

098156588

HOUSE BILL NO. 1820

Offered January 14, 2009

Prefiled January 12, 2009

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 licensure of naturopathic doctors.

Patron—Kilgore

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.

"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.

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

"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.

"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,

INTRODUCED

HB1820

59 osteopathy, chiropractic, podiatry, or dentistry, while using heat, light, sound, cold, electricity, exercise
60 or mechanical or other devices.

61 "Practice of chiropractic" means the adjustment of the 24 movable vertebrae of the spinal column,
62 and assisting nature for the purpose of normalizing the transmission of nerve energy, but does not
63 include the use of surgery, obstetrics, osteopathy or the administration or prescribing of any drugs,
64 medicines, serums or vaccines.

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

67 "*Practice of naturopathy or naturopathic medicine*" means a system of primary health care for the (i)
68 prevention, diagnosis, and treatment of human health conditions, injury, and disease; (ii) promotion or
69 restoration of health; and (iii) the support and stimulation of a patient's inherent self-healing process
70 through patient education and the use of natural therapies and therapeutic substances.

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

76 "Practice of podiatry" means the medical, mechanical and surgical treatment of the ailments of the
77 human foot and ankle, but does not include amputation of the foot proximal to the transmetatarsal level
78 through the metatarsal shafts. Amputations proximal to the metatarsal-phalangeal joints may only be
79 performed in a hospital or ambulatory surgery facility accredited by an organization listed in
80 § 54.1-2939. The Board of Medicine shall determine whether a specific type of treatment of the foot and
81 ankle is within the scope of practice of podiatry.

82 "Practice of radiologic technology" means the application of x-rays to human beings for diagnostic or
83 therapeutic purposes.

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

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

104 "Radiologic technologist" means an individual, other than a licensed doctor of medicine, osteopathy,
105 podiatry, or chiropractic, or a dentist licensed pursuant to Chapter 27 (§ 54.1-2700 et seq.) of this title,
106 who (i) performs, may be called upon to perform, or who is licensed to perform a comprehensive scope
107 of diagnostic radiologic procedures employing equipment which emits ionizing radiation and (ii) is
108 delegated or exercises responsibility for the operation of radiation-generating equipment, the shielding of
109 patient and staff from unnecessary radiation, the appropriate exposure of radiographs or other procedures
110 which contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is
111 exposed.

112 "Radiologic technologist, limited" means an individual, other than a licensed radiologic technologist,
113 dental hygienist or person who is otherwise authorized by the Board of Dentistry under Chapter 27
114 (§ 54.1-2700 et seq.) of this title and the regulations pursuant thereto, who performs diagnostic
115 radiographic procedures employing equipment which emits ionizing radiation which is limited to specific
116 areas of the human body.

117 "Respiratory care" means the practice of the allied health profession responsible for the direct and
118 indirect services, including inhalation therapy and respiratory therapy, in the treatment, management,
119 diagnostic testing, control and care of patients with deficiencies and abnormalities associated with the
120 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;~~

32. 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;

43. 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;

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

65. 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;

76. 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;

87. The domestic administration of family remedies;

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

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

~~110.~~ The advertising or sale of commercial appliances or remedies;

~~111.~~ 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;

~~112.~~ 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;

~~113.~~ The practice of the religious tenets of any church in the ministrations to the sick and suffering by mental or spiritual means without the use of any drug or material remedy, whether gratuitously or for compensation;

~~114.~~ Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;

~~115.~~ 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;

~~116.~~ 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;

~~117.~~ 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;

~~118.~~ Any person from performing services in the lawful conduct of his particular profession or business under state law;

2019. Any person from rendering emergency care pursuant to the provisions of § 8.01-225;

2420. 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;

2221. 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;

2322. 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;

2423. 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;

2524. 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;

2625. 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 administering 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;

2726. 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 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;

2827. 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;

2928. 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;

3029. 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; or

3130. Any licensed nurse practitioner in the category of certified nurse midwife from rendering care in collaboration and consultation with a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing.

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 65 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, 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; (vi) naturopathic childbirth attendance; and (vii) 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

305 use in conjunction with his name the words "naturopath" or "doctor of naturopathic medicine,"
306 "naturopathic doctor," "naturopathic medical doctor," "naturopathic physician," or to otherwise by
307 letters, words, representations, or insignias assert or imply that he is licensed to practice naturopathic
308 medicine.

309 B. The Board shall prescribe by regulation the qualifications governing the licensure of naturopaths.
310 The regulations shall at a minimum require (i) graduation from a naturopathic medical education
311 program in the United States accredited by the Council on Naturopathic Medical Education or an
312 equivalent accrediting body for the naturopathic medical profession recognized by the United States
313 Secretary of Education and the Board, that offers graduate-level, full-time didactic and supervised
314 clinical training leading to the degree of Doctor of Naturopathy or Doctor of Naturopathic Medicine;
315 and (ii) successful completion of a competency-based national naturopathic medicine licensing
316 examination administered by the North American Board of Naturopathic Examiners, or an equivalent
317 agency recognized by the Board. In lieu of graduation from an accredited naturopathic medical
318 education program and the national naturopathic medicine licensing examination, the Board may
319 require graduation from (a) an accredited institution of higher education or one that has received
320 provisional accreditation from a regional accrediting body recognized by the United States Secretary of
321 Education; or (b) an accredited degree-granting institution of higher education that offers a full-time
322 structured curriculum in basic sciences and supervised patient care consisting of a program of doctoral
323 naturopathic medical education approved by the Board that requires the completion of 132 weeks or
324 more of instruction within a period of not less than three years, as a condition for graduation. The
325 Board may license graduates of approved alternative naturopathic medical education programs upon
326 evidence of successful completion of a Board-approved, competency-based state naturopathic medicine
327 licensing examination or an equivalent Canadian provincial licensing examination for the practice of
328 naturopathic medicine.

329 § 54.1-2956.14. Advisory Board of Naturopathy established; purpose.

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

332 § 54.1-2956.15. Advisory Board of Naturopathy; composition; appointments.

333 The Advisory Board shall consist of five nonlegislative citizen members appointed by the Governor
334 for four-year terms as follows: three members who shall be, at the time of appointment, naturopaths
335 licensed in the Commonwealth of Virginia by the Board for not less than three years; one member who
336 shall be licensed by the Board to practice either medicine, osteopathy, chiropractic, or podiatry; and
337 one member who shall be a citizen of the Commonwealth at large. Appointments to fill vacancies, other
338 than by expiration of a term, shall be for the unexpired terms. All members may be reappointed;
339 however, no member shall serve more than two consecutive four-year terms. The remainder of any term
340 to which a member is appointed to fill a vacancy shall not constitute a term in determining the
341 member's eligibility for reappointment.

342 § 54.1-2956.16. Advisory Board of Naturopathy; powers.

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

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

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

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

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

357 5. Recommend to the Board, for its promulgation into regulation, a formulary for use by
358 naturopathic physicians.

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

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

365 § 54.1-3401. Definitions.

366 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.

"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 43, 65, or 4918 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

428 purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal
429 dialysis, or commercially available solutions whose purpose is to be used in the performance of
430 hemodialysis not to include any solutions administered to the patient intravenously.

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

439 "Dispenser" means a practitioner who dispenses.

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

441 "Distributor" means a person who distributes.

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

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

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

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

458 "FDA" means the United States Food and Drug Administration.

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

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

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

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

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

477 "Manufacturer" means every person who manufactures.

478 "Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or
479 resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds,
480 or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless
481 such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include
482 the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such
483 plant, unless such stalks, fiber, oil or cake is combined with other parts of plants of the genus Cannabis.

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

489 "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, 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

551 pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of
552 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353 (b)).

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

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

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

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

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

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

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

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

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

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

593 The terms "pharmacist," "pharmacy" and "practice of pharmacy" as used in this chapter shall be
594 defined as provided in Chapter 33 unless the context requires a different meaning.