VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-109, 54.1-113, 54.1-2400, 54.1-2409, 54.1-2410, 54.1-2411, 54.1-2412, 54.1-2500, 54.1-2503, 54.1-2505, 54.1-2506, 54.1-2729.2, 54.1-2729.3, 54.1-2731, 54.1-3401, and 54.1-3408 of the Code of Virginia and to repeal §§ 54.1-2409.2 and 54.1-2507 through 54.1-2510 of the Code of Virginia, relating to elimination of Board of Health Professions; transfer of powers and duties.

[S 1363]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-109, 54.1-113, 54.1-2400, 54.1-2409, 54.1-2410, 54.1-2411, 54.1-2412, 54.1-2500, 54.1-2503, 54.1-2505, 54.1-2506, 54.1-2729.2, 54.1-2729.3, 54.1-2731, 54.1-3401, and 54.1-3408 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-109. Reviews and appeals.

Any person who has been aggrieved by any action of the Department of Professional and Occupational Regulation, *the* Department of Health Professions, *the* Board for Professional and Occupational Regulation, ~~Board of Health Professions,~~ any regulatory board within the Departments, or any panel of a health regulatory board convened pursuant to § 54.1-2400 shall be entitled to a review of such action. Appeals from such actions shall be in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.).

§ 54.1-113. Regulatory boards to adjust fees; certain transfer of moneys collected on behalf of health regulatory boards prohibited.

A. Following the close of any biennium, when the account for any regulatory board within the Department of Professional and Occupational Regulation maintained under § 54.1-308 shows that unspent and unencumbered revenue exceeds $100,000 or 20 percent of the total expenses allocated to the regulatory board for the past biennium, whichever is greater, the regulatory board shall (i) distribute all such excess revenue to current regulants and (ii) reduce the fees levied by it for certification, licensure, registration, or permit and renewal thereof so that the fees are sufficient but not excessive to cover expenses.

B. Following the close of any biennium, when the account for any regulatory board within the Department of Health Professions maintained under § 54.1-2505 shows expenses allocated to it for the past biennium to be more than 10 percent greater or less than moneys collected on behalf of the regulatory board, it shall revise the fees levied by it for certification, licensure, registration, or permit and renewal thereof so that the fees are sufficient but not excessive to cover expenses.

C. Nongeneral funds generated by fees collected on behalf of the health regulatory boards and accounted for and deposited into a special fund by the Director of the Department of Health Professions shall be held exclusively to cover the expenses of the health regulatory boards, the Health Practitioners' Monitoring Program, and the Department ~~and Board~~ of Health Professions and shall not be transferred to any agency other than the Department of Health Professions, except as provided in §§ 54.1-3011.1 and 54.1-3011.2.

§ 54.1-2400. General powers and duties of health regulatory boards.

The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification, licensure, permit, or the issuance of a multistate licensure privilege in accordance with the applicable law ~~which~~ *that* are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification, licensure, or registration. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license, or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, permit, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification, permitting, or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions~~, the Board of Health Professions,~~ and the health regulatory boards.

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services,

without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license, permit, or multistate licensure privilege ~~which~~ *that* such board has authority to issue for causes enumerated in applicable law and regulations.

8. To appoint designees from their membership or immediate staff to coordinate with the Director and the Health Practitioners' Monitoring Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.). Each health regulatory board shall appoint one such designee.

9. To take appropriate disciplinary action for violations of applicable law and regulations~~,~~ and to accept, in their discretion, the surrender of a license, certificate, registration, permit, or multistate licensure privilege in lieu of disciplinary action.

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than two members of the Board and one member of the relevant advisory board, or, when required for special conference committees of the Board of Nursing, not less than one member of the Board and one member of the relevant advisory board, to act in accordance with § 2.2-4019 upon receipt of information that a practitioner or permit holder of the appropriate board may be subject to disciplinary action or to consider an application for a license, certification, registration, permit, or multistate licensure privilege in nursing. The special conference committee may (i) exonerate; (ii) reinstate; (iii) place the practitioner or permit holder on probation with such terms as it may deem appropriate; (iv) reprimand; (v) modify a previous order; (vi) impose a monetary penalty pursuant to § 54.1-2401, (vii) deny or grant an application for licensure, certification, registration, permit, or multistate licensure privilege; and (viii) issue a restricted license, certification, registration, permit, or multistate licensure privilege subject to terms and conditions. The order of the special conference committee shall become final 30 days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the 30-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 2.2-4020, and the action of the committee shall be vacated. This subdivision shall not be construed to limit the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001, the authority to conduct informal fact-finding proceedings in accordance with § 2.2-4019. The recommendation of such subordinate may be considered by a panel consisting of at least five board members, or, if a quorum of the board is less than five members, consisting of a quorum of the members, convened for the purpose of issuing a case decision. Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.

11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 2.2-4020, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 2.2-4019 shall serve on a panel conducting formal proceedings pursuant to § 2.2-4020 to consider the same matter.

12. To issue inactive licenses or certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of licenses or certificates.

13. To meet by telephone conference call to consider settlement proposals in matters pending before special conference committees convened pursuant to this section, or matters referred for formal proceedings pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of previously issued board orders when such considerations have been requested by either of the parties.

14. To request and accept *a confidential consent agreement, in lieu of disciplinary action,* from a certified, registered, or licensed practitioner; a facility holding a license, certification, registration, or permit; or a person holding a multistate licensure privilege to practice nursing~~, in lieu of disciplinary action, a confidential consent agreement~~. A confidential consent agreement shall be subject to the confidentiality provisions of § 54.1-2400.2 and shall not be disclosed by a practitioner or facility. A confidential consent agreement shall include findings of fact and may include an admission or a finding of a violation. A confidential consent agreement shall not be considered either a notice or order of any health regulatory board, but it may be considered by a board in future disciplinary proceedings. A confidential consent agreement shall be entered into only in cases involving minor misconduct where there is little or no injury to a patient or the public and little likelihood of repetition by the practitioner or facility. A board shall not enter into a confidential consent agreement if there is probable cause to believe the practitioner or facility has (i) demonstrated gross negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as

to be a danger to the health and welfare of his patients or the public. A certified, registered, or licensed practitioner, a facility holding a license, certification, registration, or permit, or a person holding a multistate licensure privilege to practice nursing who has entered into two confidential consent agreements involving a standard of care violation~~,~~ within the 10-year period immediately preceding a board's receipt of the most recent report or complaint being considered~~,~~ shall receive public discipline for any subsequent violation within the 10-year period unless the board finds there are sufficient facts and circumstances to rebut the presumption that the disciplinary action be made public.

15. When a board has probable cause to believe a practitioner is unable to practice with reasonable skill and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the board, after preliminary investigation by an informal fact-finding proceeding, may direct that the practitioner submit to a mental or physical examination. Failure to submit to the examination shall constitute grounds for disciplinary action. Any practitioner affected by this subsection shall be afforded reasonable opportunity to demonstrate that he is competent to practice with reasonable skill and safety to patients. For the purposes of this subdivision, "practitioner" shall include any person holding a multistate licensure privilege to practice nursing.

§ 54.1-2409. Mandatory suspension or revocation; reinstatement; hearing for reinstatement.

A. Upon receipt of documentation by any court or government agency that a person licensed, certified, or registered by a board within the Department of Health Professions has (i) had his license, certificate, or registration to practice the same profession or occupation revoked or suspended for reasons other than nonrenewal or accepted for surrender in lieu of disciplinary action in another jurisdiction and has not had his license, certificate, or registration to so practice reinstated within that jurisdiction, unless such revocation, suspension, or surrender was based solely on the disciplinary action of a board within the Department or mandatory suspension by the Director of the Department or (ii) been convicted of a felony or has been adjudged incapacitated, the Director shall immediately suspend, without a hearing, the license, certificate, or registration of any person so disciplined, convicted, or adjudged. The Director shall notify such person or his legal guardian, conservator, trustee, committee, or other representative of the suspension in writing to his address on record with the Department. Such notice shall include a copy of the documentation from such court or agency, certified by the Director as the documentation received from such court or agency. Such person shall not have the right to practice within ~~this~~ *the* Commonwealth until his license, certificate, or registration has been reinstated by the ~~Board~~ *relevant board within the Department of Health Professions.*

B. The clerk of any court in which a conviction of a felony or an adjudication of incapacity is made, who has knowledge that a person licensed, certified, or registered by a board within the Department has been convicted or found incapacitated, shall have a duty to report these findings promptly to the Director.

C. When a conviction has not become final, the Director may decline to suspend the license, certificate, or registration until the conviction becomes final if there is a likelihood of injury or damage to the public if the person's services are not available.

D. Any person whose license, certificate, or registration has been suspended as provided in this section may apply to the board for reinstatement of his license, certificate, or registration. Such person shall be entitled to a hearing not later than the next regular meeting of the board after the expiration of 60 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify in his behalf. The ~~Board~~ *board* may consider other information concerning possible violations of Virginia law at such hearing, if reasonable notice is given to such person of the information.

The reinstatement of the applicant's license, certificate, or registration shall require the affirmative vote of three-fourths of the members of the board at the hearing. The board may order such reinstatement without further examination of the applicant, or reinstate the license, certificate, or registration upon such terms and conditions as it deems appropriate.

E. Pursuant to the authority of the Board of Nursing provided in Chapter 30 (§ 54.1-3000 et seq.) ~~of this title~~, the provisions of this section shall apply, mutatis mutandis, to persons holding a multistate licensure privilege to practice nursing.

§ 54.1-2410. Definitions.

As used in this chapter or when referring to the ~~Board~~ *Department* of Health Professions regulatory authority therefor, unless the context requires a different meaning:

~~"Board" means the Board of Health Professions.~~

"Community" means a city or a county.

"Demonstrated need" means (i) there is no facility in the community providing similar services and (ii) alternative financing is not available for the facility~~,~~ or (iii) such other conditions as may be established by ~~Board~~ *Department* regulation.

"Department" means the Department of Health Professions.

"Entity" means any person, partnership, firm, corporation, or other business, including assisted living facilities as defined in § 63.2-100, that delivers health services.

"Group practice" means two or more health care practitioners who are members of the same legally organized partnership, professional corporation, not-for-profit corporation, faculty practice or similar

association in which (i) each member provides substantially the full range of services within his licensed or certified scope of practice at the same location as the other members through the use of the organization's office space, facilities, equipment, or personnel; (ii) payments for services received from a member are treated as receipts of the organization; and (iii) the overhead expenses and income from the practice are distributed according to methods previously determined by the members.

"Health services" means any procedures or services related to prevention, diagnosis, treatment, and care rendered by a health care worker, regardless of whether the worker is regulated by the Commonwealth.

"Immediate family member" means the individual's spouse, child, child's spouse, stepchild, stepchild's spouse, grandchild, grandchild's spouse, parent, stepparent, parent-in-law, or sibling.

"Investment interest" means the ownership or holding of an equity or debt security, including, but not limited to, shares of stock in a corporation, interests or units of a partnership, bonds, debentures, notes, or other equity or debt instruments, except investment interests in a hospital licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1.

"Investor" means an individual or entity directly or indirectly possessing a legal or beneficial ownership interest, including an investment interest.

"Office practice" means the facility or facilities at which a practitioner, on an ongoing basis, provides or supervises the provision of health services to consumers.

"Practitioner" means any individual certified or licensed by any of the health regulatory boards within the Department of Health Professions, except individuals regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

"Referral" means to send or direct a patient for health services to another health care practitioner or entity outside the referring practitioner's group practice or office practice or to establish a plan of care which requires the provision of any health services outside the referring practitioner's group practice or office practice.

§ 54.1-2411. Prohibited referrals and payments; exceptions.

A. Unless the practitioner directly provides health services within the entity and will be personally involved with the provision of care to the referred patient, or has been granted an exception by the ~~Board~~ *Department* or satisfies the provisions of subsections D or E of this section or of subsections D or E of § 54.1-2413, a practitioner shall not refer a patient for health services to an entity outside the practitioner's office or group practice if the practitioner or any of the practitioner's immediate family members is an investor in such entity.

B. The ~~Board~~ *Department* may grant an exception to the prohibitions in this chapter, and may permit a practitioner to invest in and refer to an entity, regardless of whether the practitioner provides direct services within such entity, if there is a demonstrated need in the community for the entity and all of the following conditions are met:

1. Individuals other than practitioners are afforded a bona fide opportunity to invest in the entity on the same and equal terms as those offered to any referring practitioner;

2. No investor-practitioner is required or encouraged to refer patients to the entity or otherwise generate business as a condition of becoming or remaining an investor;

3. The services of the entity are marketed and furnished to practitioner-investors and other investors on the same and equal terms;

4. The entity does not issue loans or guarantee any loans for practitioners who are in a position to refer patients to such entity;

5. The income on the practitioner's investment is based on the practitioner's equity interest in the entity and is not tied to referral volumes; and

6. The investment contract between the entity and the practitioner does not include any covenant or clause limiting or preventing the practitioner's investment in other entities.

Unless the ~~Board~~ *Department*, the practitioner, or *the* entity requests a hearing, the ~~Board~~ *Department* shall determine whether to grant or deny an exception within 90 days of the receipt of a written request from the practitioner or entity, stating the facts of the particular circumstances and certifying compliance with the conditions required by this subsection. The ~~Board's~~ *Department's* decision shall be a final administrative decision and shall be subject to judicial review pursuant to the Administrative Process Act (§ 2.2-4000 et seq.).

C. When an exception is granted pursuant to subsection B:

1. The practitioner shall disclose his investment interest in the entity to the patient at the time of referral. If alternative entities are reasonably available, the practitioner shall provide the patient with a list of such alternative entities and shall inform the patient of the option to use an alternative entity. The practitioner shall also inform the patient that choosing another entity will not affect his treatment or care;

2. Information on the practitioner's investment shall be provided if requested by any third party payor;

3. The entity shall establish and utilize an internal utilization review program to ensure that practitioner-investors are engaging in appropriate and necessary utilization; and

4. In the event of a conflict of interests between the practitioner's ownership interests and the best interests

of any patient, the practitioner shall not make a referral to such entity, but shall make alternative arrangements for the referral.

D. Further, a practitioner may refer patients for health services to a publicly traded entity in which such practitioner has an investment interest~~,~~ without applying for or receiving an exception from the ~~Board,~~ *Department* if all of the following conditions are met:

1. The entity's stock is listed for trading on the New York Stock Exchange or the American Stock Exchange or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers;

2. The entity had, at the end of the corporation's most recent fiscal year, total net assets of at least ~~$50,000,000~~ *$50 million* related to the furnishing of health services;

3. The entity markets and furnishes its services to practitioner-investors and other practitioners on the same and equal terms;

4. All stock of the entity, including the stock of any predecessor privately held company, is one class without preferential treatment as to status or remuneration;

5. The entity does not issue loans or guarantee any loans for practitioners who are in a position to refer patients to such entity;

6. The income on the practitioner's investment is not tied to referral volumes and is based on the practitioner's equity interest in the entity; and

7. The practitioner's investment interest does not exceed ~~one half~~ *one-half* of one percent of the entity's total equity.

E. In addition, a practitioner may refer a patient to such practitioner's immediate family member or such immediate family member's office or group practice for health services if all of the following conditions are met:

1. The health services to be received by the patient referred by the practitioner are within the scope of practice of the practitioner's immediate family member or the treating practitioner within such immediate family member's office or group practice;

2. The practitioner's immediate family member or the treating practitioner within such immediate family member's office or group practice is qualified and duly licensed to provide the health services to be received by the patient referred to the practitioner;

3. The primary purpose of any such referral is to obtain the appropriate professional health services for the patient being referred, which are to be rendered by the referring practitioner's immediate family member or by the treating practitioner within such immediate family member's office or group practice who is qualified and licensed to provide such professional health services; and

4. The primary purpose of the referral shall not be for the provision of designated health services as defined in 42 U.S.C. § 1395nn and the regulations promulgated thereunder.

§ 54.1-2412. Department to administer; powers and duties of Department; penalties for violation.

A. In addition to its other powers and duties, the ~~Board~~ *Department* of Health Professions shall administer the provisions of this chapter.

B. The ~~Board~~ *Department* shall promulgate, pursuant to the Administrative Process Act (§ 2.2-4000 et seq.), regulations to:

1. Establish standards, procedures, and criteria which are reasonable and necessary for the effective administration of this chapter;

2. Establish standards, procedures, and criteria for determining compliance with, exceptions to, and violations of the provisions of § 54.1-2411;

3. Establish standards, procedures, and criteria for advising practitioners and entities of the applicability of this chapter to activities and investments;

4. Levy and collect fees for processing requests for exceptions from the prohibitions set forth in this chapter and for authorization to make referrals pursuant to subsection B of § 54.1-2411;

5. Establish standards, procedures, and criteria for review and referral to the appropriate health regulatory board of all reports of investigations of alleged violations of this chapter by practitioners and for investigations and determinations of violations of this chapter by entities;

6. Establish standards, procedures, and criteria for granting exceptions from the prohibitions set forth in this chapter; and

7. Establish such other regulations as may reasonably be needed to administer this chapter.

C. Upon a determination of a violation by the ~~Board~~ *Department*, pursuant to the Administrative Process Act, any entity, other than a practitioner, that presents or causes to be presented a bill or claim for services that the entity knows or has reason to know is prohibited by § 54.1-2411 shall be subject to a monetary penalty of no more than $20,000 per referral, bill, or claim. The monetary penalty may be sued for and recovered in the name of the Commonwealth. All such monetary penalties shall be deposited in the Literary Fund.

D. Any violation of this chapter by a practitioner shall constitute grounds for disciplinary action as unprofessional conduct by the appropriate health regulatory board within the Department of Health

Professions. Sanctions for violation of this chapter may include, but are not limited to, the monetary penalty authorized in § 54.1-2401.

§ 54.1-2500. Definitions.

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

~~"Board" means the Board of Health Professions.~~

"Department" means the Department of Health Professions.

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

"Health regulatory board" or "regulatory board" means any board included within the Department of Health Professions as provided in § 54.1-2503.

§ 54.1-2503. Boards within Department.

~~In addition to the Board of Health Professions, the~~ *The* following boards are included within the Department: Board of Audiology and Speech-Language Pathology, Board of Counseling, Board of Dentistry, Board of Funeral Directors and Embalmers, Board of Long-Term Care Administrators, Board of Medicine, Board of Nursing, Board of Optometry, Board of Pharmacy, Board of Physical Therapy, Board of Psychology, Board of Social Work, and Board of Veterinary Medicine.

§ 54.1-2505. Powers and duties of Director of Department.

The Director of the Department shall have the following powers and duties:

1. To supervise and manage the Department;

2. To perform or consolidate such administrative services or functions as may assist the operation of the boards;

3. To prepare, approve, and submit to the Governor, after consultation with the boards, all requests for appropriations and be responsible for all expenditures pursuant to appropriations;

4. To provide such office facilities as will allow the boards to carry out their duties;

5. To employ personnel as required for the proper performance of the responsibilities of the Department subject to ~~Chapter 29~~ *the Virginia Personnel Act* (§ 2.2-2900 et seq.) ~~of Title 2.2~~ within the limits of appropriations made by law;

6. To receive all complaints made against regulated health care professionals;

7. To develop administrative policies and procedures governing the receipt and recording of complaints;

8. To monitor the status of actions taken under the auspices of the boards regarding complaints until the closure of each case;

9. To provide investigative and such other services as needed by the boards to enforce their respective statutes and regulations;

10. ~~To provide staff to assist in the performance of the duties of the Board of Health Professions;~~

~~11.~~ To collect and account for all fees to be paid into each board and account for and deposit the moneys so collected into a special fund from which the expenses of the health regulatory boards, the Health Practitioners' Monitoring Program, and the Department ~~and Board of Health Professions~~ shall be paid. Such fees shall be held exclusively to cover the expenses of the health regulatory boards, the Health Practitioners' Monitoring Program, and the Department ~~and Board of Health Professions~~ and shall not be transferred to any agency other than the Department ~~of Health Professions~~, except as provided in §§ 54.1-3011.1 and 54.1-3011.2;

~~12.~~ *11.* To make and enter into all contracts and agreements necessary or incidental to the performance of his duties and the execution of his powers, including, but not limited to, contracts with the United States, other states, *and* agencies and governmental subdivisions of the Commonwealth;

~~13.~~ *12.* To accept grants from the United States government, its agencies and instrumentalities, and any other source. The Director shall have the power to comply with conditions and execute agreements as may be necessary, convenient, or desirable;

~~14.~~ *13.* To promulgate and revise regulations necessary for the administration of the Department and such regulations as are necessary for the implementation of the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) ~~of this title~~ and subdivision ~~19 of this section~~ *18*;

~~15.~~ *14.* To report promptly, after consultation with the presiding officer of the appropriate health regulatory board or his designee, to the Attorney General or the appropriate attorney for the Commonwealth any information the Department obtains which, upon appropriate investigation, indicates, in the judgment of the Director, that a person licensed by any of the health regulatory boards has violated any provision of criminal law, including the laws relating to manufacturing, distributing, dispensing, prescribing, or administering drugs other than drugs classified as Schedule VI drugs. When necessary, the Attorney General or the attorney for the Commonwealth shall request that the Department of Health Professions or the Department of State Police conduct any subsequent investigation of such report. Upon request and affidavit from an attorney for the Commonwealth, the Director shall provide documents material to a criminal investigation of a person licensed by a health regulatory board; however, peer review documents shall not be released and shall remain privileged pursuant to § 8.01-581.17. For the purpose of this section, the terms manufacturing, distributing, dispensing, prescribing, or administering drugs shall not include minor administrative or clerical errors ~~which~~ *that* do not affect the inventory of drugs required by ~~Chapter 34~~ *the*

Drug Control Act (§ 54.1-3400 et seq.) ~~of this title~~ and do not indicate a pattern of criminal behavior;

~~16.~~ *15.* To keep records of the names and qualifications of registered, certified, or licensed persons;

~~17.~~ *16.* To exercise other powers and perform other duties required of the Director by the Governor;

~~18.~~ *17.* To issue subpoenas in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) for any informal fact finding or formal proceeding within the jurisdiction of the Department or any regulatory board;

~~19.~~ *18.* To establish, and revise as necessary, a health practitioners' monitoring program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) ~~of this title~~;

~~20.~~ *19.* To establish, and revise as necessary, with such federal funds, grants, or general funds as may be appropriated or made available for this program, the Prescription Monitoring Program pursuant to Chapter 25.2 (§ 54.1-2519 et seq.) ~~of this title~~; ~~and~~

~~21.~~ *20.* To assess a civil penalty against any person who is not licensed by a health regulatory board for failing to report a violation pursuant to § 54.1-2400.6 or ~~§~~ 54.1-2909*;*

21. To evaluate, at the request of the General Assembly, health care professions and occupations in the Commonwealth and to consider whether each such profession or occupation should be regulated and the degree of regulation to be imposed;

22. To receive, review, and forward to the appropriate health regulatory board, any departmental investigative reports relating to complaints of violations by practitioners of the Practitioner Self-Referral Act (§ 54.1-2410 et seq.);

23. To determine compliance with, violations of, and grant exceptions to the prohibitions set forth in the Practitioner Self-Referral Act (§ 54.1-2410 et seq.); and

24. To take appropriate actions against entities, other than practitioners, for violations of the Practitioner Self-Referral Act (§ 54.1-2410 et seq.).

§ 54.1-2506. Enforcement of laws by Director and investigative personnel; authority of investigative personnel and Director.

A. The Director and investigative personnel appointed by him shall be sworn to enforce the statutes and regulations pertaining to the Department~~, the Board,~~ and the health regulatory boards and shall have the authority to investigate any violations of those statutes and regulations and to the extent otherwise authorized by law inspect any office or facility operated, owned or employing individuals regulated by any health regulatory board. The Director or his designee shall have the power to subpoena witnesses and to request and obtain patient records, business records, papers, and physical or other evidence in the course of any investigation or to issue subpoenas requiring the production of such evidence. A subpoena issued pursuant to this section may be served by (i) any person authorized to serve process under § 8.01-293, (ii) investigative personnel appointed by the Director, (iii) registered or certified mail or by equivalent commercial parcel delivery service, or (iv) email or facsimile if requested to do so by the recipient. Upon failure of any person to comply with a subpoena duly served, the Director may, pursuant to § 54.1-111, request that the Attorney General or the attorney for the Commonwealth for the jurisdiction in which the recipient of the subpoena resides, is found, or transacts business seek enforcement of the subpoena in such jurisdiction.

B. All investigative personnel shall be vested with the authority to (i) administer oaths or affirmations for the purpose of receiving complaints of violations of this subtitle, (ii) serve and execute any warrant, paper or process issued by any court or magistrate, ~~the Board,~~ the Director or in his absence a designated subordinate, or by any regulatory board under the authority of the Director, (iii) request and receive criminal history information under the provisions of § 19.2-389, and (iv) request and receive social security numbers from practitioners or federal employee identification numbers from facilities.

C. The Director shall have the authority to issue summonses for violations of statutes and regulations governing the unlicensed practice of professions regulated by the Department. The Director may delegate such authority to investigators appointed by him. In the event a person issued such a summons fails or refuses to discontinue the unlawful acts or refuses to give a written promise to appear at the time and place specified in the summons, the investigator may appear before a magistrate or other issuing authority having jurisdiction to obtain a criminal warrant pursuant to § 19.2-72.

§ 54.1-2729.2. Dialysis patient care technician; definition.

"Dialysis patient care technician" or "dialysis care technician" means a person who has obtained certification from an organization approved by the ~~Board~~ *Department* of Health Professions to provide, under the supervision of a licensed practitioner of medicine or a registered nurse, direct care to patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility. Such direct care may include, but need not be limited to, the administration of heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers in accordance with the order of a licensed physician, an advanced practice registered nurse, or a physician assistant. However, a person who has completed a training program in dialysis patient care may engage in provisional practice to obtain practical experience in providing direct patient care under direct and immediate supervision in accordance with § 54.1-3408, until he has taken and received the results of any examination required by a certifying organization approved by the Board or for 24 months from the date of initial practice, whichever occurs sooner.

§ 54.1-2729.3. Prohibition on use of title without holding certification; continuing competency

requirements; fees; penalty.

A. No person shall hold himself out to be or advertise or permit to be advertised that he is a dialysis patient care technician or dialysis care technician as defined in this chapter unless such person has obtained certification from an organization approved by the ~~Board~~ *Department* of Health Professions as examining candidates for appropriate competency or technical proficiency to perform as dialysis patient care technicians or dialysis care technicians.

B. The title restrictions provided by this section shall apply to the use of the terms "dialysis patient care technician" and "dialysis care technician" or any other term or combination of terms used alone or in combination with the terms "licensed," "certified," or "registered," as such terms also imply a minimum level of education, training, and competence. A person who is authorized for provisional practice to provide direct patient care while obtaining practical experience shall be identified as a "trainee" while working in a renal dialysis facility.

C. The ~~Board~~ *Department* of Health Professions may require such continuing competency training as it may deem necessary for dialysis patient care technicians or dialysis care technicians.

D. Any person who willfully violates the provisions of this chapter ~~shall be~~ *is* guilty of a Class 3 misdemeanor.

§ 54.1-2731. Prohibited terms; penalty.

A. As used in this section, "nutritional genomics" means the consideration of biochemical or genetic information to evaluate how genetics affect gene function and how genetic variation alters nutrient response, including the study of how dietary and other lifestyle choices influence the function of humans at the molecular, cellular, organismal, and populational levels.

B. No person shall hold himself out to be or advertise or permit to be advertised that such person is a dietitian or nutritionist unless such person:

1. Has (i) received a baccalaureate or higher degree in nutritional sciences, community nutrition, public health nutrition, food and nutrition, dietetics, or human nutrition from a regionally accredited institution of higher education and (ii) satisfactorily completed a program of supervised clinical experience approved by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics;

2. Has active registration through the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics;

3. Has an active certificate of the Board for Certification of Nutrition Specialists as a Certified Nutrition Specialist;

4. Has an active certification as a Diplomate of the American Clinical Board of Nutrition;

5. Has a current license or certificate as a dietitian or nutritionist issued by another state; or

6. Has the minimum requisite education, training and experience determined by the ~~Board~~ *Department* of Health Professions appropriate for such person to hold himself out to be, or advertise or allow himself to be advertised as, a dietitian or nutritionist.

The restrictions of this section apply to the use of the terms "dietitian" and "nutritionist" as used alone or in any combination with the terms "licensed," "certified," or "registered," as those terms also imply a minimum level of education, training and competence.

C. Any person who meets the requirements set forth in subsection B who receives nutritional genomics testing information shall maintain such information in accordance with applicable federal and state law.

D. A person who does not meet the requirements of subsection B but who (i) has a baccalaureate degree with a major in food and nutrition or dietetics or has equivalent hours of food and nutrition coursework and (ii) has two years of work experience in nutrition or dietetics concurrent with or subsequent to completion of such degree may hold himself out as a dietitian or nutritionist, provided he is employed by or under contract to a government agency and practices solely within the scope of such employment.

E. Any person who willfully violates the provisions of this section is guilty of a Class 3 misdemeanor.

§ 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. "Agent" 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" does 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 *a* 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~~ *wholly owned* subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

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

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed advanced practice registered nurse 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. "Controlled substance" does 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~~ *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~~ *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~~ *Federal* Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect

with respect to that substance.

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

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

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

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

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

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, "dispensing" does 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" includes only the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

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

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

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

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and

includes any packaging or repackaging of the substance or labeling or relabeling of its container. "Manufacture" does not include compounding.

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

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, its resin, or any extract containing one or more cannabinoids. "Marijuana" does not include (i) the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis; (ii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent; (iii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990; (iv) a hemp product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined in § 3.2-5145.1; or (vi) any substance containing a tetrahydrocannabinol isomer, ester, ether, salt, or salts of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act (§ 54.1-3400 et seq.) pursuant to § 54.1-3443.

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

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; or (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. "Opiate" 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). "Opiate" 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, *21 U.S.C. § 301 et seq.*

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

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

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

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

"Prescriber" means a practitioner who is authorized pursuant to §§ 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, "proprietary medicine" does 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. "Radiopharmaceutical" 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).

"Remote dispensing system" means a profile-driven automated drug dispensing system that performs operations or activities relative to the storage, packaging, labeling, or dispensing of medications employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient, authorized agent of the patient, or person licensed to administer drugs, and collects, controls, and maintains all information online. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 and Board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

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

"Tetrahydrocannabinol" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of this definition, "isomer" means the optical, position, and geometric isomers.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of

"therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

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

"Total tetrahydrocannabinol" means the sum, after the application of any necessary conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of tetrahydrocannabinolic acid.

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

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

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

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

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter do 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 have the same meanings as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed advanced practice registered nurse pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice. A licensed midwife pursuant to § 54.1-2957.7 shall only obtain, possess, and administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol;

4. Persons who are employed or engaged at a medical care facility, as defined in § 32.1-3, who have a valid emergency medical services provider certification issued by the Board of Health as a requirement of being employed or engaged at the medical care facility within the scope of such certification, pursuant to an oral or written order or standing protocol to administer drugs and devices at the medical care facility; or

5. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a

local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, licensed athletic trainer under contract with a local school division, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a place of public accommodation, as defined in subsection A of § 2.2-3904, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen and IV saline for use in emergency situations; subcutaneous lidocaine for wound closure; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently

implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize the possession and administration of undesignated glucagon as set forth in subsection F of § 22.1-274.2.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for

Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, a licensed practical nurse, an advanced practice registered nurse, a physician assistant, a doctor of medicine or osteopathic medicine, or a pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his

authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the ~~Board~~ *Department* of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, an advanced practice registered nurse, or a physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the ~~Board~~ *Department* of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated by the Director of the Department of Corrections or designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers, employees of regional jails, employees of any state agency, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, school board employees who have completed training and are certified in the administration of an opioid antagonist for overdose reversal by a program administered or authorized by the Department of Health, other school board employees or individuals contracted by a school board to provide school health services, and firefighters may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, any person

may possess and administer naloxone or other opioid antagonist used for overdose reversal, other than naloxone in an injectable formulation with a hypodermic needle or syringe, in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may dispense naloxone, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

2. That §§ 54.1-2409.2 and 54.1-2507 through 54.1-2510 of the Code of Virginia are repealed.

3. That the regulations of the Board of Health Professions shall be administered by the Department of Health Professions and shall remain in full force and effect until the Department of Health Professions promulgates regulations pursuant to this act.