist in cases in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to a patient for a medicinal or therapeutic purpose within the course of his professional practice. In cases in which it is not clear to a pharmacist that a bona fide practitioner-patient relationship exists between a prescriber and a patient, a pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. Any person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

E. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, with the diagnosed patient and (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.

- F. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, an advanced practice registered nurse, or a physician assistant authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ <u>54.1-3400</u> et seq.).
- G. A licensed advanced practice registered nurse who is authorized to prescribe controlled substances pursuant to § <u>54.1-2957.01</u> may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ <u>54.1-3400</u> et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.
- H. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § <u>54.1-2952.1</u> may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ <u>54.1-3400</u> et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

I. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

J. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

K. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.

1983, c. 528, § 54-524.50:1; 1985, c. 336; 1988, c. 765; 1991, cc. 519, 524; 1992, c. 793; 1996, cc. 152, 158, 408; 1997, c. 806; 1998, c. 101; 1999, c. 745; 2000, cc. 882, 924; 2001, c. 465; 2003, c. 639; 2004, c. 744; 2006, c. 432; 2010, c. 74; 2015, cc. 32, 115; 2016, c. 86; 2017, cc. 58, 110; 2018, cc. 373, 380, 790; 2019, c. 335; 2020, c. 464; 2021, Sp. Sess. I, cc. 200, 201, 301, 302; 2023, c. 183.

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older with whom the pharmacist has a bona fide pharmacist-patient relationship and in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

- 1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;
- 2. Epinephrine;
- 3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;
- 4. Prenatal vitamins for which a prescription is required;
- 5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;
- 6. Drugs as defined in § <u>54.1-3401</u>, devices as defined in § <u>54.1-3401</u>, controlled paraphernalia as defined in § <u>54.1-3466</u>, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;
- 7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19;
- 8. Tuberculin purified protein derivative for tuberculosis testing;
- 9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention;
- 10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ <u>54.1-3400</u> et seq.), together with providing appropriate patient counseling;
- 11. Controlled substances or devices for the initiation of treatment of the following diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988: group A Streptococcus bacteria infection, influenza virus infection, COVID-19 virus infection, and urinary tract infection; and
- 12. Tests for COVID-19 and other coronaviruses.
- B. Notwithstanding the provisions of § <u>54.1-3303</u>, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:

- 1. (Contingent Effective Date) Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and
- 2. (Contingent Effective Date) Tests for COVID-19 and other coronaviruses.
- C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.). If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.
- D. A pharmacist who administers a vaccination pursuant to subdivisions A 7 and B 1 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.
- E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.
- F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the applicable standard of care.
- G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

2020, c. <u>731</u>; 2021, Sp. Sess. I, c. <u>214</u>; 2022, cc. <u>790</u>, <u>791</u>; 2023, cc. <u>171</u>, <u>172</u>.

§ 54.1-3304. Licensing of physicians to dispense drugs; renewals.

For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician or osteopath so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.

(1976, c. 614, § 54-524.34:1; 1980, c. 288; 1988, c. 765.)

§ 54.1-3304.1. Authority to license and regulate practitioners.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

C. The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, an advanced practice registered nurse, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.

1988, c. 904, § 54-524.34:2; 1989, c. 510; 2015, c. 117; 2020, cc. 609, 610; 2023, c. 183.

SELECTED LAWS FROM CHAPTER 29. MEDICINE

§ 54.1-2914. Sale of controlled substances and medical devices or appliances; requirements for vision care services.

A. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available. Practitioners who sell or dispense controlled substances shall be subject to inspection by the Department of Health Professions to ensure compliance with Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of this title and the Board of Pharmacy's regulations. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

B. A practitioner of the healing arts who may lawfully sell medical appliances or devices shall not sell such appliances or devices to persons who are not his own patients and shall not sell such articles to his own patients either for his own convenience or for the purpose of supplementing his income. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

- C. A practitioner of the healing arts may, from within the practitioner's office, engage in selling or promoting the sale of eyeglasses and may dispense contact lenses. Only those practitioners of the healing arts who engage in the examination of eyes and prescribing of eyeglasses may engage in the sale or promotion of eyeglasses. Practitioners shall not employ any unlicensed person to fill prescriptions for eyeglasses within the practitioner's office except as provided in subdivision A 6 of § 54.1-2901. A practitioner may also own, in whole or in part, an optical dispensary located adjacent to or at a distance from his office.
- D. Any practitioner of the healing arts engaging in the examination of eyes and prescribing of eyeglasses shall give the patient a copy of any prescription for eyeglasses and inform the patient of his right to have the prescription filled at the establishment of his choice. No practitioner who owns, in whole or in part, an establishment dispensing eyeglasses shall make any statement or take any action, directly or indirectly, that infringes on the patient's right to have a prescription filled at an establishment other than the one in which the practitioner has an ownership interest.

Disclosure of ownership interest by a practitioner as required by § 54.1-2964 or participation by the practitioner in contractual arrangements with third-party payors or purchasers of vision care services shall not constitute a violation of this subsection.

Code 1950, § 54-317; 1954, c. 627; 1958, c. 161; 1966, cc. 166, 657; 1968, c. 582; 1970, c. 69; 1973, c. 529; 1975, c. 508; 1978, c. 622; 1979, c. 727; 1980, c. 157; 1985, c. 96; 1986, c. 86; 1988, cc. 765, 904; 1989, c. 510; 1994, c. 70; 1998, c. 580; 2001, cc. 268, 858; 2005, c. 163; 2016, c. 495.

§ 54.1-2952.1. Prescription of certain controlled substances and devices by licensed physician assistant.

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ <u>54.1-3300</u> et seq.), a licensed physician assistant shall have the authority to prescribe controlled substances and devices as set forth in Chapter 34 (§ <u>54.1-3400</u> et seq.) and as provided in a practice agreement. Such practice agreements shall include a statement of the controlled substances the physician assistant is or is not authorized to prescribe and may restrict such prescriptive authority as deemed appropriate by the patient care team physician or patient care team podiatrist.

- B. It shall be unlawful for the physician assistant to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the practice agreement and the requirements in this section.
- C. The Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of physician assistants as are deemed reasonable and necessary to ensure an appropriate standard of care for patients. The regulations promulgated pursuant to this section shall include, at a minimum, (i) such requirements as may be necessary to ensure continued physician assistant competency, which may include continuing education, testing, and any other requirement and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients, and (ii) a requirement that the physician assistant disclose to his patients his name, address, and telephone number and that he is a physician assistant. If a patient or his representative requests to speak with the patient

care team physician or patient care team podiatrist, the physician assistant shall arrange for communication between the parties or provide the necessary information.

D. This section shall not prohibit a licensed physician assistant from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

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1992, c. 793; 1997, c. <u>806</u>; 1999, c. <u>745</u>; 2001, c. <u>465</u>; 2003, c. <u>510</u>; 2007, c. <u>16</u>; 2016, c. <u>450</u>; 2019, cc. 92, 137; 2021, Sp. Sess. I, c. 210.
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§ 54.1-2957.01. Prescription of certain controlled substances and devices by licensed advanced practice registered nurses.

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ <u>54.1-3300</u> et seq.), a licensed advanced practice registered nurse shall have the authority to prescribe Schedule II through Schedule VI controlled substances and devices as set forth in Chapter 34 (§ <u>54.1-3400</u> et seq.).

B. An advanced practice registered nurse who does not meet the requirements for practice without a written or electronic practice agreement set forth in subsection I of § 54.1-2957 shall prescribe controlled substances or devices only if such prescribing is authorized by a written or electronic practice agreement entered into by the advanced practice registered nurse and a patient care team physician or, if the advanced practice registered nurse is licensed by the Boards of Medicine and Nursing in the category of clinical nurse specialist, the advanced practice registered nurse and a licensed physician. Such advanced practice registered nurse shall provide to the Boards of Medicine and Nursing such evidence as the Boards may jointly require that the advanced practice registered nurse has entered into and is, at the time of writing a prescription, a party to a written or electronic practice agreement with a patient care team physician, or, if the advanced practice registered nurse is licensed by the Boards of Medicine and Nursing in the category of clinical nurse specialist, a licensed physician, that clearly states the prescriptive practices of the advanced practice registered nurse. Such written or electronic practice agreements shall include the controlled substances the advanced practice registered nurse is or is not authorized to prescribe and may restrict such prescriptive authority as described in the practice agreement. Evidence of a practice agreement shall be maintained by an advanced practice registered nurse pursuant to § 54.1-2957. Practice agreements authorizing an advanced practice registered nurse to prescribe controlled substances or devices pursuant to this section either shall be signed by the patient care team physician, or, if the advanced practice registered nurse is licensed by the Boards of Medicine and Nursing in the category of clinical nurse specialist, a licensed physician, or shall clearly state the name of the patient care team physician, or, if the advanced practice registered nurse is licensed by the Boards of Medicine and Nursing in the category of clinical nurse specialist, the name of the licensed physician, who has entered into the practice agreement with the advanced practice registered nurse.

It shall be unlawful for an advanced practice registered nurse to prescribe controlled substances or devices pursuant to this section unless (i) such prescription is authorized by the written or

electronic practice agreement or (ii) the advanced practice registered nurse is authorized to practice without a written or electronic practice agreement pursuant to subsection I of § <u>54.1-2957</u>.

- C. The Boards of Medicine and Nursing shall promulgate regulations governing the prescriptive authority of advanced practice registered nurses as are deemed reasonable and necessary to ensure an appropriate standard of care for patients. Such regulations shall include requirements as may be necessary to ensure continued advanced practice registered nurse competency, which may include continuing education, testing, or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients.
- D. This section shall not limit the functions and procedures of certified registered nurse anesthetists or of any advanced practice registered nurses which are otherwise authorized by law or regulation.
- E. The following restrictions shall apply to any advanced practice registered nurse authorized to prescribe drugs and devices pursuant to this section:
- 1. The advanced practice registered nurse shall disclose to the patient at the initial encounter that he is a licensed advanced practice registered nurse. Any party to a practice agreement shall disclose, upon request of a patient or his legal representative, the name of the patient care team physician, or, if the advanced practice registered nurse is licensed by the Boards of Medicine and Nursing in the category of clinical nurse specialist, the name of the licensed physician, and information regarding how to contact the patient care team physician or licensed physician.
- 2. Physicians shall not serve as a patient care team physician on a patient care team or enter into a practice agreement with more than six advanced practice registered nurses at any one time, except that a physician may serve as a patient care team physician on a patient care team with up to 10 advanced practice registered nurses licensed in the category of psychiatric-mental health advanced practice registered nurse.
- F. This section shall not prohibit a licensed advanced practice registered nurse from administering controlled substances in compliance with the definition of "administer" in § <u>54.1-3401</u> or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.
- G. Notwithstanding any provision of law or regulation to the contrary, a certified nurse midwife licensed by the Boards of Medicine and Nursing as such and holding a license for prescriptive authority may prescribe Schedules II through VI controlled substances. However, if the certified nurse midwife licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife is required, pursuant to subsection H of § 54.1-2957, to practice pursuant to a practice agreement, such prescribing shall also be in accordance with any prescriptive authority included in such practice agreement.
- H. Notwithstanding any provision of law or regulation to the contrary, a certified registered nurse anesthetist licensed by the Boards of Medicine and Nursing as such shall have the authority to prescribe Schedule II through Schedule VI controlled substances and devices in accordance with the requirements for practice set forth in subsection C of § 54.1-2957 to a patient requiring anesthesia, as part of the periprocedural care of such patient. As used in this subsection,

"periprocedural" means the period beginning prior to a procedure and ending at the time the patient is discharged.

1991, cc. 519, 524; 1992, c. 409; 1995, c. <u>506</u>; 1999, c. <u>745</u>; 2000, c. <u>924</u>; 2005, c. <u>926</u>; 2006, c. <u>494</u>; 2012, c. <u>213</u>; 2016, c. <u>495</u>; 2018, c. <u>776</u>; 2020, cc. <u>100</u>, <u>161</u>; 2021, Sp. Sess. I, cc. <u>157</u>, <u>396</u>; 2022, cc. <u>197</u>, 667; 2023, c. <u>183</u>.

§ 54.1-2971.01. Prescription in excess of recommended dosage in certain cases.

A. Consistent with § 54.1-3408.1, a physician may prescribe a dosage of a pain-relieving agent in excess of the recommended dosage upon certifying the medical necessity for the excess dosage in the patient's medical record. Any practitioner who prescribes, dispenses or administers an excess dosage in accordance with this section and § 54.1-3408.1 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 recognized medicinal or therapeutic purposes.

B. The Board of Medicine shall advise physicians of the provisions of this section and § 54.1-3408.1.

(1995, c. 277.)

CHAPTER 25.2 PRESCRIPTION MONITORING PROGRAM

§ 54.1-2519. 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, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug Diversion Unit.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

"Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled substances included in Schedule V for which a prescription is required; naloxone; and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. "Covered substance" also includes cannabis products dispensed by a pharmaceutical processor in Virginia.

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance to an ultimate user, research subject, or owner of an animal patient 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.

"Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

"Drug of concern" means any drug or substance, including any controlled substance or other drug or substance, where there has been or there is the potential for abuse and that has been identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

"Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to $\S\S 54.1-3303$ and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance.

"Recipient" means a person who receives a covered substance from a dispenser and includes the owner of an animal patient.

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including the Board of Dentistry, the Board of Medicine, the Board of Veterinary Medicine, and the Board of Pharmacy.

2002, c. <u>481</u>; 2005, cc. <u>637</u>, <u>678</u>; 2014, c. <u>664</u>; 2018, cc. <u>185</u>, <u>379</u>, <u>567</u>, <u>772</u>; 2021, Sp. Sess. I, cc. <u>227</u>, <u>228</u>.

§ 54.1-2520. Program establishment; Director's regulatory authority.

A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program.

B. The Director, after consultation with relevant health regulatory boards, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ <u>2.2-4000</u> et seq.), such regulations as are necessary to implement the prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § <u>54.1-2521</u>.

C. The Director may enter into contracts as may be necessary for the implementation and maintenance of the Prescription Monitoring Program.

- D. The Director shall provide dispensers with a basic file layout to enable electronic transmission of the information required in this chapter. For those dispensers unable to transmit the required information electronically, the Director shall provide an alternative means of data transmission.
- E. The Director shall also establish an advisory committee within the Department to assist in the implementation and evaluation of the Prescription Monitoring Program. Such advisory committee shall provide guidance to the Director regarding information disclosed pursuant to subdivision C 9 of § 54.1-2523.

2002, c. <u>481</u>; 2005, cc. <u>637</u>, <u>678</u>; 2014, c. <u>664</u>; 2016, cc. <u>410</u>, <u>568</u>; 2018, cc. <u>185</u>, <u>379</u>.

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

- B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:
- 1. The recipient's name and address.
- 2. The recipient's date of birth.
- 3. The covered substance that was dispensed to the recipient.
- 4. The quantity of the covered substance that was dispensed.
- 5. The date of the dispensing.
- 6. The prescriber's identifier number and, in cases in which the covered substance is a cannabis product, the expiration date of the written certification.
- 7. The dispenser's identifier number.
- 8. The method of payment for the prescription.
- 9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.
- 10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.
- C. Except as provided in subdivision 7 of § 54.1-2522, in cases where the ultimate user of a covered substance is an animal, the dispenser shall report the relevant information required by subsection B for the owner of the animal.
- D. The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

2002, c. <u>481</u>; 2006, c. <u>167</u>; 2012, cc. <u>21</u>, <u>71</u>; 2016, c. <u>309</u>; 2018, cc. <u>567</u>, <u>772</u>; 2021, Sp. Sess. I, cc. <u>227</u>, <u>228</u>.

§ 54.1-2522. Reporting exemptions.

The dispensing of covered substances under the following circumstances shall be exempt from the reporting requirements set forth in § 54.1-2521:

- 1. Dispensing of manufacturers' samples of such covered substances or of covered substances dispensed pursuant to an indigent patient program offered by a pharmaceutical manufacturer.
- 2. Dispensing of covered substances by a practitioner of the healing arts to his patient in a bona fide medical emergency or when pharmaceutical services are not available.
- 3. Administering of covered substances.
- 4. Dispensing of covered substances within an appropriately licensed narcotic maintenance treatment program.
- 5. Dispensing of covered substances to inpatients in hospitals or nursing facilities licensed by the Board of Health or facilities that are otherwise authorized by law to operate as hospitals or nursing homes in the Commonwealth.
- 6. Dispensing of covered substances to inpatients in hospices licensed by the Board of Health.
- 7. Dispensing of covered substances by veterinarians to animals within the usual course of their professional practice for a course of treatment to last seven days or less or if such covered substance is feline buprenorphine or canine butorphanol.
- 8. Dispensing of covered substances as otherwise provided in the Department's regulations.

2002, c. <u>481</u>; 2018, c. <u>772</u>; 2019, c. <u>686</u>.

§ 54.1-2522.1. (Effective July 1, 2024 through July 1, 2027) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ <u>54.1-3303</u> and <u>54.1-3408</u> to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. A prescriber registered with the Prescription Monitoring Program or a person to whom he has delegated authority to access information in the possession of the Prescription Monitoring Program pursuant to § 54.1-2523.2 shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

- C. A prescriber shall not be required to meet the provisions of subsection B if:
- 1. The opioid is prescribed to a patient currently receiving hospice or palliative care;

- 2. The opioid is prescribed to a patient during an inpatient hospital admission or at discharge;
- 3. The opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy;
- 4. The Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or
- 5. The prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record.
- D. Prior to issuing a written certification for the use of cannabis oil in accordance with § <u>4.1-1601</u>, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

2014, cc. <u>93</u>, <u>178</u>; 2015, c. <u>517</u>; 2016, cc. <u>113</u>, <u>406</u>; 2017, cc. <u>249</u>, <u>252</u>; 2018, cc. <u>102</u>, <u>106</u>, <u>567</u>; 2023, cc. <u>740</u>, <u>773</u>.

§ 54.1-2522.1. (Effective July 1, 2027) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ <u>54.1-3303</u> and <u>54.1-3408</u> to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

- B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.
- C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis or cancer treatments.
- D. Prior to issuing a written certification for the use of cannabis oil in accordance with § <u>4.1-1601</u>, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

2014, cc. <u>93</u>, <u>178</u>; 2015, c. <u>517</u>; 2016, cc. <u>113</u>, <u>406</u>; 2017, cc. <u>249</u>, <u>252</u>; 2018, cc. <u>102</u>, <u>106</u>, <u>567</u>; 2023, cc. <u>740</u>, <u>773</u>.

§ 54.1-2522.2. Requirements for dispensers.

The Department shall register every dispenser licensed by the Board of Pharmacy pursuant to Article 3 (§ 54.1-3310 et seq.) of Chapter 33 with the Prescription Monitoring Program.

2015, c. 517.

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring Program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision 2 of § 2.2-3705.5. Records in possession of the Prescription Monitoring Program shall not be available for civil subpoena, nor shall such records be disclosed, discoverable, or compelled to be produced in any civil proceeding, nor shall such records be deemed admissible as evidence in any civil proceeding for any reason. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

- B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:
- 1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent who has completed the Virginia State Police Drug Diversion School designated by the superintendent of the Department of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department to conduct drug diversion investigations pursuant to § 54.1-3405.
- 2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.).
- 3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.
- 4. Information relevant to a specific investigation of a specific recipient, dispenser, or prescriber to an agent of a federal law-enforcement agency with authority to conduct drug diversion investigations.
- 5. Information relevant to a specific investigation, supervision, or monitoring of a specific recipient for purposes of the administration of criminal justice pursuant to Chapter 1 (§ 9.1-100 et seq.) of Title 9.1 to a probation or parole officer as described in Article 2 (§ 53.1-141 et seq.) of Chapter 4 of Title 53.1 or a local community-based probation officer as described in § 9.1-176.1 who has completed the Virginia State Police Drug Diversion School designated by the Director of the Department of Corrections or his designee.
- 6. Information relevant to a specific investigation of a specific individual into a possible delivery of a controlled substance in violation of § 18.2-474.1 to an investigator for the Department of Corrections who has completed the Virginia State Police Drug Diversion School and who has been designated by the Director of the Department of Corrections or his designee.

- 7. Information about a specific recipient to the Smartchart Network Program in accordance with subdivision B 7 of § 32.1-372.
- C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:
- 1. Information in the possession of the Prescription Monitoring Program concerning a recipient who is over the age of 18 to that recipient. The information shall be mailed to the street or mailing address indicated on the recipient request form.
- 2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is consulting on or initiating treatment of such recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.
- 3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in (i) determining the validity of a prescription in accordance with § 54.1-3303 or (ii) providing clinical consultation on the care and treatment of the recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription Monitoring Program.
- 4. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority.
- 5. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.
- 6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.
- 7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, release of the information shall only be made pursuant to a written agreement between such qualified personnel and the Director in order to ensure compliance with this subdivision.
- 8. Information relating to prescriptions for covered substances issued by a specific prescriber, which have been dispensed and reported to the Prescription Monitoring Program, to that prescriber.
- 9. Information about a specific recipient who is a member of a Virginia Medicaid managed care program to a physician or pharmacist licensed in the Commonwealth and employed by the Virginia Medicaid managed care program or to his clinical designee who holds a multistate licensure privilege to practice nursing or a license issued by a health regulatory board within the Department of Health Professions and is employed by the Virginia Medicaid managed care program. Such information shall only be used to determine eligibility for and to manage the care of the specific recipient in a Patient Utilization Management Safety or similar program. Notice shall be given to

recipients that information may be requested by a licensed physician or pharmacist employed by the Virginia Medicaid managed care program from the Prescription Monitoring Program. 10. [Expired.]

11. Information about a specific recipient who is currently eligible for and receiving medical assistance from the Department of Medical Assistance Services to a physician or pharmacist licensed in the Commonwealth or to his clinical designee who holds a multistate licensure privilege to practice nursing or a license issued by a health regulatory board within the Department of Health Professions and is employed by the Department of Medical Assistance Services. Such information shall be used only to determine eligibility for and to manage the care of the specific recipient in a Patient Utilization Management Safety or similar program. Notice shall be given to recipients that information may be requested by a licensed physician or pharmacist employed by the Department of Medical Assistance Services from the Prescription Monitoring Program.

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter.

E. This section shall not be construed to supersede the provisions of § <u>54.1-3406</u> concerning the divulging of confidential records relating to investigative information.

F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

2002, c. <u>481</u>; 2004, c. <u>690</u>; 2005, cc. <u>637</u>, <u>678</u>; 2009, cc. <u>158</u>, <u>162</u>, <u>472</u>; 2012, cc. <u>21</u>, <u>71</u>; 2013, c. <u>739</u>; 2014, cc. <u>12</u>, <u>97</u>; 2015, cc. <u>118</u>, <u>507</u>; 2016, cc. <u>309</u>, <u>410</u>, <u>447</u>, <u>568</u>; 2017, cc. <u>186</u>, <u>778</u>; 2018, c. <u>108</u>; 2019, c. <u>679</u>; 2020, cc. <u>1066</u>, <u>1067</u>; 2023, cc. <u>628</u>, <u>629</u>.

§ 54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

A. The Director shall develop, in consultation with an advisory panel which shall include representatives of the Boards of Medicine and Pharmacy, the Department of Health, the Department of Medical Assistance Services, and the Department of Behavioral Health and Developmental Services, criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and misuse of covered substances by recipients and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse to identify unusual patterns of prescribing or dispensing of covered substances by individual prescribers or dispensers or potential misuse of a covered substance by a recipient. The Director, in consultation with the panel, shall annually review controlled substance prescribing and dispensing patterns and shall (i) make any necessary changes to the criteria for unusual patterns of prescribing and dispensing required by

this subsection and (ii) report any findings and recommendations for best practices to the Joint Commission on Health Care by November 1 of each year.

- B. In cases in which analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse indicates an unusual pattern of prescribing or dispensing of a covered substance by an individual prescriber or dispenser or potential misuse of a covered substance by a recipient, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523:
- 1. Disclose information about the unusual prescribing or dispensing of a covered substance by an individual prescriber or dispenser to the Enforcement Division of the Department of Health Professions; or
- 2. Disclose information about the specific recipient to (i) the prescriber or prescribers who have prescribed a covered substance to the recipient for the purpose of intervention to prevent misuse of such covered substance or (ii) an agent who has completed the Virginia State Police Drug Diversion School designated by the Superintendent of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department for the purpose of an investigation into possible drug diversion.

2005, cc. <u>637</u>, <u>678</u>; 2012, cc. <u>21</u>, <u>71</u>; 2013, c. <u>739</u>; 2016, c. <u>98</u>; 2018, cc. <u>190</u>, <u>239</u>.

§ 54.1-2523.2. (Effective July 1, 2027) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to individuals who are employed or engaged at the same facility and under the direct supervision of the prescriber or dispenser and (i) are licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction or (ii) have routine access to confidential patient data and have signed a patient data confidentiality agreement.

2009, cc. <u>158</u>, <u>162</u>; 2012, cc. <u>21</u>, <u>71</u>; 2014, c. <u>72</u>; 2016, cc. <u>113</u>, <u>406</u>; 2022 c. <u>747</u>.

§ 54.1-2523.2. (Effective until July 1, 2027) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to health care professionals who are (i) licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction and (ii) employed at the same facility and under the direct supervision of the prescriber or dispenser.

2009, cc. 158, 162; 2012, cc. 21, 71; 2014, c. 72; 2022 c. 747.

§ 54.1-2524. Immunity from liability.

A. The Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the accuracy or inaccuracy of any information reported to and compiled and maintained by the Department pursuant to this chapter.

Further, the Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the disclosure of or failure to disclose any information in compliance with subsections B and C of § 54.1-2523 and the Department's regulations.

B. In the absence of gross negligence or willful misconduct, prescribers or dispensers complying in good faith with the reporting requirements of this chapter shall not be liable for any civil damages for any act or omission resulting from the submission of such required reports.

2002, c. 481.

§ 54.1-2525. Unlawful disclosure of information; disciplinary action authorized; penalties.

A. It shall be unlawful for any person having access to the confidential information in the possession of the program or any data or reports produced by the program to disclose such confidential information except as provided in this chapter. Any person having access to the confidential information in the possession of the program or any data or reports produced by the program who discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.

B. It shall be unlawful for any person who lawfully receives confidential information from the Prescription Monitoring Program to redisclose or use such confidential information in any way other than the authorized purpose for which the request was made. Any person who lawfully receives information from the Prescription Monitoring Program and discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.

C. Nothing in this section shall prohibit (i) a person who prescribes or dispenses a covered substance to a recipient required to be reported to the program from redisclosing information obtained from the Prescription Monitoring Program to another prescriber or dispenser who has responsibility for treating the recipient or (ii) a person who prescribes a covered substance from placing information obtained from the Prescription Monitoring Program in the recipient's medical record.

D. Information obtained from the Prescription Monitoring Program pursuant to subdivision B 7 of § 32.1-372 shall become part of the patient's medical record.

E. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.

2002, c. 481; 2011, cc. 812, 844; 2016, c. 309; 2020, cc. 1066, 1067; 2023, cc. 628, 629.

SELECTED SECTIONS FROM CHAPTER 34. DRUG CONTROL ACT.

Code of Virginia

Drug Control Act Chapter 34 of Title 54.1

§ 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 (§ <u>54.1-2729.1</u> 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 (§ <u>54.1-3437</u> 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 $\S\S 54.1-3303$ 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 § <u>54.1-3415.1</u>. 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 (§ <u>54.1-3300</u> 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 (§ <u>54.1-3300</u> 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.

§ 54.1-3404. 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 \S 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 \S 54.1-3410.2.

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

§ 54.1-3408. 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 § <u>54.1-2957.04</u>, a licensed physician assistant pursuant to § <u>54.1-2952.1</u>, or a TPA-certified optometrist pursuant to Article 5 (§ <u>54.1-3222</u> 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 § <u>54.1-2957.7</u> 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 § <u>54.1-2954</u> 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 (§ <u>54.1-3041</u> 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 (§ <u>54.1-2729.1</u> 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 (§ <u>54.1-2729.1</u> 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.

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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.
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§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § <u>54.1-3408</u> 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.

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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. <u>135</u>, <u>861</u>; 2002, c. <u>411</u>; 2003, c. <u>639</u>; 2006, c. <u>195</u>; 2009, cc. <u>813</u>, <u>840</u>; 2020, c. <u>464</u>.

§ 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;

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- 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. <u>412</u>, <u>544</u>.

§ 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 (§ <u>54.1-3443</u> et seq.) pursuant to § <u>54.1-3443</u> or by enactment into law.

2017, cc. <u>416</u>, <u>432</u>.

§ 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. <u>277</u>.

§ 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 lawenforcement 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. 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.

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2015, cc. <u>7</u>, <u>8</u>; 2017, c. <u>613</u>; 2018, cc. <u>246</u>, <u>809</u>; 2019, cc. <u>653</u>, <u>654</u>, <u>681</u>, <u>690</u>; 2020, cc. <u>730</u>, <u>831</u>, <u>928</u>, <u>1278</u>; 2021 Sp. Sess. I, cc. <u>205</u>, <u>227</u>, <u>228</u>; 2022, cc. <u>259</u>, <u>391</u>, <u>392</u>, <u>642</u>; 2023, cc. <u>183</u>, <u>740</u>, <u>744</u>, <u>760</u>, <u>773</u>, <u>780</u>, <u>794</u>, <u>799</u>.
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§ 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 $\S 54.1-3303$ 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 § <u>54.1-3408.02</u> applies and may dispense such controlled substance pursuant to such prescription and applicable law.

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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.
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§ 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 §§ <u>54.1-3301</u>, <u>54.1-3304</u>, and <u>54.1-3304.1</u> 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 (§ <u>54.1-3300</u> et seq.) or Chapter 34 (§ <u>54.1-3400</u> 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. <u>408</u>; 2023, c. <u>341</u>.

§ 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 § <u>54.1-3411.2</u>, 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 § <u>54.1-3422</u>, 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 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. <u>241</u>, <u>242</u>.

§ 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.

§ 54.1-3420. 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. <u>193</u>; 2011, cc. <u>262</u>, <u>318</u>.

§ 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. <u>597</u>; 2002, c. <u>411</u>; 2010, c. <u>28</u>; 2015, c. <u>505</u>.

§ 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. <u>135</u>.

§ 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.

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

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

§ 54.1-3426. 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. <u>408</u>.

§ 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.

§ 54.1-3442.1. 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. <u>655</u>, <u>656</u>.

§ 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. <u>655</u>, <u>656</u>.

§ 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. <u>655</u>, <u>656</u>.

§ 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 § <u>8.01-581.1</u> who recommends, prescribes, administers, distributes, or supplies an investigational drug, biological product, or device to a person who meets the criteria set forth in § <u>54.1-3442.2</u> 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. <u>655</u>, <u>656</u>.

§ 54.1-3442.5. Repealed.

Repealed pursuant to cc. 740, 773 of the 2023 Acts of Assembly.

§ 54.1-3442.6. Repealed.

Repealed pursuant to cc. 740, 773 of the 2023 Acts of Assembly.

§ 54.1-3442.7. Repealed.

Repealed pursuant to cc. 740, 773 of the 2023 Acts of Assembly.

§ 54.1-3442.8. Repealed.

Repealed pursuant to cc. 740, 773 of the 2023 Acts of Assembly.

§ 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 $\S 4.1-600, 18.2-247$, or 54.1-3401.

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

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

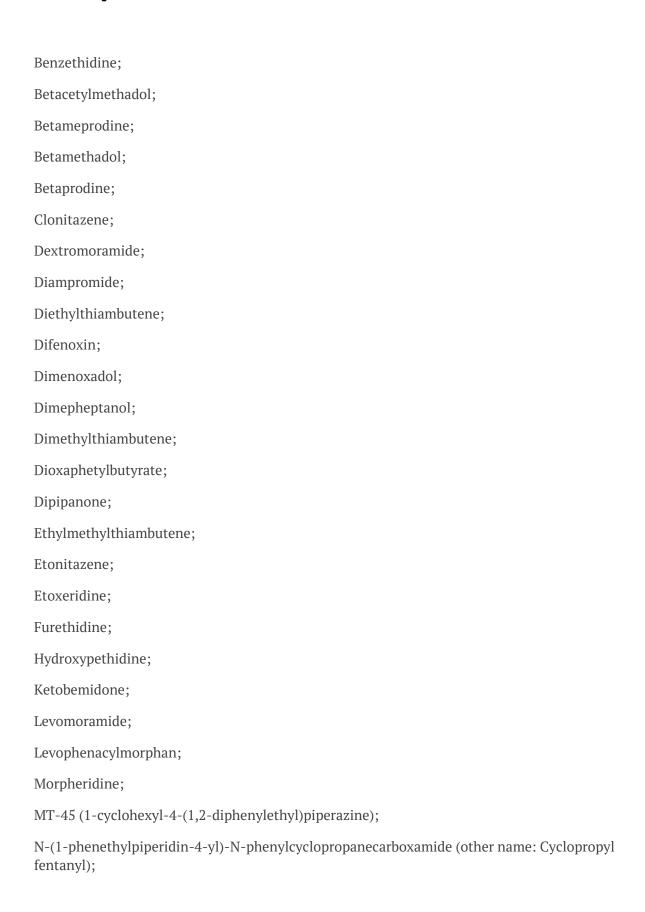
Acetylmethadol;

Allylprodine;

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

Alphameprodine;

Alphamethadol;



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: alphamethylthiofentanyl);

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

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: parachlorofentanyl, 4-chlorofentanyl);

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

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

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

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);

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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);
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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;



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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);
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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);
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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);
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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);
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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);
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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).
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Fenethylline;

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; 4hydroxybutyrate; 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, alphaaminopropiophenone, 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);

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.

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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);
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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);
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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-[<u>1-4</u>-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. <u>763</u>; 1996, c. <u>408</u>; 1997, c. <u>594</u>; 1999, c. <u>722</u>; 2000, c. <u>348</u>; 2005, c. <u>119</u>; 2008, c. <u>59</u>; 2011, cc. <u>384</u>, <u>410</u>; 2012, cc. <u>762</u>, <u>816</u>; 2013, cc. <u>295</u>, <u>785</u>;

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2014, cc. <u>674</u>, <u>719</u>; 2015, cc. <u>726</u>, <u>757</u>; 2016, cc. <u>103</u>, <u>112</u>; 2017, cc. <u>414</u>, <u>434</u>; 2018, c. <u>372</u>; 2019, cc. <u>85</u>, <u>653</u>, <u>654</u>; 2020, cc. <u>101</u>, <u>229</u>, <u>1285</u>, <u>1286</u>; 2021, Sp. Sess. I, cc. <u>73</u>, <u>110</u>; 2022, cc. <u>114</u>, <u>115</u>; 2023, cc. <u>188</u>, <u>189</u>, <u>744</u>, <u>794</u>.
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§ 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.

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1972, c. 798, § 54-524.84:5; 1988, c. 765.
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§ 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:

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Raw opium;
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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;

Oxycodone;

Oxymorphone;

Thebaine.

Thiafentanil.

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:

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specific chemical designation:
Alfentanil:
Alphaprodine;
Anileridine:
Bezitramide;
Bulk dextropropoxyphene (nondosage forms);
Carfentanil;
Dihvdrocodeine:
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;
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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).

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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. <u>763</u>; 1998, c. <u>105</u>; 2000, c. <u>135</u>; 2005, c. <u>119</u>; 2008, c. <u>74</u>; 2010, c. <u>423</u>; 2011, c. <u>700</u>; 2017, c. <u>612</u>; 2019, c. <u>85</u>.
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§ 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);

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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);
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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]-
pv 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.
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§ 54.1-3451. Placement of substance in Schedule IV.

c. <u>423</u>; 2013, c. <u>233</u>; 2014, c. <u>74</u>; 2015, c. <u>303</u>.

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;

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. <u>135</u>, <u>348</u>; 2003, c. <u>640</u>; 2005, c. <u>119</u>; 2006, c. <u>346</u>; 2007, c. <u>14</u>; 2010,

- 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;

including its saits, isomers, and saits 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.

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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. <u>763</u>; 1998, c. <u>105</u>; 1999, c. <u>605</u>; 2000, c. <u>135</u>; 2003, c. <u>640</u>; 2006, c. <u>346</u>; 2010, c. <u>423</u>; 2012, c. <u>540</u>; 2014, c. <u>74</u>; 2015, c. <u>303</u>; 2016, c. <u>499</u>; 2022, cc. <u>114</u>, <u>115</u>.
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§ 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].

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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. <u>763</u>; 2003, c. <u>640</u>; 2006, c. <u>346</u>; 2010, c. <u>423</u>; 2012, c. <u>541</u>; 2017, c. <u>612</u>; 2019, c. <u>214</u>; 2022, cc. <u>114</u>, <u>115</u>.
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§ 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. <u>605</u>.

§ 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. <u>674</u>, <u>719</u>.

§ 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. <u>664</u>; 2017, c. <u>181</u>; 2019, c. <u>214</u>.

§ 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 § <u>54.1-3459</u>.
- 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 § <u>54.1-3408.03</u> 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 § <u>54.1-3408.04</u> related to dispensing of interchangeable biosimilars.

1970, c. 650, § 54-524.85; 1988, c. 765; 2003, c. <u>639</u>; 2013, cc. <u>412</u>, <u>544</u>.

§ 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 $\S 54.1-3460$; 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 $\S 54.1-3460$.

- 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 § <u>54.1-3462</u> 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. <u>408</u>.

§ 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 § $\underline{18.2-265.3}$ shall not apply to (i) a person who dispenses naloxone in accordance with the provisions of subsection Y of § $\underline{54.1-3408}$ 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 § $\underline{54.1-3408}$ 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 § $\underline{18.2-265.3}$ 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 § $\underline{32.1-45.4}$ or (ii) a person who possesses controlled paraphernalia obtained from a comprehensive harm reduction program established pursuant to § $\underline{32.1-45.4}$.

1971, Ex. Sess., cc. 210, 245; 1976, c. 614; 1988, c. 765; 2016, c. <u>229</u>; 2018, c. <u>97</u>; 2019, c. <u>215</u>; 2020, c. <u>839</u>.

§ 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. <u>183</u>; 2018, c. <u>97</u>; 2020, cc. <u>609</u>, <u>610</u>; 2023, cc. <u>142</u>, <u>143</u>.

§ 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 § <u>54.1-3467</u> 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 § <u>54.1-3467</u> 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.

SELECTED SECTIONS FROM TITLE 18.2, CHAPTER 7. CRIMES INVOLVING HEALTH AND SAFETY.

§ 18.2-247. Use of terms "controlled substances," "marijuana," "Schedules I, II, III, IV, V, and VI," "imitation controlled substance" and "counterfeit controlled substance" in Title 18.2.

A. Wherever the terms "controlled substances" and "Schedules I, II, III, IV, V, and VI" are used in Title 18.2, such terms refer to those terms as they are used or defined in the Drug Control Act (§ 54.1-3400 et seq.).

- B. The term "imitation controlled substance" when used in this article means (i) a counterfeit controlled substance or (ii) a pill, capsule, tablet, or substance in any form whatsoever which is not a controlled substance subject to abuse, and:
- 1. Which by overall dosage unit appearance, including color, shape, size, marking and packaging or by representations made, would cause the likelihood that such a pill, capsule, tablet, or substance in any other form whatsoever will be mistaken for a controlled substance unless such substance was introduced into commerce prior to the initial introduction into commerce of the controlled substance which it is alleged to imitate; or
- 2. Which by express or implied representations purports to act like a controlled substance as a stimulant or depressant of the central nervous system and which is not commonly used or recognized for use in that particular formulation for any purpose other than for such stimulant or depressant effect, unless marketed, promoted, or sold as permitted by the U.S. Food and Drug Administration.
- C. In determining whether a pill, capsule, tablet, or substance in any other form whatsoever, is an "imitation controlled substance," there shall be considered, in addition to all other relevant factors, comparisons with accepted methods of marketing for legitimate nonprescription drugs for medicinal purposes rather than for drug abuse or any similar nonmedicinal use, including consideration of the packaging of the drug and its appearance in overall finished dosage form, promotional materials or representations, oral or written, concerning the drug, and the methods of distribution of the drug and where and how it is sold to the public.
- D. The term "marijuana" when used in this article means any part of a plant of the genus Cannabis, whether growing or not, its seeds or 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, oil or cake made from the seed 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.

- E. The term "counterfeit controlled substance" means a controlled substance that, without authorization, bears, is packaged in a container or wrapper that bears, or is otherwise labeled to bear, the trademark, trade name, or other identifying mark, imprint or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the manufacturer, processor, packer, or distributor who did in fact so manufacture, process, pack or distribute such drug.
- F. The term "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.
- G. The term "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.
- H. The Department of Forensic Science shall determine the proper methods for detecting the concentration of tetrahydrocannabinol in substances for the purposes of this title, Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1, and § 54.1-3401. The testing methodology shall use post-decarboxylation testing or other equivalent method and shall consider the potential conversion of tetrahydrocannabinolic acid into tetrahydrocannabinol.

1975, cc. 14, 15; 1979, c. 435; 1982, c. 462; 1984, c. 684; 1992, c. 756; 1999, cc. <u>661</u>, <u>722</u>; 2004, c. <u>688</u>; 2019, cc. <u>653</u>, <u>654</u>; 2020, cc. <u>831</u>, <u>1285</u>, <u>1286</u>; 2021, Sp. Sess. I, c. <u>110</u>; 2023, cc. <u>744</u>, <u>794</u>.

§ 18.2-248. Manufacturing, selling, giving, distributing, or possessing with intent to manufacture, sell, give, or distribute a controlled substance or an imitation controlled substance prohibited; penalties.

A. Except as authorized in the Drug Control Act (§ <u>54.1-3400</u> et seq.), it shall be unlawful for any person to manufacture, sell, give, distribute, or possess with intent to manufacture, sell, give or distribute a controlled substance or an imitation controlled substance.

B. In determining whether any person intends to manufacture, sell, give or distribute an imitation controlled substance, the court may consider, in addition to all other relevant evidence, whether any distribution or attempted distribution of such pill, capsule, tablet or substance in any other form whatsoever included an exchange of or a demand for money or other property as consideration, and, if so, whether the amount of such consideration was substantially greater than the reasonable value of such pill, capsule, tablet or substance in any other form whatsoever, considering the actual chemical composition of such pill, capsule, tablet or substance in any other form whatsoever and, where applicable, the price at which over-the-counter substances of like chemical composition sell.

C. Except as provided in subsection C1, any person who violates this section with respect to a controlled substance classified in Schedule I or II shall upon conviction be imprisoned for not less than five nor more than 40 years and fined not more than \$500,000. Upon a second conviction of such a violation, and it is alleged in the warrant, indictment, or information that the person has been before convicted of such an offense or of a substantially similar offense in any other jurisdiction, which offense would be a felony if committed in the Commonwealth, and such prior conviction occurred before the date of the offense alleged in the warrant, indictment, or information, any such person may, in the discretion of the court or jury imposing the sentence, be sentenced to imprisonment for life or for any period not less than five years, three years of which shall be a mandatory minimum term of imprisonment to be served consecutively with any other sentence, and he shall be fined not more than \$500,000.

When a person is convicted of a third or subsequent offense under this subsection and it is alleged in the warrant, indictment or information that he has been before convicted of two or more such offenses or of substantially similar offenses in any other jurisdiction which offenses would be felonies if committed in the Commonwealth and such prior convictions occurred before the date of the offense alleged in the warrant, indictment, or information, he shall be sentenced to imprisonment for life or for a period of not less than 10 years, 10 years of which shall be a mandatory minimum term of imprisonment to be served consecutively with any other sentence, and he shall be fined not more than \$500,000.

Any person who manufactures, sells, gives, distributes or possesses with the intent to manufacture, sell, give, or distribute the following is guilty of a felony punishable by a fine of not more than \$1 million and imprisonment for five years to life, five years of which shall be a mandatory minimum term of imprisonment to be served consecutively with any other sentence:

- 1. 100 grams or more of a mixture or substance containing a detectable amount of heroin;
- 2. 500 grams or more of a mixture or substance containing a detectable amount of:
- a. Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;
- b. Cocaine, its salts, optical and geometric isomers, and salts of isomers;
- c. Ecgonine, its derivatives, their salts, isomers, and salts of isomers; or
- d. Any compound, mixture, or preparation that contains any quantity of any of the substances referred to in subdivisions 2a through 2c;
- 3. 250 grams or more of a mixture or substance described in subdivisions 2a through 2d that contain cocaine base; or
- 4. 10 grams or more of methamphetamine, its salts, isomers, or salts of its isomers or 20 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

The mandatory minimum term of imprisonment to be imposed for a violation of this subsection shall not be applicable if the court finds that:

a. The person does not have a prior conviction for an offense listed in subsection C of § 17.1-805;

- b. The person did not use violence or credible threats of violence or possess a firearm or other dangerous weapon in connection with the offense or induce another participant in the offense to do so;
- c. The offense did not result in death or serious bodily injury to any person;
- d. The person was not an organizer, leader, manager, or supervisor of others in the offense, and was not engaged in a continuing criminal enterprise as defined in subsection I; and
- e. Not later than the time of the sentencing hearing, the person has truthfully provided to the Commonwealth all information and evidence the person has concerning the offense or offenses that were part of the same course of conduct or of a common scheme or plan, but the fact that the person has no relevant or useful other information to provide or that the Commonwealth already is aware of the information shall not preclude a determination by the court that the defendant has complied with this requirement.
- C1. Any person who violates this section with respect to the manufacturing of methamphetamine, its salts, isomers, or salts of its isomers or less than 200 grams of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers shall, upon conviction, be imprisoned for not less than 10 nor more than 40 years and fined not more than \$500,000. Upon a second conviction of such a violation, any such person may, in the discretion of the court or jury imposing the sentence, be sentenced to imprisonment for life or for any period not less than 10 years, and be fined not more than \$500,000. When a person is convicted of a third or subsequent offense under this subsection and it is alleged in the warrant, indictment, or information that he has been previously convicted of two or more such offenses or of substantially similar offenses in any other jurisdiction, which offenses would be felonies if committed in the Commonwealth and such prior convictions occurred before the date of the offense alleged in the warrant, indictment, or information, he shall be sentenced to imprisonment for life or for a period not less than 10 years, three years of which shall be a mandatory minimum term of imprisonment to be served consecutively with any other sentence and he shall be fined not more than \$500,000.

Upon conviction, in addition to any other punishment, a person found guilty of this offense shall be ordered by the court to make restitution, as the court deems appropriate, to any innocent property owner whose property is damaged, destroyed, or otherwise rendered unusable as a result of such methamphetamine production. This restitution shall include the person's or his estate's estimated or actual expenses associated with cleanup, removal, or repair of the affected property. If the property that is damaged, destroyed, or otherwise rendered unusable as a result of such methamphetamine production is property owned in whole or in part by the person convicted, the court shall order the person to pay to the Methamphetamine Cleanup Fund authorized in § 18.2-248.04 the reasonable estimated or actual expenses associated with cleanup, removal, or repair of the affected property or, if actual or estimated expenses cannot be determined, the sum of \$10,000. The convicted person shall also pay the cost of certifying that any building that is cleaned up or repaired pursuant to this section is safe for human occupancy according to the guidelines established pursuant to § 32.1-11.7.

D. If such person proves that he gave, distributed or possessed with intent to give or distribute a controlled substance classified in Schedule I or II only as an accommodation to another individual who is not an inmate in a community correctional facility, local correctional facility or state correctional facility as defined in § 53.1-1 or in the custody of an employee thereof, and not with intent to profit thereby from any consideration received or expected nor to induce the recipient or intended recipient of the controlled substance to use or become addicted to or dependent upon such controlled substance, he shall be guilty of a Class 5 felony.

E. If the violation of the provisions of this article consists of the filling by a pharmacist of the prescription of a person authorized under this article to issue the same, which prescription has not been received in writing by the pharmacist prior to the filling thereof, and such written prescription is in fact received by the pharmacist within one week of the time of filling the same, or if such violation consists of a request by

such authorized person for the filling by a pharmacist of a prescription which has not been received in writing by the pharmacist and such prescription is, in fact, written at the time of such request and delivered to the pharmacist within one week thereof, either such offense shall constitute a Class 4 misdemeanor.

- E1. Any person who violates this section with respect to a controlled substance classified in Schedule III except for an anabolic steroid classified in Schedule III, constituting a violation of § 18.2-248.5, shall be guilty of a Class 5 felony.
- E2. Any person who violates this section with respect to a controlled substance classified in Schedule IV shall be guilty of a Class 6 felony.
- E3. Any person who proves that he gave, distributed or possessed with the intent to give or distribute a controlled substance classified in Schedule III or IV, except for an anabolic steroid classified in Schedule III, constituting a violation of § 18.2-248.5, only as an accommodation to another individual who is not an inmate in a community correctional facility, local correctional facility or state correctional facility as defined in § 53.1-1 or in the custody of an employee thereof, and not with the intent to profit thereby from any consideration received or expected nor to induce the recipient or intended recipient of the controlled substance to use or become addicted to or dependent upon such controlled substance, is guilty of a Class 1 misdemeanor.
- F. Any person who violates this section with respect to a controlled substance classified in Schedule V or Schedule VI or an imitation controlled substance which imitates a controlled substance classified in Schedule V or Schedule VI, shall be guilty of a Class 1 misdemeanor.
- G. Any person who violates this section with respect to an imitation controlled substance which imitates a controlled substance classified in Schedule I, II, III, or IV shall be guilty of a Class 6 felony. In any prosecution brought under this subsection, it is not a defense to a violation of this subsection that the defendant believed the imitation controlled substance to actually be a controlled substance.
- H. Any person who manufactures, sells, gives, distributes or possesses with the intent to manufacture, sell, give or distribute the following:
- 1. 1.0 kilograms or more of a mixture or substance containing a detectable amount of heroin;
- 2. 5.0 kilograms or more of a mixture or substance containing a detectable amount of:
- a. Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;
- b. Cocaine, its salts, optical and geometric isomers, and salts of isomers;
- c. Ecgonine, its derivatives, their salts, isomers, and salts of isomers; or
- d. Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subdivisions a through c;
- 3. 2.5 kilograms or more of a mixture or substance described in subdivision 2 which contains cocaine base:
- 4. 100 kilograms or more of a mixture or substance containing a detectable amount of marijuana; or
- 5. 100 grams or more of methamphetamine, its salts, isomers, or salts of its isomers or 200 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers shall be guilty of a felony punishable by a fine of not more than \$1 million and imprisonment for 20 years to life, 20 years of which shall be a mandatory minimum sentence. Such mandatory minimum sentence shall not be applicable if the court finds that (i) the person does not have a prior conviction for an offense listed in subsection C of § 17.1-805; (ii) the person did not use violence or credible threats of violence or possess a firearm or other dangerous weapon in connection with the offense

or induce another participant in the offense to do so; (iii) the offense did not result in death or serious bodily injury to any person; (iv) the person was not an organizer, leader, manager, or supervisor of others in the offense, and was not engaged in a continuing criminal enterprise as defined in subsection I of this section; and (v) not later than the time of the sentencing hearing, the person has truthfully provided to the Commonwealth all information and evidence the person has concerning the offense or offenses that were part of the same course of conduct or of a common scheme or plan, but the fact that the person has no relevant or useful other information to provide or that the Commonwealth already is aware of the information shall not preclude a determination by the court that the defendant has complied with this requirement.

- H1. Any person who was the principal or one of several principal administrators, organizers or leaders of a continuing criminal enterprise shall be guilty of a felony if (i) the enterprise received at least \$100,000 but less than \$250,000 in gross receipts during any 12-month period of its existence from the manufacture, importation, or distribution of heroin or cocaine or ecgonine or methamphetamine or the derivatives, salts, isomers, or salts of isomers thereof or marijuana or (ii) the person engaged in the enterprise to manufacture, sell, give, distribute or possess with the intent to manufacture, sell, give or distribute the following during any 12-month period of its existence:
- 1. At least 1.0 kilograms but less than 5.0 kilograms of a mixture or substance containing a detectable amount of heroin;
- 2. At least 5.0 kilograms but less than 10 kilograms of a mixture or substance containing a detectable amount of:
- a. Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;
- b. Cocaine, its salts, optical and geometric isomers, and salts of isomers;
- c. Ecgonine, its derivatives, their salts, isomers, and salts of isomers; or
- d. Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subdivisions a through c;
- 3. At least 2.5 kilograms but less than 5.0 kilograms of a mixture or substance described in subdivision 2 which contains cocaine base;
- 4. At least 100 kilograms but less than 250 kilograms of a mixture or substance containing a detectable amount of marijuana; or
- 5. At least 100 grams but less than 250 grams of methamphetamine, its salts, isomers, or salts of its isomers or at least 200 grams but less than 1.0 kilograms of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

A conviction under this section shall be punishable by a fine of not more than \$1 million and imprisonment for 20 years to life, 20 years of which shall be a mandatory minimum sentence.

H2. Any person who was the principal or one of several principal administrators, organizers or leaders of a continuing criminal enterprise if (i) the enterprise received \$250,000 or more in gross receipts during any 12-month period of its existence from the manufacture, importation, or distribution of heroin or cocaine or ecgonine or methamphetamine or the derivatives, salts, isomers, or salts of isomers thereof or marijuana or (ii) the person engaged in the enterprise to manufacture, sell, give, distribute or possess with the intent to manufacture, sell, give or distribute the following during any 12-month period of its existence:

- 1. At least 5.0 kilograms of a mixture or substance containing a detectable amount of heroin;
- 2. At least 10 kilograms of a mixture or substance containing a detectable amount of:
- a. Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;
- b. Cocaine, its salts, optical and geometric isomers, and salts of isomers;

- c. Ecgonine, its derivatives, their salts, isomers, and salts of isomers; or
- d. Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subdivisions a through c;
- 3. At least 5.0 kilograms of a mixture or substance described in subdivision 2 which contains cocaine base:
- 4. At least 250 kilograms of a mixture or substance containing a detectable amount of marijuana; or
- 5. At least 250 grams of methamphetamine, its salts, isomers, or salts of its isomers or at least 1.0 kilograms of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers shall be guilty of a felony punishable by a fine of not more than \$1 million and imprisonment for life, which shall be served with no suspension in whole or in part. Such punishment shall be made to run consecutively with any other sentence. However, the court may impose a mandatory minimum sentence of 40 years if the court finds that the defendant substantially cooperated with lawenforcement authorities.
- I. For purposes of this section, a person is engaged in a continuing criminal enterprise if (i) he violates any provision of this section, the punishment for which is a felony and either (ii) such violation is a part of a continuing series of violations of this section which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and from which such person obtains substantial income or resources or (iii) such violation is committed, with respect to methamphetamine or other controlled substance classified in Schedule I or II, for the benefit of, at the direction of, or in association with any criminal street gang as defined in § 18.2-46.1.
- J. Except as authorized in the Drug Control Act (§ <u>54.1-3400</u> et seq.), any person who possesses any two or more different substances listed below with the intent to manufacture methamphetamine, methcathinone, or amphetamine is guilty of a Class 6 felony: liquefied ammonia gas, ammonium nitrate, ether, hypophosphorus acid solutions, hypophosphite salts, hydrochloric acid, iodine crystals or tincture of iodine, phenylacetone, phenylacetic acid, red phosphorus, methylamine, methyl formamide, lithium, sodium metal, sulfuric acid, sodium hydroxide, potassium dichromate, sodium dichromate, potassium permanganate, chromium trioxide, methylbenzene, methamphetamine precursor drugs, trichloroethane, or 2-propanone.

K. The term "methamphetamine precursor drug," when used in this article, means a drug or product containing ephedrine, pseudoephedrine, or phenylpropanolamine or any of their salts, optical isomers, or salts of optical isomers.

Code 1950, § 54-524.101:1; 1972, c. 798; 1973, c. 479; 1974, c. 586; 1975, cc. 14, 15; 1976, c. 614; 1977, c. 409; 1978, cc. 177, 779; 1979, c. 435; 1982, cc. 276, 462; 1985, c. 569; 1986, c. 453; 1988, c. 355; 1990, c. 82; 1991, c. 13; 1992, cc. 685, 737, 756; 1995, c. <u>538</u>; 1999, c. <u>722</u>; 2000, cc. <u>1020</u>, <u>1041</u>; 2004, c. <u>461</u>; 2005, cc. <u>174</u>, <u>759</u>, <u>796</u>, <u>923</u>, <u>941</u>; 2006, cc. <u>697</u>, <u>759</u>; 2008, cc. <u>79</u>, <u>618</u>; 2009, c. <u>750</u>; 2012, cc. 219, 710, 844; 2013, c. 426; 2014, c. 513.

§ 18.2-248.01. Transporting controlled substances into the Commonwealth; penalty.

Except as authorized in the Drug Control Act (§ <u>54.1-3400</u> et seq.) it is unlawful for any person to transport into the Commonwealth by any means with intent to sell or distribute one ounce or more of cocaine, coca leaves or any salt, compound, derivative or preparation thereof as described in Schedule II of the Drug Control Act or one ounce or more of any other Schedule I or II controlled substance or five or more pounds of marijuana. A violation of this section shall constitute a separate and distinct felony. Upon conviction, the person shall be sentenced to not less than five years nor more than 40 years imprisonment, three years of which shall be a mandatory minimum term of imprisonment, and a fine not to exceed

\$1,000,000. A second or subsequent conviction hereunder shall be punishable by a mandatory minimum term of imprisonment of 10 years, which shall be served consecutively with any other sentence.

1992, c. 723; 2000, cc. <u>1020</u>, <u>1041</u>; 2004, c. <u>461</u>.

§ 18.2-248.1. Penalties for sale, gift, distribution or possession with intent to sell, give or distribute marijuana.

Except as authorized in the Drug Control Act (§ <u>54.1-3400</u> et seq.), it is unlawful for any person to sell, give, distribute or possess with intent to sell, give, or distribute marijuana.

- (a) Any person who violates this section with respect to:
- (1) Not more than one ounce of marijuana is guilty of a Class 1 misdemeanor;
- (2) More than one ounce but not more than five pounds of marijuana is guilty of a Class 5 felony;
- (3) More than five pounds of marijuana is guilty of a felony punishable by imprisonment of not less than five nor more than 30 years.

There shall be a rebuttable presumption that a person who possesses no more than one ounce of marijuana possesses it for personal use.

If such person proves that he gave, distributed, or possessed with intent to give or distribute marijuana only as an accommodation to another individual and not with intent to profit thereby from any consideration received or expected nor to induce the recipient or intended recipient of the marijuana to use or become addicted to or dependent upon such marijuana, he is guilty of a Class 1 misdemeanor.

- (b) Any person who gives, distributes, or possesses marijuana as an accommodation and not with intent to profit thereby, to an inmate of a state or local correctional facility, as defined in § 53.1-1, or in the custody of an employee thereof is guilty of a Class 4 felony.
- (c) Any person who manufactures marijuana, or possesses marijuana with the intent to manufacture such substance, not for his own use is guilty of a felony punishable by imprisonment of not less than five nor more than 30 years and a fine not to exceed \$10,000.
- (d) When a person is convicted of a third or subsequent felony offense under this section and it is alleged in the warrant, indictment or information that he has been before convicted of two or more felony offenses under this section or of substantially similar offenses in any other jurisdiction which offenses would be felonies if committed in the Commonwealth, and such prior convictions occurred before the date of the offense alleged in the warrant, indictment, or information, he shall be sentenced to imprisonment for life or for any period not less than five years, five years of which shall be a mandatory minimum term of imprisonment to be served consecutively with any other sentence and he shall be fined not more than \$500,000.

1979, c. 435; 1986, c. 467; 2000, cc. <u>819</u>, <u>1020</u>, <u>1041</u>; 2004, c. <u>461</u>; 2006, cc. <u>697</u>, <u>759</u>; 2020, cc. <u>1285</u>, <u>1286</u>.

§ 18.2-248.3. Professional use of imitation controlled substances.

No civil or criminal liability shall be imposed by virtue of this article on any person licensed under the Drug Control Act, Chapter 34 of Title 54.1, who manufactures, sells, gives or distributes an imitation controlled substance for use as a placebo by a licensed practitioner in the course of professional practice or research.

1982, c. 462.

§ 18.2-250. Possession of controlled substances unlawful.

A. It is unlawful for any person knowingly or intentionally to possess a controlled substance unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.).

Upon the prosecution of a person for a violation of this section, ownership or occupancy of premises or vehicle upon or in which a controlled substance was found shall not create a presumption that such person either knowingly or intentionally possessed such controlled substance.

- (a) Any person who violates this section with respect to any controlled substance classified in Schedule I or II of the Drug Control Act shall be guilty of a Class 5 felony, except that any person other than an inmate of a penal institution as defined in § 53.1-1 or in the custody of an employee thereof who violates this section with respect to a cannabimimetic agent is guilty of a Class 1 misdemeanor.
- (b) Any person other than an inmate of a penal institution as defined in § 53.1-1 or in the custody of an employee thereof, who violates this section with respect to a controlled substance classified in Schedule III shall be guilty of a Class 1 misdemeanor.
- (b1) Violation of this section with respect to a controlled substance classified in Schedule IV shall be punishable as a Class 2 misdemeanor.
- (b2) Violation of this section with respect to a controlled substance classified in Schedule V shall be punishable as a Class 3 misdemeanor.
- (c) Violation of this section with respect to a controlled substance classified in Schedule VI shall be punishable as a Class 4 misdemeanor.
- B. The provisions of this section shall not apply to members of state, federal, county, city or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of a controlled substance or substances is necessary in the performance of their duties.

Code 1950, § 54-524.101:2; 1972, c. 798; 1973, c. 64; 1975, cc. 14, 15; 1976, c. 614; 1978, cc. 151, 177, 179; 1979, c. 435; 1980, c. 285; 1991, c. 649; 1998, c. 116; 2014, cc. 674, 719.

§ 18.2-251.03. Arrest and prosecution when experiencing or reporting overdoses.

- A. For purposes of this section, "overdose" means a life-threatening condition resulting from the consumption or use of a controlled substance, alcohol, or any combination of such substances.
- B. No individual shall be subject to arrest or prosecution for the unlawful purchase, possession, or consumption of alcohol pursuant to \S 4.1-305, unlawful purchase, possession, or consumption of marijuana pursuant to \S 4.1-1105.1, possession of a controlled substance pursuant to \S 18.2-250, intoxication in public pursuant to \S 18.2-388, or possession of controlled paraphernalia pursuant to \S 54.1-3466 if:
- 1. Such individual (i) in good faith, seeks or obtains emergency medical attention (a) for himself, if he is experiencing an overdose, or (b) for another individual, if such other individual is experiencing an overdose; (ii) is experiencing an overdose and another individual, in good faith, seeks or obtains emergency medical attention for such individual, by contemporaneously reporting such overdose to a firefighter, as defined in § 65.2-102, emergency medical services personnel, as defined in § 32.1-111.1, a law-enforcement officer, as defined in § 9.1-101, or an emergency 911 system; or (iii) in good faith, renders emergency care or assistance, including cardiopulmonary resuscitation (CPR) or the administration of naloxone or other opioid antagonist for overdose reversal, to an individual experiencing an overdose while another individual seeks or obtains emergency medical attention in accordance with this subdivision:

- 2. Such individual remains at the scene of the overdose or at any alternative location to which he or the person requiring emergency medical attention has been transported until a law-enforcement officer responds to the report of an overdose. If no law-enforcement officer is present at the scene of the overdose or at the alternative location, then such individual shall cooperate with law enforcement as otherwise set forth herein;
- 3. Such individual identifies himself to the law-enforcement officer who responds to the report of the overdose; and
- 4. The evidence for the prosecution of an offense enumerated in this subsection was obtained as a result of the individual seeking or obtaining emergency medical attention or rendering emergency care or assistance.
- C. The provisions of this section shall not apply to any person who seeks or obtains emergency medical attention for himself or another individual, to a person experiencing an overdose when another individual seeks or obtains emergency medical attention for him, or to a person who renders emergency care or assistance to an individual experiencing an overdose while another person seeks or obtains emergency medical attention during the execution of a search warrant or during the conduct of a lawful search or a lawful arrest.
- D. This section does not establish protection from arrest or prosecution for any individual or offense other than those listed in subsection B.
- E. No law-enforcement officer acting in good faith shall be found liable for false arrest if it is later determined that the person arrested was immune from prosecution under this section.

2015, cc. <u>418</u>, <u>436</u>; 2019, c. <u>626</u>; 2020, c. <u>1016</u>; 2021, Sp. Sess. I, cc. <u>29</u>, <u>550</u>, <u>551</u>.

§ 18.2-251.1. Possession or distribution of marijuana for medical purposes permitted.

- A. No person shall be prosecuted under § <u>18.2-250</u> or § <u>18.2-250.1</u> for the possession of marijuana or tetrahydrocannabinol when that possession occurs pursuant to a valid prescription issued by a medical doctor in the course of his professional practice for treatment of cancer or glaucoma.
- B. No medical doctor shall be prosecuted under § 18.2-248 or § 18.2-248.1 for dispensing or distributing marijuana or tetrahydrocannabinol for medical purposes when such action occurs in the course of his professional practice for treatment of cancer or glaucoma.
- C. No pharmacist shall be prosecuted under §§ 18.2-248 to 18.2-248.1 for dispensing or distributing marijuana or tetrahydrocannabinol to any person who holds a valid prescription of a medical doctor for such substance issued in the course of such doctor's professional practice for treatment of cancer or glaucoma.

1979, c. 435.

18.2-251.1:1. Possession or distribution of cannabis oil; public schools

No school nurse employed by a local school board, person employed by a local health department who is assigned to the public school pursuant to an agreement between the local health department and the school board, or other person employed by or contracted with a local school board to deliver health-related services shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title

4.1 or § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-255 for the possession or distribution of cannabis oil for storing, dispensing, or administering cannabis oil, in accordance with a policy adopted by the local school board, to a student who has been issued a valid written certification for the use of cannabis oil in accordance with § 4.1-1601.

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2019, cc. <u>573</u>, <u>574</u>; 2021 Sp. Sess. I, cc. <u>550</u>, <u>551</u>; 2023, cc. <u>740</u>, <u>773</u>.
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18.2-251.1:2. Possession or distribution of cannabis oil; nursing homes and certified nursing facilities; hospice and hospice facilities; assisted living facilities

No person employed by a nursing home, hospice, hospice facility, or assisted living facility and authorized to possess, distribute, or administer medications to patients or residents shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-248, 18.2-248.1, or 18.2-250 for the possession or distribution of cannabis oil for the purposes of storing, dispensing, or administering cannabis oil to a patient or resident who has been issued a valid written certification for the use of cannabis oil in accordance with § 4.1-1601.

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2020, c. <u>846</u>; 2021 Sp. Sess. I, cc. <u>550</u>, <u>551</u>; 2023, cc. <u>740</u>, <u>773</u>.
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§ 18.2-251.2. Possession and distribution of flunitrazepam; enhanced penalty.

Notwithstanding the provisions of §§ <u>54.1-3446</u> and <u>54.1-3452</u>, the drug flunitrazepam shall be deemed to be listed on Schedule I for the purposes of penalties for violations of the Drug Control Act (§ <u>54.1-3400</u> et seq.). Any person knowingly manufacturing, selling, giving, distributing or possessing the drug flunitrazepam shall be punished under the penalties prescribed for such violations in accordance with §§ <u>18.2-248</u> and 18.2-250.

1997, c. 595.

§ 18.2-251.3. Possession and distribution of gamma-butyrolactone; 1, 4-butanediol; enhanced penalty.

Any person who knowingly manufactures, sells, gives, distributes or possesses with the intent to distribute the substances gamma-butyrolactone; or 1, 4-butanediol, when intended for human consumption shall be guilty of a Class 3 felony.

2000, c. 348.

§ 18.2-251.4. Defeating drug and alcohol screening tests; penalty.

A. It is unlawful for a person to:

- 1. Sell, give away, distribute, transport or market human urine in the Commonwealth with the intent of using the urine to defeat a drug or alcohol screening test;
- 2. Attempt to defeat a drug or alcohol screening test by the substitution of a sample;

- 3. Adulterate a urine or other bodily fluid sample with the intent to defraud a drug or alcohol screening test.
- B. A violation of this section is a Class 1 misdemeanor.

2001, c. 379.

§ 18.2-256. Conspiracy.

Any person who conspires to commit any offense defined in this article or in the Drug Control Act (§ 54.1-3400 et seq.) is punishable by imprisonment or fine or both which may not be less than the minimum punishment nor exceed the maximum punishment prescribed for the offense, the commission of which was the object of the conspiracy.

Code 1950, § 54-524.104; 1970, c. 650; 1972, c. 798; 1975, cc. 14, 15; 1978, c. 130.

§ 18.2-257. Attempts.

- (a) Any person who attempts to commit any offense defined in this article or in the Drug Control Act (§ 54.1-3400 et seq.) which is a felony shall be imprisoned for not less than one nor more than ten years; provided, however, that any person convicted of attempting to commit a felony for which a lesser punishment may be imposed may be punished according to such lesser penalty.
- (b) Any person who attempts to commit any offense defined in this article or in the Drug Control Act which is a misdemeanor shall be guilty of a Class 2 misdemeanor; provided, however, that any person convicted of attempting to commit a misdemeanor for which a lesser punishment may be imposed may be punished according to such lesser penalty.

Code 1950, § 54-524.104:1; 1972, c. 798; 1973, c. 447; 1975, cc. 14, 15; 1979, c. 435.

§ 18.2-258.1. Obtaining drugs, procuring administration of controlled substances, etc., by fraud, deceit or forgery.

A. It shall be unlawful for any person to obtain or attempt to obtain any drug or procure or attempt to procure the administration of any controlled substance or marijuana: (i) by fraud, deceit, misrepresentation, embezzlement, or subterfuge; (ii) by the forgery or alteration of a prescription or of any written order; (iii) by the concealment of a material fact; or (iv) by the use of a false name or the giving of a false address.

- B. It shall be unlawful for any person to furnish false or fraudulent information in or omit any information from, or willfully make a false statement in, any prescription, order, report, record, or other document required by Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1.
- C. It shall be unlawful for any person to use in the course of the manufacture or distribution of a controlled substance or marijuana a license number which is fictitious, revoked, suspended, or issued to another person.
- D. It shall be unlawful for any person, for the purpose of obtaining any controlled substance or marijuana to falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian or other authorized person.

- E. It shall be unlawful for any person to make or utter any false or forged prescription or false or forged written order.
- F. It shall be unlawful for any person to affix any false or forged label to a package or receptacle containing any controlled substance.
- G. This section shall not apply to officers and employees of the United States, of this Commonwealth or of a political subdivision of this Commonwealth acting in the course of their employment, who obtain such drugs for investigative, research or analytical purposes, or to the agents or duly authorized representatives of any pharmaceutical manufacturer who obtain such drugs for investigative, research or analytical purposes and who are acting in the course of their employment; provided that such manufacturer is licensed under the provisions of the Federal Food, Drug and Cosmetic Act; and provided further, that such pharmaceutical manufacturer, its agents and duly authorized representatives file with the Board such information as the Board may deem appropriate.
- H. Except as otherwise provided in this subsection, any person who shall violate any provision herein shall be guilty of a Class 6 felony.

Whenever any person who has not previously been convicted of any offense under this article or under any statute of the United States or of any state relating to narcotic drugs, marijuana, or stimulant, depressant, or hallucinogenic drugs, or has not previously had a proceeding against him for violation of such an offense dismissed, or reduced as provided in this section, pleads guilty to or enters a plea of not guilty to the court for violating this section, upon such plea if the facts found by the court would justify a finding of guilt, the court may place him on probation upon terms and conditions.

As a term or condition, the court shall require the accused to be evaluated and enter a treatment and/or education program, if available, such as, in the opinion of the court, may be best suited to the needs of the accused. This program may be located in the judicial circuit in which the charge is brought or in any other judicial circuit as the court may provide. The services shall be provided by a program certified or licensed by the Department of Behavioral Health and Developmental Services. The court shall require the person entering such program under the provisions of this section to pay all or part of the costs of the program, including the costs of the screening, evaluation, testing and education, based upon the person's ability to pay unless the person is determined by the court to be indigent.

As a condition of supervised probation, the court shall require the accused to remain drug free during the period of probation and submit to such tests during that period as may be necessary and appropriate to determine if the accused is drug free. Such testing may be conducted by the personnel of any screening, evaluation, and education program to which the person is referred or by the supervising agency.

Unless the accused was fingerprinted at the time of arrest, the court shall order the accused to report to the original arresting law-enforcement agency to submit to fingerprinting.

Upon violation of a term or condition, the court may enter an adjudication of guilt upon the felony and proceed as otherwise provided. Upon fulfillment of the terms and conditions of probation, the court shall find the defendant guilty of a Class 1 misdemeanor.

1977, c. 558; 1979, c. 435; 1992, c. 76; 1997, c. <u>542</u>; 2009, cc. <u>813</u>, <u>840</u>; 2011, cc. <u>384</u>, <u>410</u>; 2014, cc. <u>674</u>, <u>719</u>.

§ 18.2-260. Prescribing, dispensing, etc., drug except as authorized in article and Drug Control Act; violations for which no penalty provided.

It shall be unlawful for any person to prescribe, administer or dispense any drug except as authorized in the Drug Control Act (§ <u>54.1-3400</u> et seq.) or in this article. Any person who violates any provision of the Drug Control Act or of this article, for which no penalty is elsewhere specified in this article or in Article 7 (§ <u>54.1-3466</u> et seq.) of the Drug Control Act, shall be guilty of a Class 1 misdemeanor.

Code 1950, § 54-524.106; 1970, c. 650; 1973, c. 548; 1975, cc. 14, 15.

§ 18.2-260.1. Falsifying patient records.

Any person who, with the intent to defraud, falsifies any patient record shall be guilty of a Class 1 misdemeanor.

1997, c. <u>619</u>; 2011, c. <u>204</u>.

§ 18.2-261. Monetary penalty.

Any person licensed by the State Board of Pharmacy who violates any of the provisions of the Drug Control Act (§ <u>54.1-3400</u> et seq.) or of this article, and who is not criminally prosecuted, shall be subject to the monetary penalty provided in this section. If, by a majority vote, the Board shall determine that the respondent is guilty of the violation complained of, the Board shall proceed to determine the amount of the monetary penalty for such violation, which shall not exceed the sum of \$1,000 for each violation. Such penalty may be sued for and recovered in the name of the Commonwealth.

Code 1950, § 54-524.107; 1970, c. 650; 1975, cc. 14, 15; 1980, c. 678.

§ 18.2-265.6. Definitions.

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

"Pharmacy" means any establishment or institution from which drugs, medicines, or medicinal chemicals are dispensed or offered for sale or on which a sign is displayed bearing the words "apothecary," "druggist," "drugs," "drug store," "drug sundries," "medicine store," "pharmacist," "pharmacy," or "prescriptions filled" or any similar words intended to indicate that the practice of pharmacy is being conducted pursuant to a license issued under Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1.

"Retail distributor" means an entity licensed to conduct business in the Commonwealth that offers for sale to the public at a retail outlet any nonprescription compound, mixture, or preparation containing ephedrine or related compounds.

"System" or "electronic system" means a real-time electronic recordkeeping and monitoring system for the sale of ephedrine or related compounds.

2012, cc. <u>160</u>, <u>252</u>.

§ 18.2-265.7. Sale of the methamphetamine precursors ephedrine or related compounds; penalty.

[&]quot;Department" means the Department of State Police.

[&]quot;Ephedrine or related compounds" means ephedrine and pseudoephedrine base or their salts, isomers, or salts of isomers.

- A. The sale of any product containing ephedrine or related compounds sold by a pharmacy or retail distributor shall be limited to no more than 3.6 grams per day and 9 grams per 30-day period per individual customer. The limits shall apply to the total amount of base ephedrine or related compounds contained in the products and not to the overall weight of the products.
- B. Ephedrine or related compounds shall only be displayed for sale behind a store counter that is not accessible to consumers or in a locked case that requires assistance by a store employee for customer access.
- C. Any person purchasing, receiving, or otherwise acquiring ephedrine or related compounds shall, prior to taking possession, present photo identification issued by a government or an educational institution.
- D. The pharmacy or retail distributor shall maintain a written log or electronic system with the purchaser's name and address, birth date, and signature; the product name and quantity sold; and the date and time of the transaction. Unless exempt under subsection B of § 18.2-265.8 or § 18.2-265.11, the pharmacy or retail distributor shall use the electronic recordkeeping and monitoring system to report all nonprescription sales of any product containing ephedrine or related compounds.
- E. The purchaser shall sign the record acknowledging an understanding of the applicable sales limit and that providing false statements or misrepresentations may subject the purchaser to criminal penalties under § 1001 of Title 18 of the United States Code.
- F. The pharmacy or retail distributor shall maintain records of all sales required to be entered into the electronic system or written log for a period of two years from the date of the last entry.
- G. The provisions of this article do not apply to sales of ephedrine or related compounds pursuant to a valid prescription.
- H. Any person who willfully violates this section is guilty of a Class 1 misdemeanor.

2012, cc. 160, 252.

§ 18.2-265.8. Real-time electronic recording of sales of ephedrine or related compounds; memorandum of understanding.

- A. The Department shall enter into a memorandum of understanding with an appropriate entity to establish the Commonwealth's participation in a real-time electronic recordkeeping and monitoring system for the sale of ephedrine or related compounds. The memorandum of understanding shall include the following:
- 1. A real-time electronic recordkeeping and monitoring system shall be provided at no charge to the Commonwealth or to participating pharmacies and retail distributors and shall be approved by the Department.
- 2. The system shall provide, at no charge to participating pharmacies and retail distributors, appropriate training, 24-hour online support, and a toll-free telephone help line that is staffed 24 hours a day.
- 3. The system shall be able to communicate in real time with similar systems operated in other states and the District of Columbia and similar systems containing information submitted by more than one state.
- 4. The system shall comply with information exchange standards adopted by the National Information Exchange Model.
- 5. The system shall include a stop sales alert, which shall be a notification that completion of the sale would result in the seller or purchaser violating the quantity limits set forth in § 18.2-265.7, with an

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override function that may be used by a pharmacy or retail distributor under the circumstances set forth in § 18.2-265.9 and shall record each instance in which the override function is utilized.

- 6. The system shall provide for the recording of the following:
- a. The date and time of the transaction;
- b. The name, address, date of birth, and photo identification number of the purchaser; the type of identification; and the government or educational institution of issuance;
- c. The number of packages purchased; the total number of grams of ephedrine or related compounds per package; and the name of the compound, mixture, or preparation containing ephedrine or related compounds; and
- d. The signature of the purchaser or unique number connecting the transaction to a paper signature maintained at the retail premises.
- 7. The system shall ensure that submitted data is retained within the system for at least two years from the date of submission.
- B. The Department shall provide a process for a pharmacy or retail distributor to apply for, obtain, and periodically renew an exemption from the requirement to report transactions to the electronic system if the pharmacy or retail distributor lacks broadband access or maintains a sales volume of less than 72 grams of ephedrine or related compounds in a 30-day period.
- C. The Superintendent of State Police shall promulgate regulations pursuant to the Administrative Process Act (§ <u>2.2-4000</u> et seq.) for the implementation of this section. Regulations adopted under this section shall be deemed a customary police function for purposes of subdivision B 6 of § <u>2.2-4002</u>.

2012, cc. <u>160</u>, <u>252</u>.

§ 18.2-265.9. Stop sales alerts; interruption of electronic system.

A. A pharmacy or retail distributor shall not complete the sale if the system generates a stop sales alert unless the individual distributing the ephedrine or related compound has a reasonable fear of imminent bodily harm if the sale is not completed.

B. In the event of a mechanical or electronic interruption of the system, the pharmacy or retail establishment shall maintain a written log of sales of ephedrine or related compounds until the system is restored. The information written in the log shall be transmitted to the system as soon as practicable after the system is restored.

2012, cc. 160, 252.

§ 18.2-265.10. Exemption from participation in electronic system; requirement to maintain log.

Any pharmacy or retail distributor that has been granted an exemption from participation in the system pursuant to subsection B of § 18.2-265.8 shall forward to the Department every seven days by fax or electronic means a legible copy of the log required by § 18.2-265.7.

2012, cc. <u>160</u>, <u>252</u>.

§ 18.2-265.11. Exemption from participation in electronic system and maintenance of a written log.

A. The following entities shall not be required to participate in the electronic system and shall not be required to maintain a written log:

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- 1. Licensed manufacturers that manufacture and lawfully distribute products in the channels of commerce.
- 2. Wholesalers that lawfully distribute products in the channels of commerce.
- 3. Inpatient pharmacies of health care facilities licensed in the Commonwealth.
- 4. Licensed long-term health care facilities.
- 5. Government-operated health care clinics or departments or centers.
- 6. Physicians who dispense drugs pursuant to § 54.1-3304.
- 7. Pharmacies located in correctional facilities.
- 8. Government-operated or industry-operated medical facilities serving the employees of the Commonwealth or local or federal government.
- B. Purchases of ephedrine or related compounds pursuant to a valid prescription are not required to be reported to the system or entered into a written log.
- C. The sale of a single package containing no more than 60 milligrams of ephedrine or related compounds to an individual is not required to be reported to the system or entered into a log provided it is an isolated sale.

2012, cc. <u>160</u>, <u>252</u>.

§ 18.2-265.12. Authority to access data, records, and reports.

The Department or other law-enforcement agency of the Commonwealth or any federal agency conducting a criminal investigation involving the manufacture of methamphetamine consistent with state or federal law may access data, records, and reports regarding the sale of ephedrine or related compounds. In addition, such information may be accessed if relevant to proceedings in any court, investigatory grand jury, or special grand jury that has been impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

The Superintendent of State Police shall promulgate regulations, pursuant to the Administrative Process Act (§ <u>2.2-4000</u> et seq.), for the implementation of this section. Regulations adopted under this section shall be deemed a customary police function for purposes of subdivision B 6 of § <u>2.2-4002</u>.

2012, cc. <u>160</u>, <u>252</u>.

§ 18.2-265.13. Confidentiality of data in possession of Department.

All data, records, and reports related to the sale of ephedrine or related compounds to retail customers and any abstracts of such data, records, and reports that are in the possession of the Department pursuant to this article shall be confidential and exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) and the Government Data Collection and Dissemination Practices Act (§ 2.2-3800 et seq.).

2012, cc. 160, 252.

§ 18.2-265.14. Prohibition on disclosure of information by entity operating the system.

The entity operating the system pursuant to the memorandum of understanding with the Department shall not use or disclose the information collected on behalf of the Department from a pharmacy or retail distributor for any purpose other than (i) to ensure compliance with this article or the federal Combat Methamphetamine Epidemic Act of 2005, (ii) to comply with the United States government or a political

subdivision thereof for law-enforcement purposes pursuant to state or federal law, or (iii) to facilitate a product recall necessary to protect public health and safety.

2012, cc. <u>160</u>, <u>252</u>.

\S 18.2-265.15. Prohibition on disclosure of information by pharmacy or retail distributor; civil immunity.

A pharmacy or retail distributor that sells any product containing ephedrine or related compounds shall not use or disclose the information in the system or a written log for any purpose other than (i) to ensure compliance with this article or the federal Combat Methamphetamine Epidemic Act of 2005, (ii) to comply with the United States government or a political subdivision thereof for law-enforcement purposes pursuant to state or federal law, or (iii) to facilitate a product recall necessary to protect public health and safety. A pharmacy or retail distributor shall report information in the written log or electronic system to law-enforcement personnel upon request, and any pharmacy or retail distributor that in good faith releases such information to federal, state, or local law-enforcement officers, or to any person acting on behalf of such officers, shall be immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

2012, cc. <u>160</u>, <u>252</u>.

§ 18.2-265.16. Compliance with statutory provisions; civil immunity.

Absent gross negligence, recklessness, or willful misconduct, any pharmacy or retail distributor utilizing the system or written log in compliance with this article shall be immune from civil liability as a result of actions or omissions in carrying out such statutory duties.

2012, cc. <u>160</u>, <u>252</u>.

§ 18.2-265.18. Failure to report certain sales; penalty.

Any person subject to the recordkeeping and reporting requirements set forth in this article that willfully fails to report nonprescription sales of ephedrine or related compounds is guilty of a Class 1 misdemeanor.

2012, cc. 160, 252.

§ 18.2-265.19. Definitions.

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

"Dextromethorphan" means the dextrorotatory isomer of 3-methoxy-N-methylmorphinan and its salts. "Pharmacy" means any establishment or institution from which drugs, medicines, or medicinal chemicals are dispensed or offered for sale or on which a sign is displayed bearing the words "apothecary," "druggist," "drugs," "drug store," "drug sundries," "medicine store," "pharmacist," "pharmacy," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted pursuant to a license issued under Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1. "Retail distributor" means an entity licensed to conduct business in the Commonwealth that offers for sale to the public at a retail outlet any nonprescription compound, mixture, or preparation containing dextromethorphan.

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"Unfinished dextromethorphan" means dextromethorphan in the form of a "bulk drug substance" as defined in § <u>54.1-3401</u>.

2014, cc. <u>101</u>, <u>362</u>.

§ 18.2-265.20. Sale or distribution of dextromethorphan to minors; purchase by minors; civil penalty.

A. It is unlawful for any pharmacy or retail distributor knowingly or intentionally to sell or distribute any product containing dextromethorphan to a minor.

B. A pharmacy or retail distributor, or its employee or agent, shall not sell or distribute a product containing dextromethorphan unless the purchaser presents a federal, state, or local government-issued document that contains a photograph and the birth date of the purchaser that shows that the purchaser is at least 18 years of age or unless from the purchaser's outward appearance the pharmacy or retail distributor would reasonably presume the purchaser to be 25 years of age or older.

C. It is unlawful for any minor knowingly or intentionally to purchase any product containing dextromethorphan.

D. Any pharmacy or retail distributor, or its employee or agent, that violates subsection A or any minor who violates subsection C is subject to a civil penalty of \$25. Any pharmacy or retail distributor, or its employee or agent, that violates subsection B shall receive a notice of noncompliance and, upon any subsequent violation of subsection B, shall be subject to a civil penalty of \$25. Such penalty shall be collected by the attorney for the Commonwealth for the locality where the violation occurred, and the proceeds shall be deposited into the Literary Fund.

E. The provisions of this section shall not apply if the product was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ <u>54.1-3400</u> et seq.).

2014, cc. 101, 362.

§ 18.2-265.21. Possession or distribution of unfinished dextromethorphan; penalty.

Any person who distributes or possesses with the intent to distribute unfinished dextromethorphan who is not registered under § 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) or otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.) to distribute or possess unfinished dextromethorphan is guilty of a Class 1 misdemeanor. This section does not apply to a common carrier that receives or possesses unfinished dextromethorphan for the purpose of distributing such unfinished dextromethorphan between persons registered under § 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) or otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.) to distribute or possess unfinished dextromethorphan.

2014, cc. <u>101</u>, <u>362</u>.