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SENATE BILL NO. 620

Offered January 15, 2016

A BILL to amend and reenact §§ 32.1-263, 32.1-282, 54.1-2900, 54.1-2901, 54.1-2914, 54.1-2957, 54.1-2957.01, 54.1-2957.03, 54.1-2957.9, 54.1-3300, 54.1-3300.1, 54.1-3301, 54.1-3401, 54.1-3482, and 54.1-3482.1 of the Code of Virginia and to repeal § 32.1-11.5 of the Code of Virginia, relating to nurse practitioners; eliminating requirement to practice as part of a patient care team.

Patron—Stanley

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-263, 32.1-282, 54.1-2900, 54.1-2901, 54.1-2914, 54.1-2957, 54.1-2957.01, 54.1-2957.03, 54.1-2957.9, 54.1-3300, 54.1-3300.1, 54.1-3301, 54.1-3401, 54.1-3482, and 54.1-3482.1 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-263. Filing death certificates; medical certification; investigation by Office of the Chief Medical Examiner.

A. A death certificate, including, if known, the social security number or control number issued by the Department of Motor Vehicles pursuant to § 46.2-342 of the deceased, shall be filed for each death which occurs in this Commonwealth with the registrar of the district in which the death occurred within three days after such death and prior to final disposition or removal of the body from the Commonwealth, and shall be registered by such registrar if it has been completed and filed in accordance with the following requirements:

1. If the place of death is unknown, but the dead body is found in this Commonwealth, a death certificate shall be filed in the registration district in which the dead body is found in accordance with this section. The place where the dead body is found shall be shown as the place of death. If the date of death is unknown, it shall be determined by approximation, taking into consideration all relevant information, including but not limited to, information provided by the immediate family regarding the date and time that the deceased was last seen alive, if the individual died in his home; and

2. When death occurs in a moving conveyance, in the United States of America and the body is first removed from the conveyance in this Commonwealth, the death shall be registered in this Commonwealth and the place where it is first removed shall be considered the place of death. When a death occurs on a moving conveyance while in international waters or air space or in a foreign country or its air space and the body is first removed from the conveyance in this Commonwealth, the death shall be registered in this Commonwealth but the certificate shall show the actual place of death insofar as can be determined.

B. The licensed funeral director, funeral service licensee, office of the state anatomical program, or next of kin as defined in § 54.1-2800 who first assumes custody of a dead body shall file the certificate of death with the registrar. He shall obtain the personal data, including the social security number of the deceased or control number issued to the deceased by the Department of Motor Vehicles pursuant to § 46.2-342, from the next of kin or the best qualified person or source available and obtain the medical certification from the person responsible therefor.

C. The medical certification shall be completed, signed in black or dark blue ink, and returned to the funeral director within 24 hours after death by the physician in charge of the patient's care for the illness or condition which resulted in death except when inquiry or investigation by the Office of the Chief Medical Examiner is required by § 32.1-283 or 32.1-285.1, or by the physician that pronounces death pursuant to § 54.1-2972.

In the absence of such physician or with his approval, the certificate may be completed and signed by the following: (i) another physician employed or engaged by the same professional practice; (ii) a physician assistant supervised by such physician; (iii) a nurse practitioner ~~practicing as part of a patient care team as defined in § 54.1-2900~~; (iv) the chief medical officer or medical director, or his designee, of the institution, hospice, or nursing home in which death occurred; (v) a physician specializing in the delivery of health care to hospitalized or emergency department patients who is employed by or engaged by the facility where the death occurred; (vi) the physician who performed an autopsy upon the decedent; or (vii) an individual to whom the physician has delegated authority to complete and sign the certificate, if such individual has access to the medical history of the case and death is due to natural causes.

D. When inquiry or investigation by the Office of the Chief Medical Examiner is required by § 32.1-283 or 32.1-285.1, the Chief Medical Examiner shall cause an investigation of the cause of death

to be made and the medical certification portion of the death certificate to be completed and signed within 24 hours after being notified of the death. If the Office of the Chief Medical Examiner refuses jurisdiction, the physician last furnishing medical care to the deceased shall prepare and sign the medical certification portion of the death certificate.

E. If the death is a natural death and a death certificate is being prepared pursuant to § 54.1-2972 and the physician, nurse practitioner, or physician assistant is uncertain about the cause of death, he shall use his best medical judgment to certify a reasonable cause of death or contact the health district physician director in the district where the death occurred to obtain guidance in reaching a determination as to a cause of death and document the same.

If the cause of death cannot be determined within 24 hours after death, the medical certification shall be completed as provided by regulations of the Board. The attending physician or the Chief Medical Examiner, an Assistant Chief Medical Examiner, or a medical examiner appointed pursuant to § 32.1-282 shall give the funeral director or person acting as such notice of the reason for the delay, and final disposition of the body shall not be made until authorized by the attending physician, the Chief Medical Examiner, an Assistant Chief Medical Examiner, or a medical examiner appointed pursuant to § 32.1-282.

F. A physician, nurse practitioner, or physician assistant who, in good faith, signs a certificate of death or determines the cause of death shall be immune from civil liability, only for such signature and determination of causes of death on such certificate, absent gross negligence or willful misconduct.

§ 32.1-282. Medical examiners.

A. The Chief Medical Examiner shall appoint for each county and city one or more medical examiners, who shall be licensed as a doctor of medicine or osteopathic medicine, a physician assistant, or a nurse practitioner in the Commonwealth and appointed as agents of the Commonwealth, to assist the Office of the Chief Medical Examiner with medicolegal death investigations. A physician assistant appointed as a medical examiner shall have a practice agreement with and be under the continuous supervision of a physician medical examiner in accordance with § 54.1-2952. ~~A nurse practitioner appointed as a medical examiner shall have a practice agreement with and practice in collaboration with a physician medical examiner in accordance with § 54.1-2957.~~

B. Each medical examiner appointed pursuant to subsection A shall take office on the first day of October of the year of appointment. The term of each medical examiner so appointed shall be three years.

C. The Chief Medical Examiner shall fill any medical examiner vacancy for the unexpired term and shall make any necessary temporary appointments.

§ 54.1-2900. Definitions.

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

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

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

"Board" means the Board of Medicine.

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

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

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

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

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

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

~~"Patient care team" means a multidisciplinary team of health care providers actively functioning as a unit with the management and leadership of one or more patient care team physicians for the purpose of~~

providing and delivering health care to a patient or group of patients.

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

"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 the patient's physician or under the direction of any doctor of medicine, osteopathy, chiropractic, podiatry, or dentistry, while using heat, light, sound, cold, electricity, exercise or mechanical or other devices.

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

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

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

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

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

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

the scope of practice of podiatry.

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

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

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

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

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

"Radiologist assistant" means an individual who has met the requirements of the Board for licensure as an advanced-level radiologic technologist and who, under the direct supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology, is authorized to (i) assess and evaluate the physiological and psychological responsiveness of patients undergoing radiologic procedures; (ii) evaluate image quality, make initial observations, and communicate observations to the supervising radiologist; (iii) administer contrast media or other medications prescribed by the supervising radiologist; and (iv) perform, or assist the supervising radiologist to perform, any other procedure consistent with the guidelines adopted by the American College of Radiology, the American Society of Radiologic Technologists, and the American Registry of Radiologic Technologists.

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

§ 54.1-2901. Exceptions and exemptions generally.

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

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

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

3. Any licensed nurse practitioner from rendering care ~~in collaboration and consultation with a patient care team physician as part of a patient care team pursuant to § 54.1-2957~~ when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing;

4. Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of

intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine or osteopathy, a nurse practitioner, or a physician assistant;

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

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

8. The domestic administration of family remedies;

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

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

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

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

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

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

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

16. Any practitioner of the healing arts licensed or certified and in good standing with the applicable regulatory agency in another state or Canada when that practitioner of the healing arts is in Virginia temporarily and such practitioner has been issued a temporary 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. The performance of the duties of any active duty health care provider in active service in the army, navy, coast guard, marine corps, air force, or public health service of the United States at any public or private health care facility while such individual is so commissioned or serving and in accordance with his official military orders;

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

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

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

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

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

23. Any provider of a chemical dependency treatment program who is certified as an "acupuncture detoxification specialist" by the National Acupuncture Detoxification Association or an equivalent

certifying body, from administering auricular acupuncture treatment under the appropriate supervision of a National Acupuncture Detoxification Association certified licensed physician or licensed acupuncturist;

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

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

26. Any employee of a school board, authorized by a prescriber and trained in the administration of insulin and glucagon, when, upon the authorization of a prescriber and the written request of the parents as defined in § 22.1-1, assisting with the administration of insulin or administrating glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia;

27. Any practitioner of the healing arts or other profession regulated by the Board from rendering free health care to an underserved population of Virginia who (i) does not regularly practice his profession in Virginia, (ii) holds a current valid license or certificate to practice his profession in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of the Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certification issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any practitioner of the healing arts whose license or certificate has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a practitioner of the healing arts who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state;

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

29. Any physician of medicine or osteopathy or nurse practitioner from delegating to a registered nurse under his supervision the screening and testing of children for elevated blood-lead levels when such testing is conducted (i) in accordance with a written protocol between the physician or nurse practitioner and the registered nurse and (ii) in compliance with the Board of Health's regulations promulgated pursuant to §§ 32.1-46.1 and 32.1-46.2. Any follow-up testing or treatment shall be conducted at the direction of a physician or nurse practitioner;

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

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

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

~~B. Notwithstanding any provision of law or regulation to the contrary, 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 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.

§ 54.1-2957. Licensure and practice of nurse practitioners.

A. The Board of Medicine and the Board of Nursing shall jointly prescribe the regulations governing the licensure of nurse practitioners. It shall be unlawful for a person to practice as a nurse practitioner in the Commonwealth unless he holds such a joint license.

B. ~~A nurse practitioner shall only practice as part of a patient care team. Each member of a patient care team shall have specific responsibilities related to the care of the patient or patients and shall provide health care services within the scope of his usual professional activities. Nurse practitioners practicing as part of a patient care team shall maintain appropriate collaboration and consultation, as evidenced in a written or electronic practice agreement, with at least one patient care team physician. Nurse practitioners who are certified registered nurse anesthetists shall practice under the supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry. Nurse practitioners appointed as medical examiners pursuant to § 32.1-282 shall practice in collaboration with a licensed doctor of medicine or osteopathic medicine who has been appointed to serve as a medical examiner pursuant to § 32.1-282. Collaboration and consultation among nurse practitioners and patient care team physicians may be provided through telemedicine as described in § 38.2-3418.16. Practice of patient care teams in all settings shall include the periodic review of patient charts or electronic health records and may include visits to the site where health care is delivered in the manner and at the frequency determined by the patient care team.Physicians on patient care teams may require that a nurse practitioner be covered by a professional liability insurance policy with limits equal to the current limitation on damages set forth in § 8.01-581.15.Service on a patient care team by a patient care team member shall not, by the existence of such service alone, establish or create liability for the actions or inactions of other team members.~~ *In promulgating regulations pursuant to subsection A, the Board of Medicine and the Board of Nursing shall (i) include necessary requirements to ensure continued practitioner competence, which may include continuing education, testing, or any other requirement, and (ii) consider (a) the need to promote ethical practice, (b) an appropriate standard of care, (c) patient safety, (d) the use of new pharmaceuticals, and (d) appropriate communication with patients. Nurse practitioners who are certified registered nurse anesthetists shall practice under the supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry.*

C. ~~The Board of Medicine and the Board of Nursing shall jointly promulgate regulations specifying collaboration and consultation among physicians and nurse practitioners working as part of patient care teams that shall include the development of, and periodic review and revision of, a written or electronic practice agreement; guidelines for availability and ongoing communications that define consultation among the collaborating parties and the patient; and periodic joint evaluation of the services delivered.~~

Practice agreements shall include a provision for appropriate physician input in complex clinical cases and patient emergencies and for referrals. Evidence of a practice agreement shall be maintained by a nurse practitioner and provided to the Boards upon request. For nurse practitioners providing care to patients within a hospital or health care system, the practice agreement may be included as part of documents delineating the nurse practitioner's clinical privileges or the electronic or written delineation of duties and responsibilities in collaboration and consultation with a patient care team physician. *The Committee of the Joint Boards of Nursing and Medicine shall administer regulations governing the licensure of nurse practitioners. The Committee shall consist of five members. Two members shall be appointed by the president of the Board of Medicine from its membership, and three members shall be appointed by the president of the Board of Nursing from its membership, at least one of whom shall be a licensed nurse practitioner.*

D. The Boards may issue a license by endorsement to an applicant to practice as a nurse practitioner if the applicant has been licensed as a nurse practitioner under the laws of another state and, in the opinion of the Boards, the applicant meets the qualifications for licensure required of nurse practitioners in the Commonwealth.

E. Pending the outcome of the next National Specialty Examination, the Boards may jointly grant temporary licensure to nurse practitioners.

F. As used in this section:

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

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

§ 54.1-2957.01. Prescription of certain controlled substances and devices by licensed nurse practitioners.

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.), a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe Schedule II through Schedule VI controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.). Nurse practitioners shall have such prescriptive authority upon the provision to the Board of Medicine and the Board of Nursing of such evidence as they may jointly require that the nurse practitioner has entered into and is, at the time of writing a prescription, a party to a written or electronic practice agreement with a patient care team physician that clearly states the prescriptive practices of the nurse practitioner. Such written or electronic practice agreements shall include the controlled substances the nurse practitioner is or is not authorized to prescribe and may restrict such prescriptive authority as described in the practice agreement. Evidence of a practice agreement shall be maintained by a nurse practitioner pursuant to § 54.1-2957. Practice agreements authorizing a nurse practitioner to prescribe controlled substances or devices pursuant to this section shall either be signed by the patient care team physician who is practicing as part of a patient care team with the nurse practitioner or shall clearly state the name of the patient care team physician who has entered into the practice agreement with the nurse practitioner.

B. It shall be unlawful for a nurse practitioner to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written or electronic practice agreement.

C. The Board of Nursing and the Board of Medicine shall promulgate such regulations governing the prescriptive authority of nurse practitioners as are deemed reasonable and necessary to ensure an appropriate standard of care for patients.

Regulations promulgated pursuant to this section shall include, at a minimum, such requirements as may be necessary to ensure continued nurse practitioner competency, which may include continuing education, testing, or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients.

D. *C.* This section shall not limit the functions and procedures of certified registered nurse anesthetists or of any nurse practitioners which are otherwise authorized by law or regulation.

E. The following restrictions shall apply to any nurse practitioner authorized to prescribe drugs and devices pursuant to this section:

1. The *D. A* nurse practitioner shall disclose to the patient at the initial encounter that he is a licensed nurse practitioner. Any member of a patient care team shall disclose, upon request of a patient or his legal representative, the name of the patient care team physician and information regarding how to contact the patient care team physician.

~~2. Physicians shall not serve as a patient care team physician on a patient care team at any one time to more than six nurse practitioners.~~

~~F.~~ *E.* This section shall not prohibit a licensed nurse practitioner from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

~~G. 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 and holding a license for prescriptive authority may prescribe Schedules II through VI controlled substances without the requirement for collaboration and consultation with a patient care team physician as part of a patient care team pursuant to § 54.1-2957 or a written or electronic practice agreement between the licensed nurse practitioner and a licensed physician while participating in a pilot program approved by the Board of Health pursuant to § 32.1-11.5.~~

§ 54.1-2957.03. Certified nurse midwives; required disclosures; liability.

A. *As used in this section, "birthing center" means a facility outside a hospital that provides maternity services.*

B. A certified nurse midwife who provides health care services to a patient outside of a hospital or birthing center~~, as defined in subsection E of § 32.1-11.5,~~ shall disclose to that patient, when appropriate, information on health risks associated with births outside of a hospital or birthing center, including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation.

~~B.~~ *C.* The certified nurse midwife who provided health care to a patient shall be liable for the midwife's negligent, grossly negligent, or willful and wanton acts or omissions. Except as otherwise provided by law, any (i) doctor of medicine or osteopathy who did not collaborate or consult with the midwife regarding the patient and who has not previously treated the patient for this pregnancy, (ii) nurse, (iii) prehospital emergency medical personnel, or (iv) hospital as defined in § 32.1-123 or agents thereof, who provides screening and stabilization health care services to a patient as a result of a certified nurse midwife's negligent, grossly negligent, or willful and wanton acts or omissions, shall be immune from liability for acts or omissions constituting ordinary negligence.

§ 54.1-2957.9. Regulation of the practice of midwifery.

The Board shall adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall (i) address the requirements for licensure to practice midwifery, including the establishment of standards of care, (ii) be consistent with the North American Registry of Midwives' current job description for the profession and the National Association of Certified Professional Midwives' standards of practice, except that prescriptive authority and the possession and administration of controlled substances shall be prohibited, (iii) ensure independent practice, (iv) require midwives to disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center, as defined in ~~subsection E of~~ § ~~32.1-11.5~~ *54.1-2957.03,* including ~~but not limited to~~ risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation, (v) provide for an appropriate license fee, and (vi) include requirements for licensure renewal and continuing education. Such regulations shall not (a) require any agreement, written or otherwise, with another health care professional or (b) require the assessment of a woman who is seeking midwifery services by another health care professional.

License renewal shall be contingent upon maintaining a Certified Professional Midwife certification.

§ 54.1-3300. Definitions.

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

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner ~~working as part of a patient care team as defined in § 54.1-2900, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners~~. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or

limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

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

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

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

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

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

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

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

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

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner ~~working as part of a patient care team as defined in § 54.1-2900, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes~~. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

No patient shall be required to participate in a collaborative procedure without such patient's consent. A patient who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically

accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

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

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;

2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;

3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;

4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;

5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;

6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;

7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;

8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;

9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe ~~according to his practice setting and a written or electronic agreement with a physician~~ *in accordance with his scope of practice*;

10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor

the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

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

§ 54.1-3401. Definitions.

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

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

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

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

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

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

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

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

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

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

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

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word

of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

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

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

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

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

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

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

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

"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 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3482. Practice of physical therapy; certain experience and referrals required; physical therapist assistants.

A. It shall be unlawful for a person to engage in the practice of physical therapy except as a licensed physical therapist, upon the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician, except as provided in this section.

B. A physical therapist who has completed a doctor of physical therapy program approved by the Commission on Accreditation of Physical Therapy Education or who has obtained a certificate of authorization pursuant to § 54.1-3482.1 may evaluate and treat a patient for no more than 30

consecutive days after an initial evaluation without a referral under the following conditions: (i) the patient is not receiving care from any licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician for the symptoms giving rise to the presentation at the time of the presentation to the physical therapist for physical therapy services or (ii) the patient is receiving care from a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician at the time of his presentation to the physical therapist for the symptoms giving rise to the presentation for physical therapy services and (a) the patient identifies a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician from whom he is currently receiving care; (b) the patient gives written consent for the physical therapist to release all personal health information and treatment records to the identified practitioner; and (c) the physical therapist notifies the practitioner identified by the patient no later than 14 days after treatment commences and provides the practitioner with a copy of the initial evaluation along with a copy of the patient history obtained by the physical therapist. Treatment for more than 30 consecutive days after evaluation of such patient shall only be upon the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician. A physical therapist may contact the practitioner identified by the patient at the end of the 30-day period to determine if the practitioner will authorize additional physical therapy services until such time as the patient can be seen by the practitioner. A physical therapist shall not perform an initial evaluation of a patient under this subsection if the physical therapist has performed an initial evaluation of the patient under this subsection for the same condition within the immediately preceding 60 days.

C. A physical therapist who has not completed a doctor of physical therapy program approved by the Commission on Accreditation of Physical Therapy Education or who has not obtained a certificate of authorization pursuant to § 54.1-3482.1 may conduct a one-time evaluation that does not include treatment of a patient without the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician; if appropriate, the physical therapist shall immediately refer such patient to the appropriate practitioner.

D. Invasive procedures within the scope of practice of physical therapy shall at all times be performed only under the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician.

E. It shall be unlawful for any licensed physical therapist to fail to immediately refer any patient to a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, or a licensed nurse practitioner ~~practicing in accordance with his practice agreement~~ when such patient's medical condition is determined, at the time of evaluation or treatment, to be beyond the physical therapist's scope of practice. Upon determining that the patient's medical condition is beyond the scope of practice of a physical therapist, a physical therapist shall immediately refer such patient to an appropriate practitioner.

F. Any person licensed as a physical therapist assistant shall perform his duties only under the direction and control of a licensed physical therapist.

G. However, a licensed physical therapist may provide, without referral or supervision, physical therapy services to (i) a student athlete participating in a school-sponsored athletic activity while such student is at such activity in a public, private, or religious elementary, middle or high school, or public or private institution of higher education when such services are rendered by a licensed physical therapist who is certified as an athletic trainer by the National Athletic Trainers' Association Board of Certification or as a sports certified specialist by the American Board of Physical Therapy Specialties; (ii) employees solely for the purpose of evaluation and consultation related to workplace ergonomics; (iii) special education students who, by virtue of their individualized education plans (IEPs), need physical therapy services to fulfill the provisions of their IEPs; (iv) the public for the purpose of wellness, fitness, and health screenings; (v) the public for the purpose of health promotion and education; and (vi) the public for the purpose of prevention of impairments, functional limitations, and disabilities.

§ 54.1-3482.1. Certain certification required.

A. The Board shall promulgate regulations establishing criteria for certification of physical therapists to provide certain physical therapy services pursuant to subsection B of § 54.1-3482 without referral from a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse

practitioner ~~practicing~~ ~~in~~ ~~accordance~~ ~~with~~ ~~his~~ ~~practice~~ ~~agreement~~, or a licensed physician assistant acting under the supervision of a licensed physician. The regulations shall include but not be limited to provisions for (i) the promotion of patient safety; (ii) an application process for a one-time certification to perform such procedures; and (iii) minimum education, training, and experience requirements for certification to perform such procedures.

B. The minimum education, training, and experience requirements for certification shall include evidence that the applicant has successfully completed (i) a transitional program in physical therapy as recognized by the Board or (ii) at least three years of active practice with evidence of continuing education relating to carrying out direct access duties under § 54.1-3482.

2. That § 32.1-11.5 of the Code of Virginia is repealed.

3. That the Board of Medicine and the Board of Nursing shall jointly promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.