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HOUSE BILL NO. 1040

Offered January 8, 2020
Prefiled January 7, 2020

A BILL to amend and reenact §§ 54.1-2900, 54.1-2901, 54.1-2914, 54.1-2973.1 and 54.1-3401, as it is currently effective and as it will become effective, of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 54.1-2956.14 through 54.1-2956.17, relating to licensure of naturopathic doctors.

Patrons—Rasoul, Adams, D.M., Carr, Guzman, Morefield, Samirah and Tyler

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2900, 54.1-2901, 54.1-2914, 54.1-2973.1 and 54.1-3401, as it is currently effective and as it will become effective, of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding sections numbered 54.1-2956.14 through 54.1-2956.17 as follows:

§ 54.1-2900. Definitions.

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

"Acupuncturist" means an individual approved by the Board to practice acupuncture. This is limited to "licensed acupuncturist" which means an individual other than a doctor of medicine, osteopathy, chiropractic or podiatry who has successfully completed the requirements for licensure established by the Board (approved titles are limited to: Licensed Acupuncturist, Lic.Ac., and L.Ac.).

"Auricular acupuncture" means the subcutaneous insertion of sterile, disposable acupuncture needles in predetermined, bilateral locations in the outer ear when used exclusively and specifically in the context of a chemical dependency treatment program.

"Board" means the Board of Medicine.

"Certified nurse midwife" means an advanced practice registered nurse who is certified in the specialty of nurse midwifery and who is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957.

"Certified registered nurse anesthetist" means an advanced practice registered nurse who is certified in the specialty of nurse anesthesia, who is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957, and who practices under the supervision of a doctor of medicine, osteopathy, podiatry, or dentistry but is not subject to the practice agreement requirement described in § 54.1-2957.

"Collaboration" means the communication and decision-making process among health care providers who are members of a patient care team related to the treatment of a patient that includes the degree of cooperation necessary to provide treatment and care of the patient and includes (i) communication of data and information about the treatment and care of a patient, including the exchange of clinical observations and assessments, and (ii) development of an appropriate plan of care, including decisions regarding the health care provided, accessing and assessment of appropriate additional resources or expertise, and arrangement of appropriate referrals, testing, or studies.

"Consultation" means communicating data and information, exchanging clinical observations and assessments, accessing and assessing additional resources and expertise, problem-solving, and arranging for referrals, testing, or studies.

"Genetic counselor" means a person licensed by the Board to engage in the practice of genetic counseling.

"Healing arts" means the arts and sciences dealing with the prevention, diagnosis, treatment and cure or alleviation of human physical or mental ailments, conditions, diseases, pain or infirmities.

"Medical malpractice judgment" means any final order of any court entering judgment against a licensee of the Board that arises out of any tort action or breach of contract action for personal injuries or wrongful death, based on health care or professional services rendered, or that should have been rendered, by a health care provider, to a patient.

"Medical malpractice settlement" means any written agreement and release entered into by or on behalf of a licensee of the Board in response to a written claim for money damages that arises out of any personal injuries or wrongful death, based on health care or professional services rendered, or that should have been rendered, by a health care provider, to a patient.

"Naturopathic doctor" means an individual, other than a doctor of medicine, osteopathy, chiropractic, or podiatry, who may diagnose, treat, and help prevent diseases using a system of practice

that is based on the natural healing capacity of individuals, using physiological, psychological, or physical methods, and who may also use natural medicines, prescriptions, legend drugs, foods, herbs, or other natural remedies, including light and air.

"Nurse practitioner" means an advanced practice registered nurse who is jointly licensed by the Boards of Medicine and Nursing pursuant to § 54.1-2957.

"Occupational therapy assistant" means an individual who has met the requirements of the Board for licensure and who works under the supervision of a licensed occupational therapist to assist in the practice of occupational therapy.

"Patient care team" means a multidisciplinary team of health care providers actively functioning as a unit with the management and leadership of one or more patient care team physicians for the purpose of providing and delivering health care to a patient or group of patients.

"Patient care team physician" means a physician who is actively licensed to practice medicine in the Commonwealth, who regularly practices medicine in the Commonwealth, and who provides management and leadership in the care of patients as part of a patient care team.

"Patient care team podiatrist" means a podiatrist who is actively licensed to practice podiatry in the Commonwealth, who regularly practices podiatry in the Commonwealth, and who provides management and leadership to physician assistants in the care of patients as part of a patient care team.

"Physician assistant" means a health care professional who has met the requirements of the Board for licensure as a physician assistant.

"Practice of acupuncture" means the stimulation of certain points on or near the surface of the body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain ailments or conditions of the body and includes the techniques of electroacupuncture, cupping and moxibustion. The practice of acupuncture does not include the use of physical therapy, chiropractic, or osteopathic manipulative techniques; the use or prescribing of any drugs, medications, serums or vaccines; or the procedure of auricular acupuncture as exempted in § 54.1-2901 when used in the context of a chemical dependency treatment program for patients eligible for federal, state or local public funds by an employee of the program who is trained and approved by the National Acupuncture Detoxification Association or an equivalent certifying body.

"Practice of athletic training" means the prevention, recognition, evaluation, and treatment of injuries or conditions related to athletic or recreational activity that requires physical skill and utilizes strength, power, endurance, speed, flexibility, range of motion or agility or a substantially similar injury or condition resulting from occupational activity immediately upon the onset of such injury or condition; and subsequent treatment and rehabilitation of such injuries or conditions under the direction of the patient's physician or under the direction of any doctor of medicine, osteopathy, chiropractic, podiatry, or dentistry, while using heat, light, sound, cold, electricity, exercise or mechanical or other devices.

"Practice of behavior analysis" means the design, implementation, and evaluation of environmental modifications, using behavioral stimuli and consequences, to produce socially significant improvement in human behavior, including the use of direct observation, measurement, and functional analysis of the relationship between environment and behavior.

"Practice of chiropractic" means the adjustment of the 24 movable vertebrae of the spinal column, and assisting nature for the purpose of normalizing the transmission of nerve energy, but does not include the use of surgery, obstetrics, osteopathy or the administration or prescribing of any drugs, medicines, serums or vaccines. "Practice of chiropractic" shall include performing the physical examination of an applicant for a commercial driver's license or commercial learner's permit pursuant to § 46.2-341.12 if the practitioner has (i) applied for and received certification as a medical examiner pursuant to 49 C.F.R. Part 390, Subpart D and (ii) registered with the National Registry of Certified Medical Examiners.

"Practice of genetic counseling" means (i) obtaining and evaluating individual and family medical histories to assess the risk of genetic medical conditions and diseases in a patient, his offspring, and other family members; (ii) discussing the features, history, diagnosis, environmental factors, and risk management of genetic medical conditions and diseases; (iii) ordering genetic laboratory tests and other diagnostic studies necessary for genetic assessment; (iv) integrating the results with personal and family medical history to assess and communicate risk factors for genetic medical conditions and diseases; (v) evaluating the patient's and family's responses to the medical condition or risk of recurrence and providing client-centered counseling and anticipatory guidance; (vi) identifying and utilizing community resources that provide medical, educational, financial, and psychosocial support and advocacy; and (vii) providing written documentation of medical, genetic, and counseling information for families and health care professionals.

"Practice of medicine or osteopathic medicine" means the prevention, diagnosis, and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method.

"Practice of naturopathic medicine" means a system of primary health care for the (i) prevention,

diagnosis, and treatment of human health conditions, injury, and disease; (ii) promotion or restoration of health; and (iii) support and stimulation of a patient's inherent self-healing process through patient education and use of naturopathic therapies and therapeutic substances.

"Practice of occupational therapy" means the therapeutic use of occupations for habilitation and rehabilitation to enhance physical health, mental health, and cognitive functioning and includes the evaluation, analysis, assessment, and delivery of education and training in basic and instrumental activities of daily living; the design, fabrication, and application of orthoses (splints); the design, selection, and use of adaptive equipment and assistive technologies; therapeutic activities to enhance functional performance; vocational evaluation and training; and consultation concerning the adaptation of physical, sensory, and social environments.

"Practice of podiatry" means the prevention, diagnosis, treatment, and cure or alleviation of physical conditions, diseases, pain, or infirmities of the human foot and ankle, including the medical, mechanical and surgical treatment of the ailments of the human foot and ankle, but does not include amputation of the foot proximal to the transmetatarsal level through the metatarsal shafts. Amputations proximal to the metatarsal-phalangeal joints may only be performed in a hospital or ambulatory surgery facility accredited by an organization listed in § 54.1-2939. The practice includes the diagnosis and treatment of lower extremity ulcers; however, the treatment of severe lower extremity ulcers proximal to the foot and ankle may only be performed by appropriately trained, credentialed podiatrists in an approved hospital or ambulatory surgery center at which the podiatrist has privileges, as described in § 54.1-2939. The Board of Medicine shall determine whether a specific type of treatment of the foot and ankle is within the scope of practice of podiatry.

"Practice of radiologic technology" means the application of ionizing radiation to human beings for diagnostic or therapeutic purposes.

"Practice of respiratory care" means the (i) administration of pharmacological, diagnostic, and therapeutic agents related to respiratory care procedures necessary to implement a treatment, disease prevention, pulmonary rehabilitative, or diagnostic regimen prescribed by a practitioner of medicine or osteopathic medicine; (ii) transcription and implementation of the written or verbal orders of a practitioner of medicine or osteopathic medicine pertaining to the practice of respiratory care; (iii) observation and monitoring of signs and symptoms, general behavior, general physical response to respiratory care treatment and diagnostic testing, including determination of whether such signs, symptoms, reactions, behavior or general physical response exhibit abnormal characteristics; and (iv) implementation of respiratory care procedures, based on observed abnormalities, or appropriate reporting, referral, respiratory care protocols or changes in treatment pursuant to the written or verbal orders by a licensed practitioner of medicine or osteopathic medicine or the initiation of emergency procedures, pursuant to the Board's regulations or as otherwise authorized by law. The practice of respiratory care may be performed in any clinic, hospital, skilled nursing facility, private dwelling or other place deemed appropriate by the Board in accordance with the written or verbal order of a practitioner of medicine or osteopathic medicine, and shall be performed under qualified medical direction.

"Qualified medical direction" means, in the context of the practice of respiratory care, having readily accessible to the respiratory therapist a licensed practitioner of medicine or osteopathic medicine who has specialty training or experience in the management of acute and chronic respiratory disorders and who is responsible for the quality, safety, and appropriateness of the respiratory services provided by the respiratory therapist.

"Radiologic technologist" means an individual, other than a licensed doctor of medicine, osteopathy, podiatry, or chiropractic or a dentist licensed pursuant to Chapter 27 (§ 54.1-2700 et seq.), who (i) performs, may be called upon to perform, or is licensed to perform a comprehensive scope of diagnostic or therapeutic radiologic procedures employing ionizing radiation and (ii) is delegated or exercises responsibility for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, the administration of radioactive chemical compounds under the direction of an authorized user as specified by regulations of the Department of Health, or other procedures that contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is exposed.

"Radiologic technologist, limited" means an individual, other than a licensed radiologic technologist, dental hygienist, or person who is otherwise authorized by the Board of Dentistry under Chapter 27 (§ 54.1-2700 et seq.) and the regulations pursuant thereto, who performs diagnostic radiographic procedures employing equipment that emits ionizing radiation that is limited to specific areas of the human body.

"Radiologist assistant" means an individual who has met the requirements of the Board for licensure as an advanced-level radiologic technologist and who, under the direct supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology, is authorized to (i) assess and evaluate the physiological and psychological responsiveness of patients undergoing radiologic procedures; (ii)

evaluate image quality, make initial observations, and communicate observations to the supervising radiologist; (iii) administer contrast media or other medications prescribed by the supervising radiologist; and (iv) perform, or assist the supervising radiologist to perform, any other procedure consistent with the guidelines adopted by the American College of Radiology, the American Society of Radiologic Technologists, and the American Registry of Radiologic Technologists.

"Respiratory care" means the practice of the allied health profession responsible for the direct and indirect services, including inhalation therapy and respiratory therapy, in the treatment, management, diagnostic testing, control, and care of patients with deficiencies and abnormalities associated with the cardiopulmonary system under qualified medical direction.

§ 54.1-2901. Exceptions and exemptions generally.

A. The provisions of this chapter shall not prevent or prohibit:

1. Any person entitled to practice his profession under any prior law on June 24, 1944, from continuing such practice within the scope of the definition of his particular school of practice;

2. ~~Any person licensed to practice naturopathy prior to June 30, 1980, from continuing such practice in accordance with regulations promulgated by the Board;~~

~~3.~~ Any licensed nurse practitioner from rendering care in accordance with the provisions of §§ 54.1-2957 and 54.1-2957.01 or any nurse practitioner licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife practicing pursuant to subsection H of § 54.1-2957 when such services are authorized by regulations promulgated jointly by the Boards of Medicine and Nursing;

~~4.~~ *3.* Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine or osteopathy, a nurse practitioner, or a physician assistant;

~~5.~~ *4.* Any dentist, pharmacist or optometrist from rendering care or services within the scope of his usual professional activities;

~~6.~~ *5.* Any practitioner licensed or certified by the Board from delegating to personnel supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by practitioners of the healing arts, if such activities or functions are authorized by and performed for such practitioners of the healing arts and responsibility for such activities or functions is assumed by such practitioners of the healing arts;

~~7.~~ *6.* The rendering of medical advice or information through telecommunications from a physician licensed to practice medicine in Virginia or an adjoining state, or from a licensed nurse practitioner, to emergency medical personnel acting in an emergency situation;

~~8.~~ *7.* The domestic administration of family remedies;

8. Any person who sells vitamins and herbs from providing information about such products;

9. The giving or use of massages, steam baths, dry heat rooms, infrared heat or ultraviolet lamps in public or private health clubs and spas;

10. The manufacture or sale of proprietary medicines in this Commonwealth by licensed pharmacists or druggists;

11. The advertising or sale of commercial appliances or remedies;

12. The fitting by nonitinerant persons or manufacturers of artificial eyes, limbs or other apparatus or appliances or the fitting of plaster cast counterparts of deformed portions of the body by a nonitinerant bracemaker or prosthetist for the purpose of having a three-dimensional record of the deformity, when such bracemaker or prosthetist has received a prescription from a licensed physician, licensed nurse practitioner, or licensed physician assistant directing the fitting of such casts and such activities are conducted in conformity with the laws of Virginia;

13. Any person from the rendering of first aid or medical assistance in an emergency in the absence of a person licensed to practice medicine or osteopathy under the provisions of this chapter;

14. The practice of the religious tenets of any church in the ministration to the sick and suffering by mental or spiritual means without the use of any drug or material remedy, whether gratuitously or for compensation;

15. Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;

16. Any practitioner of the healing arts licensed or certified and in good standing with the applicable regulatory agency in another state or Canada when that practitioner of the healing arts is in Virginia temporarily and such practitioner has been issued a temporary authorization by the Board from practicing medicine or the duties of the profession for which he is licensed or certified (i) in a summer camp or in conjunction with patients who are participating in recreational activities, (ii) while

participating in continuing educational programs prescribed by the Board, or (iii) by rendering at any site any health care services within the limits of his license, voluntarily and without compensation, to any patient of any clinic which is organized in whole or in part for the delivery of health care services without charge as provided in § 54.1-106;

17. The performance of the duties of any active duty health care provider in active service in the army, navy, coast guard, marine corps, air force, or public health service of the United States at any public or private health care facility while such individual is so commissioned or serving and in accordance with his official military duties;

18. Any masseur, who publicly represents himself as such, from performing services within the scope of his usual professional activities and in conformance with state law;

19. Any person from performing services in the lawful conduct of his particular profession or business under state law;

20. Any person from rendering emergency care pursuant to the provisions of § 8.01-225;

21. Qualified emergency medical services personnel, when acting within the scope of their certification, and licensed health care practitioners, when acting within their scope of practice, from following Durable Do Not Resuscitate Orders issued in accordance with § 54.1-2987.1 and Board of Health regulations, or licensed health care practitioners from following any other written order of a physician not to resuscitate a patient in the event of cardiac or respiratory arrest;

22. Any commissioned or contract medical officer of the army, navy, coast guard or air force rendering services voluntarily and without compensation while deemed to be licensed pursuant to § 54.1-106;

23. Any provider of a chemical dependency treatment program who is certified as an "acupuncture detoxification specialist" by the National Acupuncture Detoxification Association or an equivalent certifying body, from administering auricular acupuncture treatment under the appropriate supervision of a National Acupuncture Detoxification Association certified licensed physician or licensed acupuncturist;

24. Any employee of any assisted living facility who is certified in cardiopulmonary resuscitation (CPR) acting in compliance with the patient's individualized service plan and with the written order of the attending physician not to resuscitate a patient in the event of cardiac or respiratory arrest;

25. Any person working as a health assistant under the direction of a licensed medical or osteopathic doctor within the Department of Corrections, the Department of Juvenile Justice or local correctional facilities;

26. Any employee of a school board, authorized by a prescriber and trained in the administration of insulin and glucagon, when, upon the authorization of a prescriber and the written request of the parents as defined in § 22.1-1, assisting with the administration of insulin or administrating 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;

27. Any practitioner of the healing arts or other profession regulated by the Board from rendering free health care to an underserved population of Virginia who (i) does not regularly practice his profession in Virginia, (ii) holds a current valid license or certificate to practice his profession in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of the 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 certification 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 practitioner of the healing arts whose license or certificate 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 practitioner of the healing arts 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;

28. Any registered nurse, acting as an agent of the Department of Health, from obtaining specimens of sputum or other bodily fluid from persons in whom the diagnosis of active tuberculosis disease, as defined in § 32.1-49.1, is suspected and submitting orders for testing of such specimens to the Division of Consolidated Laboratories or other public health laboratories, designated by the State Health Commissioner, for the purpose of determining the presence or absence of tubercle bacilli as defined in § 32.1-49.1;

29. Any physician of medicine or osteopathy or nurse practitioner from delegating to a registered nurse under his supervision the screening and testing of children for elevated blood-lead levels when

such testing is conducted (i) in accordance with a written protocol between the physician or nurse practitioner and the registered nurse and (ii) in compliance with the Board of Health's regulations promulgated pursuant to §§ 32.1-46.1 and 32.1-46.2. Any follow-up testing or treatment shall be conducted at the direction of a physician or nurse practitioner;

30. Any practitioner of one of the professions regulated by the Board of Medicine who is in good standing with the applicable regulatory agency in another state or Canada from engaging in the practice of that profession when the practitioner is in Virginia temporarily with an out-of-state athletic team or athlete for the duration of the athletic tournament, game, or event in which the team or athlete is competing;

31. Any person from performing state or federally funded health care tasks directed by the consumer, which are typically self-performed, for an individual who lives in a private residence and who, by reason of disability, is unable to perform such tasks but who is capable of directing the appropriate performance of such tasks; or

32. Any practitioner of one of the professions regulated by the Board of Medicine who is in good standing with the applicable regulatory agency in another state from engaging in the practice of that profession in Virginia with a patient who is being transported to or from a Virginia hospital for care.

B. Notwithstanding any provision of law or regulation to the contrary, military medical personnel, as defined in § 2.2-2001.4, while participating in a program established by the Department of Veterans Services pursuant to § 2.2-2001.4, may practice under the supervision of a licensed physician or podiatrist or the chief medical officer of an organization participating in such program, or his designee who is a licensee of the Board and supervising within his scope of practice.

§ 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~~ *5* 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.

§ 54.1-2956.14. Unlawful to practice naturopathic medicine without a license; unlawful designation as naturopathic doctors; Board to regulate naturopathic medicine.

A. It shall be unlawful for a person not holding a current and valid license from the Board to practice naturopathic medicine or to claim to be a licensed naturopath, naturopathic doctor, naturopathic medical doctor, naturopathic physician, doctor of natural medicine, doctor of naturopathy, or doctor of naturopathic medicine or to assume the title naturopath, naturopathic doctor, naturopathic medical doctor, naturopathic physician, doctor of natural medicine, doctor of naturopathy, or doctor of naturopathic medicine or to use the designations "N.D.," "ND," "N.M.D.," "NMD," "D.N.M.," or "DNM" or any variation thereof.

In addition, it shall be unlawful for any person who is not licensed under this chapter, whose licensure has been suspended or revoked, or whose licensure has lapsed and has not been renewed to use in conjunction with his name the words "naturopath," "naturopathic doctor," "naturopathic medical doctor," "naturopathic physician," "doctor of natural medicine," "doctor of naturopathy," or "doctor of naturopathic medicine" or to otherwise by letters, words, representations, or insignias assert or imply that he is licensed to practice naturopathic medicine.

B. The Board shall adopt regulations governing the licensure of naturopathic doctors, upon consultation with the Advisory Board on Naturopathy. The regulations shall set forth the requirements to practice naturopathic medicine, provide for appropriate application and renewal fees, include requirements for licensure renewal and continuing education, and allow for independent practice. The regulations shall at a minimum require:

1. Graduation from (i) a naturopathic medical education program in the United States providing the degree of Doctor of Naturopathy or Doctor of Naturopathic Medicine, which shall offer graduate-level, full-time didactic and supervised clinical training and shall be accredited or have achieved candidacy status for accreditation by the Council on Naturopathic Medical Education (CNME) or an equivalent federally recognized accrediting body for naturopathic medical programs also recognized by the Board, and which shall be an institution of higher education or part of an institution of higher education that is either accredited or is a candidate for accreditation by a regional or national institutional accrediting agency recognized by the U.S. Secretary of Education; (ii) a degree-granting institution of higher education that, prior to the existence of the CNME, offered a full-time, structured curriculum in basic sciences and supervised patient care comprising a doctoral naturopathic medical education requiring not less than 132 weeks of coursework to be completed within a period of not less than 35 months, which was reputable and in good standing in the judgment of the Board and which if still in existence has current programmatic accreditation by the CNME or a federally recognized equivalent accrediting agency; (iii) a diploma-granting, degree-equivalent institution of higher education located in Canada that, prior to the existence of the CNME, had provincial approval for participation in government-funded student aid programs, offered a full-time, structured curriculum in basic sciences and supervised patient care comprising a doctoral naturopathic medical education requiring not less than 132 weeks of coursework to be completed within a period of not less than 30 months, was reputable and in good standing in the judgment of the Board, and, if still in existence, has current programmatic accreditation by the CNME or a federally recognized equivalent accrediting agency, and currently has provincial approval for participation in government-funded student aid programs; or (iv) a diploma-granting, degree-equivalent institution of higher education located in Canada that has provincial approval for participation in government-funded student aid programs, offers graduate-level, full-time didactic and supervised clinical training, and is accredited or has achieved candidacy status for accreditation by the CNME or an equivalent federally recognized accrediting body for naturopathic medical programs also recognized by the Board; and

2. Successful completion of a competency-based national naturopathic medicine licensing examination administered by the North American Board of Naturopathic Examiners, or an equivalent agency recognized by the Board, or, for graduates of approved naturopathic medical programs in the United States prior to the existence of the CNME, a competency-based state naturopathic medicine licensing examination or equivalent Canadian provincial licensing examination for the practice of naturopathic medicine approved by the Board.

§ 54.1-2956.15. Scope of practice for naturopaths; limitations.

A. A naturopathic physician may:

1. Order and perform physical and laboratory examinations, consistent with naturopathic education and training, for diagnostic purposes, including but not limited to phlebotomy, clinical laboratory tests, orificial examinations, and physiological function tests;

2. Order diagnostic imaging studies consistent with naturopathic medical education and training; studies that are not so consistent must be referred to an appropriately licensed health care professional for performance and interpretation;

3. Dispense, administer, order, and prescribe or perform (i) food and food extracts, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines and nosodes, all dietary supplements, and nonprescription drugs as defined by the Federal Food, Drug, and Cosmetic Act; (ii) prescription substances as determined by the Advisory Board on Naturopathy in conjunction with the Board; (iii) hot or cold hydrotherapy, naturopathic physical assessment and medicine, electromagnetic energy, and therapeutic exercise; (iv) devices including, but not limited to, therapeutic devices, barrier contraception, and durable medical equipment; (v) health education and health counseling; (vi) minor surgical procedures, provided the naturopathic physician participates annually in ongoing training and continuing education equivalent to that of other general practitioners within the Commonwealth; and (vii) musculoskeletal physical assessment and

treatment consistent with naturopathic education and training;

4. Utilize oral, anal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular routes of administration, consistent with the education and training of a naturopathic physician, provided that the naturopathic physician must participate in continuing education biannually to be eligible to utilize intravenous routes of administration; and

5. Perform those therapies as trained, educated, and approved by the Board.

B. A naturopathic doctor shall not:

1. Perform surgical procedures, unless such procedures are minor and the naturopathic physician maintains continuing education requirements consistent in amount and type with those of other general practitioners in the Commonwealth, as required by the Board;

2. Practice or claim to practice as a medical doctor, osteopath, dentist, podiatrist, optometrist, chiropractor, psychologist, advanced practical professional nurse, physician assistant, physical therapist, acupuncturist, or any other health care professional not authorized herein unless licensed by the Commonwealth as such;

3. Use general or spinal anesthetics;

4. Administer ionizing radioactive substances for therapeutic purposes;

5. Perform surgical procedures using a laser device;

6. Perform surgical procedures involving the eye, ear, tendons, nerves, veins, or arteries extending beyond superficial tissue;

7. Perform chiropractic adjustments or musculoskeletal manipulation;

8. Perform acupuncture, unless licensed as an acupuncturist as defined in the Code of Virginia or by standards set forth for substance abuse and addiction protocols of auricular acupuncture; or

9. Perform midwifery or birthing services for obstetric patients unless deemed a medical emergency.

C. The provisions of this section shall not prohibit:

1. The practice of naturopathic medicine by an individual employed by the United States government while the individual is engaged in the performance of duties prescribed by the laws and regulations of the United States;

2. The practice of naturopathic medicine by students enrolled in approved naturopathic medical colleges, provided services performed are pursuant to a course of instruction and under the supervision of an instructor who is a licensed naturopathic doctor or a duly licensed professional in the instructional field; or

3. The practice of naturopathy provided that the naturopathy does not include the practice of naturopathic medicine as defined in § 54.1-2900.

§ 54.1-2956.16. Advisory Board on Naturopathy established; purpose.

The Advisory Board on Naturopathy (Advisory Board) shall assist the Board in the manner set forth in this chapter. The Advisory Board shall consist of five nonlegislative citizen members appointed by the Governor for four-year terms as follows: three members who shall be, at the time of appointment, licensed naturopathic doctors; one member who shall be a physician licensed in Virginia; and one member who has received care under a licensed naturopathic doctor. Members of the Advisory Board shall be citizens of the Commonwealth. Appointments to fill vacancies, other than by expiration of a term, shall be for the unexpired terms. All members may be reappointed; however, no member shall serve more than two consecutive four-year terms. The remainder of any term to which a member is appointed to fill a vacancy shall not constitute a term in determining the member's eligibility for reappointment. Vacancies shall be filled in the same manner as the original appointments.

§ 54.1-2956.17. Advisory Board on Naturopathy; powers.

The Advisory Board on Naturopathy (Advisory Board) shall assist the Board of Medicine in formulating regulations related to the practice of naturopathic medicine. The Advisory Board shall also assist in such other matters related to the practice of naturopathic medicine as the Board may require.

§ 54.1-2973.1. Practice of laser hair removal.

The practice of laser hair removal shall be performed by a properly trained person licensed to practice medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 or by a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 who may delegate such practice in accordance with subdivision A ~~6~~ *5* of § 54.1-2901.

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

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

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

"Advertisement" means all representations disseminated in any manner or by any means, other than

by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

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

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a 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~~ *5* or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 *3* of § 54.1-2901 shall not be considered compounding.

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

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar

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

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

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

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

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

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

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

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

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include (i) 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, or (ii) a hemp product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

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

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

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

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

Board.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food

and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"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~~ *5* or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A ~~4~~ *3* of § 54.1-2901 shall not be considered compounding.

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

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

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

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

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

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

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

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

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

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids

unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include (i) 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, or (ii) a hemp product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

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

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

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

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

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

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

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

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

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

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

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

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and

dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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