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HOUSE BILL NO. 1389

Offered January 12, 2006

A BILL to amend and reenact §§ 54.1-2900, 54.1-2901, 54.1-2914, and 54.1-3401 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 54.1-2956.12 through 54.1-2956.16, relating to the practice of naturopathy; definition; requirements for licensure; advisory board established.

Patron—Phillips

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, and 54.1-3401 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding sections numbered 54.1-2956.12 through 54.1-2956.16 as follows:

§ 54.1-2900. Definitions.

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

"Acupuncturist" means individuals 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.

"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.

"Naturopath" means an individual, other than a doctor of medicine, osteopathy, chiropractic, or podiatry, who has successfully completed the requirements established for licensure by the Board to practice naturopathic medicine.

"Physician assistant" means an individual who has met the requirements of the Board for licensure and who works under the supervision of a licensed doctor of medicine, osteopathy, or podiatry.

"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 a licensed physical therapist and 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 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 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 naturopathy or 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) the support and stimulation of a patient's inherent self-healing process

through patient education and the use of natural therapies and therapeutic substances.

"Practice of occupational therapy" means the evaluation, analysis, assessment, and delivery of education and training in activities of daily living (ADL); the design, fabrication, and application of orthoses (splints); guidance in the selection and use of adaptive equipment; therapeutic activities to enhance functional performance; prevocational evaluation and training; and consultation concerning the adaptation of physical environments for individuals who have disabilities.

"Practice of podiatry" means 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 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 x-rays 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 care practitioner 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 care practitioner.

"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.) of this title, who (i) performs, may be called upon to perform, or who is licensed to perform a comprehensive scope of diagnostic radiologic procedures employing equipment which emits 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 or other procedures which 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.) of this title and the regulations pursuant thereto, who performs diagnostic radiographic procedures employing equipment which emits ionizing radiation which is limited to specific areas of the human body.

"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~~*2*. Any licensed nurse practitioner from rendering care under the supervision of a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of 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;

~~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 to emergency medical personnel acting in an emergency situation;

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

~~9~~*8*. 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~~*9*. The manufacture or sale of proprietary medicines in this Commonwealth by licensed pharmacists or druggists;

~~11~~*10*. The advertising or sale of commercial appliances or remedies;

~~12~~*11*. 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 directing the fitting of such casts and such activities are conducted in conformity with the laws of Virginia;

~~13~~*12*. 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~~*13*. 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~~*14*. Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;

~~16~~*15*. 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 license or certification 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~~*16*. The performance of the duties of any commissioned or contract medical officer, or podiatrist in active service in the army, navy, coast guard, marine corps, air force, or public health service of the United States while such individual is so commissioned or serving;

~~18~~*17*. 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~~*18*. Any person from performing services in the lawful conduct of his particular profession or business under state law;

~~20~~*19*. Any person from rendering emergency care pursuant to the provisions of § 8.01-225;

~~21~~*20*. 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~~*21*. 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~~*22*. 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~~*23*. 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~~*24*. 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~~*25*. 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~~*26*. 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 this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization with no paid employees that sponsors the provision of health care to populations of underserved people throughout the world, (iv) files a copy of the license or certification issued in such other jurisdiction with the Board, (v) notifies the Board at least 15 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;

~~28~~*27*. 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~~*28*. 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; or

~~30~~*29*. 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.

B. Notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of Nursing and Medicine in the category of certified nurse midwife may practice without the requirement for physician supervision while participating in a pilot program approved by the Board of Health pursuant to § 32.1-11.5.

§ 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.

§ 54.1-2956.12. Regulations relating to the practice of naturopathy or naturopathic medicine.

The Board shall promulgate regulations governing the practice of naturopathy or naturopathic medicine. The regulations shall include, at a minimum, standards for (i) performing and ordering physical and laboratory examinations for diagnostic purposes, consistent with naturopathic medical education and training, including, but not limited to, phlebotomy, clinical laboratory tests, orificial examinations, and physiological function tests, and diagnostic imaging studies; (ii) repair and care incidental to superficial lacerations and abrasions; (iii) removal of foreign bodies located in the superficial tissues; (iv) prescribing, dispensing, ordering, administering, or performing the following: (a) food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and nonprescription drugs as defined by the Federal Food, Drug, and Cosmetic Act; (b) hot or cold hydrotherapy; naturopathic physical medicine; electromagnetic energy; colon hydrotherapy; and therapeutic exercise; (c) devices, including, but not limited to, therapeutic devices, barrier contraception, and durable medical equipment; (v) utilization of routes of administration that include oral, nasal, auricular, oscular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular consistent with naturopathic medical education and training; and (vi) performing other therapies consistent with naturopathic medical education and training that are approved by the Board.

§ 54.1-2956.13. Unlawful to practice naturopathy or naturopathic medicine without a license; unlawful designation as naturopath; Board to regulate naturopaths; scope of practice.

A. It shall be unlawful for a person not holding a current and valid license from the Board to practice naturopathy or naturopathic medicine or to claim to be a naturopath, naturopathic doctor, naturopathic medical doctor, naturopathic physician, doctor of naturopathy or doctor of naturopathic medicine or to assume the title doctor of naturopathic medicine, naturopathic doctor, naturopathic medical doctor, naturopathic physician, or to use the designations "N.D.," "ND," "N.M.D.," or NMD 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" or "doctor of naturopathic medicine," "naturopathic doctor," "naturopathic medical doctor," "naturopathic physician," or to otherwise by letters, words, representations, or insignias assert or imply that he is licensed to practice naturopathic medicine.

B. The Board shall prescribe by regulation the qualifications governing the licensure of naturopaths. The regulations shall at a minimum require (i) graduation from a naturopathic medical education program in the United States accredited by the Council on Naturopathic Medical Education or an equivalent accrediting body for the naturopathic medical profession recognized by the United States Secretary of Education and the Board, that offers graduate-level, full-time didactic and supervised clinical training leading to the degree of Doctor of Naturopathy or Doctor of Naturopathic Medicine; and (ii) 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. In lieu of graduation from an accredited naturopathic medical education program and the national naturopathic medicine licensing examination, the Board may require graduation from (i) an accredited institution of higher education or one that has received provisional accreditation from a regional accrediting body recognized by the United States Secretary of

Education; or (ii) an accredited degree-granting institution of higher education that offers a full-time structured curriculum in basic sciences and supervised patient care consisting of a program of doctoral naturopathic medical education approved by the Board that requires the completion of 132 weeks or more of instruction within a period of not less than three years, as a condition for graduation. The Board may license graduates of approved alternative naturopathic medical education programs upon evidence of successful completion of a Board-approved, competency-based state naturopathic medicine licensing examination or an equivalent Canadian provincial licensing examination for the practice of naturopathic medicine.

§ 54.1-2956.14. Advisory Board of Naturopathy established; purpose.

The Advisory Board on Naturopathy, referred to hereinafter as "Advisory Board," shall assist the Board in the manner set forth in this chapter.

§ 54.1-2956.15. Advisory Board of Naturopathy; composition; appointments.

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, naturopaths licensed in the Commonwealth of Virginia by the Board for not less than three years; one member who shall be licensed by the Board to practice either medicine, osteopathy, chiropractic, or podiatry; and one member who shall be a citizen of the Commonwealth at large. 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.

§ 54.1-2956.16. Advisory Board of Naturopathy; powers.

A. The Advisory Board shall, under the authority of the Board:

1. Recommend to the Board, for its promulgation into regulation, the criteria for licensure as a naturopath and the standards of professional conduct for holders of licenses.

2. Assess the qualifications of applicants for licensure and recommend licensure when applicants meet the required criteria. The recommendations of the Advisory Board relating to the licensure of applicants shall be presented to the Board, which shall then issue or deny licenses. Any applicant who is aggrieved by a denial of recommendation on licensure of the Advisory Board may appeal to the Board.

3. Recommend to the Board, for its promulgation into regulation, accrediting agencies, institutions of higher education, and competency-based examinations to be approved for naturopathic medical education and licensure.

4. Receive investigative reports of professional misconduct and unlawful acts and recommend sanctions when appropriate. Any recommendation of sanctions shall be presented to the Board, which may then impose sanctions or take such other action as may be warranted by law.

5. Assist in such other matters dealing with naturopathic medicine as the Board may in its discretion direct.

B. Nothing in this chapter shall be construed to authorize the Advisory Board to advise the Board in matters pertaining to regulations governing the practice of medicine, osteopathy, chiropractic, or podiatry, or matters pertaining to doctors of medicine, osteopathy, chiropractic, or podiatry who are also licensed by the Board to practice naturopathy or naturopathic medicine.

§ 54.1-3401. Definitions.

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

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

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

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

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

"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.

"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.

"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 prescribing patterns; (ii) by or for 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.) or a person supervised by such practitioner pursuant to subdivisions 4*3*, ~~6~~*5*, or ~~19~~*18* 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 3.1 or Title 4.1.

"DEA" means the Drug Enforcement Administration, United States 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.

"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; or (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii) or (iii). "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, which 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 United States 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.

"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.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, 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, 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.

(Effective until October 1, 2005) "Medical equipment supplier" means any person, as defined in § 1-13.19, 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 which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

(Effective October 1, 2005) "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 which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

"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 United States 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.) of this chapter, 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.

"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 which is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug which 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.

"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 United States 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."

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

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

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 unless the context requires a different meaning.