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SENATE BILL NO. 330

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Governor
on March 6, 1996)

(Patron Prior to Substitute—Senator Lambert)

A BILL to amend and reenact §§ 9-6.14:4.1, 54.1-2900 as it is currently effective and as it will become effective, 54.1-3200, 54.1-3207, 54.1-3303, 54.1-3401 and 54.1-3408 of the Code of Virginia; to amend the Code of Virginia by adding in Chapter 32 of Title 54.1 an article numbered 5, consisting of sections numbered 54.1-3222, 54.1-3223 and 54.1-3224; and to repeal §§ 54.1-2957.1, 54.1-2957.2 and 54.1-2957.3 of the Code of Virginia, all relating to the practice of optometry.

Be it enacted by the General Assembly of Virginia:

1. That §§ 9-6.14:4.1, 54.1-2900 as it is currently effective and as it will become effective, 54.1-3200, 54.1-3207, 54.1-3303, 54.1-3401, and 54.1-3408 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Chapter 32 of Title 54.1 an article numbered 5, consisting of sections numbered 54.1-3222, 54.1-3223 and 54.1-3224, as follows:

§ 9-6.14:4.1. Exemptions and exclusions.

A. Although required to comply with § 9-6.18 of the Virginia Register Act (§ 9-6.15 et seq.), the following agencies are exempted from the provisions of this chapter, except to the extent that they are specifically made subject to §§ 9-6.14:14.1, 9-6.14:21 and 9-6.14:22:

1. The General Assembly.

2. Courts, any agency of the Supreme Court, and any agency which by the Constitution is expressly granted any of the powers of a court of record.

3. The Department of Game and Inland Fisheries in promulgating regulations regarding the management of wildlife and for all case decisions rendered pursuant to any provisions of Chapters 2 (§ 29.1-200 et seq.), 3 (§ 29.1-300 et seq.), 4 (§ 29.1-400 et seq.), 5 (§ 29.1-500 et seq.), and 7 (§ 29.1-700 et seq.) of Title 29.1.

4. The Virginia Housing Development Authority.

5. Municipal corporations, counties, and all local, regional or multijurisdictional authorities created under this Code, including those with federal authorities, except for those created under Chapter 27 (§ 15.1-1228 et seq.) of Title 15.1.

6. Educational institutions operated by the Commonwealth provided that, with respect to § 9-6.14:22, such educational institutions shall be exempt from the publication requirements only with respect to regulations which pertain to (i) their academic affairs; (ii) the selection, tenure, promotion and disciplining of faculty and employees; (iii) the selection of students; and (iv) rules of conduct and disciplining of students.

7. The Milk Commission in promulgating regulations regarding (i) producers' license and base, (ii) classification and allocation of milk, computation of sales and shrinkage, and (iii) class prices for producers' milk, time and method of payment, butterfat testing and differential.

8. The Virginia Resources Authority.

9. Agencies expressly exempted by any other provision of this Code.

10. The Virginia Voluntary Formulary Board in formulating recommendations regarding amendments to the Formulary pursuant to § 32.1-81.

11. The Council on Information Management.

12. The Department of General Services in promulgating standards for the inspection of buildings for asbestos pursuant to § 2.1-526.14.

13, 14. [Repealed.]

15. The State Council of Higher Education for Virginia, in developing, issuing, and revising guidelines pursuant to § 23-9.6:2.

16. The Commissioner of Agriculture and Consumer Services in adopting regulations pursuant to subsection B of § 3.1-726.

17. The Commissioner of Agriculture and Consumer Services and the Board of Agriculture and Consumer Services in promulgating regulations pursuant to subsections B and C of § 3.1-106.4, subsection B of § 3.1-126.12:1, § 3.1-271.1, subsections B and C of § 3.1-828.4, and subsection A of § 3.1-884.21:1.

18. The Board of ~~Medicine~~ *Optometry* when specifying therapeutic pharmaceutical agents ~~for the treatment of certain~~, *treatment guidelines, and diseases and abnormal* conditions of the human eye and its adnexa ~~by certified~~ *for TPA-certification of* optometrists pursuant to ~~§ 54.1-2957.2~~ *Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of Title 54.1*.

19. The Board of Medicine, in consultation with the Board of Pharmacy, when promulgating

amendments to the Physician's Assistant Formulary established pursuant to § 54.1-2952.1.

20. The Boards of Medicine and Nursing in promulgating amendments to the Nurse Practitioner Formulary established pursuant to § 54.1-2957.01.

21. The Virginia War Memorial Foundation.

22. The Virginia Medicaid Prior Authorization Advisory Committee in making recommendations to the Board of Medical Assistance Services regarding prior authorization for prescription drug coverage pursuant to Article 4 (§ 32.1-331.12 et seq.) of Chapter 10 of Title 32.1.

23. The State Board of Education, in developing, issuing, and revising guidelines pursuant to § 22.1-280.3.

B. Agency action relating to the following subjects is exempted from the provisions of this chapter:

1. Money or damage claims against the Commonwealth or agencies thereof.

2. The award or denial of state contracts, as well as decisions regarding compliance therewith.

3. The location, design, specifications or construction of public buildings or other facilities.

4. Grants of state or federal funds or property.

5. The chartering of corporations.

6. Customary military, naval or police functions.

7. The selection, tenure, dismissal, direction or control of any officer or employee of an agency of the Commonwealth.

8. The conduct of elections or eligibility to vote.

9. Inmates of prisons or other such facilities or parolees therefrom.

10. The custody of persons in, or sought to be placed in, mental, penal or other state institutions as well as the treatment, supervision, or discharge of such persons.

11. Traffic signs, markers or control devices.

12. Instructions for application or renewal of a license, certificate, or registration required by law.

13. Content of, or rules for the conduct of, any examination required by law.

14. The administration of a pool or pools authorized by Article 7.1 (§ 2.1-234.9:1 et seq.) of Chapter 14 of Title 2.1.

15. Any rules for the conduct of specific lottery games, so long as such rules are not inconsistent with duly adopted regulations of the State Lottery Board, and provided that such regulations are published and posted.

16. Orders condemning or closing any shellfish, finfish, or crustacea growing area and the shellfish, finfish or crustacea located thereon pursuant to Article 2 (§ 28.2-803 et seq.) of Chapter 8, Title 28.2.

17. Any operating procedures for review of child deaths developed by the State Child Fatality Review Team pursuant to § 32.1-283.1.

C. The following agency actions otherwise subject to this chapter and § 9-6.18 of the Virginia Register Act are excluded from the operation of Article 2 (§ 9-6.14:7.1 et seq.) of this chapter:

1. Agency orders or regulations fixing rates or prices.

2. Regulations which establish or prescribe agency organization, internal practice or procedures, including delegations of authority.

3. Regulations which consist only of changes in style or form or corrections of technical errors. Each promulgating agency shall review all references to sections of the Code of Virginia within their regulations each time a new supplement or replacement volume to the Code of Virginia is published to ensure the accuracy of each section or section subdivision identification listed.

4. Regulations which:

(a) Are necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved;

(b) Are required by order of any state or federal court of competent jurisdiction where no agency discretion is involved; or

(c) Are necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation, and the Registrar has so determined in writing; notice of the proposed adoption of these regulations and the Registrar's above determination shall be published in the Virginia Register not less than thirty days prior to the effective date thereof.

5. Regulations which an agency finds are necessitated by an emergency situation. For the purposes of this subdivision, "emergency situation" means (i) a situation involving an imminent threat to public health or safety or (ii) a situation in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation shall be effective in 280 days or less from enactment of the law or the appropriation act or the effective date of the federal regulation, and the regulation is not exempt under the provisions of subdivision C 4 of this section. In such cases, the agency shall state in writing the nature of the emergency and of the necessity for such action and may adopt such regulations with the prior approval of the Governor. Such regulations shall be limited to no more than twelve months in duration. During the twelve-month period, an agency may issue additional emergency

regulations as needed addressing the subject matter of the initial emergency regulation, but any such additional emergency regulations shall not be effective beyond the twelve-month period from the effective date of the initial emergency regulation. If the agency wishes to continue regulating the subject matter governed by the emergency regulation beyond the twelve-month limitation, a regulation to replace the emergency regulation shall be promulgated in accordance with Article 2 (§ 9-6.14:7.1 et seq.) of this chapter. The Notice of Intended Regulatory Action to promulgate a replacement regulation shall be published within sixty days of the effective date of the emergency regulation, and the proposed replacement regulation shall be published within 180 days after the effective date of the emergency regulation.

6. [Repealed.]

7. Preliminary program permit fees of the Department of Environmental Quality assessed pursuant to subsection C of § 10.1-1322.2.

8. Regulations of the Pesticide Control Board adopted pursuant to subsection B of § 3.1-249.51 or clause (v) or (vi) of subsection C of § 3.1-249.53 after having been considered at two or more Board meetings and one public hearing.

Whenever regulations are adopted under this subsection C, the agency shall state as part thereof that it will receive, consider and respond to petitions by any interested person at any time with respect to reconsideration or revision. The effective date of regulations adopted under this subsection shall be in accordance with the provisions of § 9-6.14:9.3, except in the case of emergency regulations, which shall become effective as provided in subsection A of § 9-6.14:9.

D. The following agency actions otherwise subject to this chapter are excluded from the operation of Article 3 (§ 9-6.14:11 et seq.) of this chapter:

1. The assessment of taxes or penalties under the tax laws.

2. The award or denial of claims for workers' compensation.

3. The grant or denial of public assistance.

4. Temporary injunctive or summary orders authorized by law.

5. The determination of claims for unemployment compensation or special unemployment.

6. The award or denial of individual student loans by the Virginia Education Loan Authority.

7. The determination of applications for guaranty of individual student loans or the determination of default claims by the State Education Assistance Authority.

E. The Marine Resources Commission, otherwise subject to this chapter and § 9-6.18 of the Virginia Register Act, is excluded from the operation of subsection C of this section and of Article 2 (§ 9-6.14:7.1 et seq.) of this chapter; however, the authorization for any general permit or guidelines for activity undertaken pursuant to Title 62.1 by the Marine Resources Commission shall be in accordance with the provisions of this chapter.

F. A regulation for which an exemption is claimed under this section and which is placed before a board or commission for consideration shall be provided at least two days in advance of the board or commission meeting to members of the public that request a copy of that regulation. A copy of that regulation shall be made available to the public attending such meeting.

G. The Joint Legislative Audit and Review Commission shall conduct a review periodically of exemptions and exclusions authorized by this section. The purpose of this review shall be to assess whether there are any exemptions or exclusions which should be discontinued or modified.

H. Minor changes to regulations being published in the Virginia Administrative Code under the Virginia Register Act, Chapter 1.2 (§ 9-6.15 et seq.) of this title, made by the Virginia Code Commission pursuant to § 9-77.10:1 shall be exempt from the provisions of this chapter.

§ 54.1-2900. (Effective until January 1, 1997) Definitions.

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

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

"Auricular acupuncture" means the subcutaneous insertion of sterile, disposable acupuncture needles in predetermined, bilateral locations in the outer ear when used exclusively and specifically in the context of an approved chemical dependency treatment program, under the appropriate supervision of a licensed physician acupuncturist or licensed acupuncturist.

"Board" means the Board of Medicine.

~~"Certified optometrist" means an optometrist who is licensed under Chapter 32 of this title and who has successfully completed the requirements for certification established by the Board of Medicine. Such certification shall enable an optometrist to treat certain diseases, including abnormal conditions, of the~~

~~human eye and its adnexa, as specified by the Board of Medicine, with certain therapeutic pharmaceutical agents specified by the Board. However, such certification shall not permit treatment through surgery or other invasive modalities.~~

"Clinical psychologist" means a psychologist who is competent in the diagnosis, prevention, treatment and amelioration of psychological problems, behavioral or emotional disorders or conditions or mental conditions, by the application of psychological principles, psychological methods, or psychological procedures, including but not limited to psychological assessment and evaluation and psychotherapy, which does not amount to the practice of medicine. This definition shall not be construed to limit or restrict any person licensed by a health regulatory board as defined in § 54.1-2500 from rendering services which he is licensed to provide.

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

"Practice of acupuncture" means the stimulation of certain points on or near the surface of the body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain ailments or conditions of the body and includes the techniques of electroacupuncture, cupping and ~~moxabustion~~ *moxibustion*. The practice of acupuncture does not include the use of physical therapy, chiropractic, osteopathic manipulative techniques, the use or prescribing of any drugs, medications, herbal preparations, nutritional supplements, serums or vaccines, nor the procedure of auricular acupuncture as exempted in § 54.1-2901 when used specifically and exclusively in the context of a publicly supported comprehensive drug treatment program by an employee of the program who is trained and approved by the National Acupuncture Detoxification Association.

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

"Practice of clinical psychology" means the offering by an individual of his services to the public as a clinical psychologist.

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

"Practice of physical therapy" means, upon medical referral and direction, the evaluation, testing, treatment, reeducation and rehabilitation by physical, mechanical or electronic measures and procedures of individuals who, because of trauma, disease or birth defect, present physical and emotional disorders, but does not include the use of Roentgen rays and radium for diagnostic or therapeutic purposes or the use of electricity for shock therapy and surgical purposes including cauterization.

"Practice of podiatry" means the medical, mechanical and surgical treatment of the ailments of the human foot and ankle, but does not include amputation proximal to the metatarsal-phalangeal joints. The Board of Medicine shall determine whether a specific type of treatment of the foot and ankle is within the scope of practice of podiatry.

§ 54.1-2900. (Effective January 1, 1997) Definitions.

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

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

"Auricular acupuncture" means the subcutaneous insertion of sterile, disposable acupuncture needles in predetermined, bilateral locations in the outer ear when used exclusively and specifically in the context of an approved chemical dependency treatment program, under the appropriate supervision of a licensed physician acupuncturist or licensed acupuncturist.

"Board" means the Board of Medicine.

~~"Certified optometrist" means an optometrist who is licensed under Chapter 32 (§ 54.1-3200 et seq.) of this title and who has successfully completed the requirements for certification established by the Board of Medicine. Such certification shall enable an optometrist to treat certain diseases, including abnormal conditions, of the human eye and its adnexa, as specified by the Board of Medicine, with certain therapeutic pharmaceutical agents specified by the Board. However, such certification shall not permit treatment through surgery or other invasive modalities.~~

"Clinical psychologist" means a psychologist who is competent in the diagnosis, prevention, treatment and amelioration of psychological problems, behavioral or emotional disorders or conditions or mental conditions, by the application of psychological principles, psychological methods, or psychological procedures, including but not limited to psychological assessment and evaluation and psychotherapy,

which does not amount to the practice of medicine. This definition shall not be construed to limit or restrict any person licensed by a health regulatory board as defined in § 54.1-2500 from rendering services which he is licensed to provide.

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

"Practice of acupuncture" means the stimulation of certain points on or near the surface of the body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain ailments or conditions of the body and includes the techniques of electroacupuncture, cupping and ~~moxabustion~~ *moxibustion*. The practice of acupuncture does not include the use of physical therapy, chiropractic, osteopathic manipulative techniques, the use or prescribing of any drugs, medications, herbal preparations, nutritional supplements, serums or vaccines, nor the procedure of auricular acupuncture as exempted in § 54.1-2901 when used specifically and exclusively in the context of a publicly supported comprehensive drug treatment program by an employee of the program who is trained and approved by the National Acupuncture Detoxification Association.

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

"Practice of clinical psychology" means the offering by an individual of his services to the public as a clinical psychologist.

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

"Practice of physical therapy" means, upon medical referral and direction, the evaluation, testing, treatment, reeducation and rehabilitation by physical, mechanical or electronic measures and procedures of individuals who, because of trauma, disease or birth defect, present physical and emotional disorders, but does not include the use of Roentgen rays and radium for diagnostic or therapeutic purposes or the use of electricity for shock therapy and surgical purposes including cauterization.

"Practice of podiatry" means the medical, mechanical and surgical treatment of the ailments of the human foot and ankle, but does not include amputation proximal to the metatarsal-phalangeal joints. The Board of Medicine shall determine whether a specific type of treatment of the foot and ankle is within the scope of practice of podiatry.

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

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

"Radiologic technologist, limited" means an individual, other than a licensed radiologic technologist, dental hygienist or who is otherwise authorized by the Board of Dentistry under Chapter 27 of this title and the regulations pursuant thereto, who performs diagnostic radiographic procedures employing equipment which emits ionizing radiation which is limited to specific areas of the human body.

§ 54.1-3200. Definitions.

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

"Board" means the Board of Optometry.

"Optometrist" means any person practicing the profession of optometry as defined in this chapter and the regulations of the Board.

"Practice of optometry" means the examination of the human eye to ascertain the presence of defects or abnormal conditions which may be corrected or relieved by the use of lenses, prisms or ocular exercises, visual training or orthoptics; the employment of any subjective or objective mechanism to determine the accommodative or refractive states of the human eye or range or power of vision of the human eye; the use of testing appliances for the purpose of the measurement of the powers of vision; the examination, diagnosis, and optometric treatment in accordance with this chapter, of conditions and visual or muscular anomalies of the human eye; and the prescribing or adapting of lenses, prisms or ocular exercises, visual training or orthoptics for the correction, relief, remediation or prevention of such conditions. An optometrist may treat certain diseases or abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents only as permitted under ~~Chapter 29 (§ 54.1-2900~~

~~et seq.)~~ ~~of~~ this ~~title~~ *chapter*.

"TPA-certified optometrist" means an optometrist who is licensed under this chapter and who has successfully completed the requirements for TPA certification established by the Board pursuant to Article 5 (§ 54.1-3222 et seq.) of this chapter. Such certification shall enable an optometrist to treat certain diseases, including abnormal conditions, of the human eye and its adnexa, as determined by the Board, with certain therapeutic pharmaceutical agents specified by the Board. Such certification shall not, however, permit treatment through surgery, including, but not limited to, laser surgery or other invasive modalities, except for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine.

The foregoing shall not restrict the authority of any optometrist licensed or certified under this chapter *for the removal of superficial foreign bodies from the human eye and its adnexa or* from delegating to personnel in his personal employ and supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by optometrists, if such activities or functions are authorized by and performed for such optometrists and responsibility for such activities or functions is assumed by such optometrists.

§ 54.1-3207. Board of Optometry.

The Board of Optometry shall be composed of six members as follows: five licensed optometrists and one citizen member. The terms of office of the members shall be four years. The professional members of the Board shall have been engaged in the practice of optometry for at least five years prior to the date of their appointment. *After July 1, 1996, all professional members newly appointed to the Board shall be certified in the administration of therapeutic pharmaceutical agents pursuant to Article 5 (§ 54.1-3222 et seq.) of this chapter.*

Article 5.

Certification for Administration of Therapeutic Pharmaceutical Agents.

§ 54.1-3222. TPA certification; certification for treatment of certain diseases or abnormal conditions with certain therapeutic pharmaceutical agents.

A. The Board shall certify an optometrist to prescribe for and treat certain diseases or abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents, if the optometrist files a written application, accompanied by the fee required by the Board and satisfactory proof that the applicant:

1. Is licensed by the Board as an optometrist and certified to administer diagnostic pharmaceutical agents pursuant to Article 4 (§ 54.1-3220 et seq.) of this chapter;

2. Has satisfactorily completed such didactic and clinical training programs for the treatment of diseases and abnormal conditions of the eye and its adnexa as are determined, after consultation with a school or college of optometry and a school of medicine, to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients; and

3. Passes such examinations as are determined to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients.

B. TPA certification shall enable an optometrist to treat certain diseases and abnormal conditions of the human eye and its adnexa as determined by the Board with certain therapeutic pharmaceutical agents specified by the Board, within the following conditions:

1. Treatment with oral therapeutic pharmaceutical agents shall be limited to the analgesics included on Schedules III and VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to alleviate ocular pain.

2. Prescriptions for oral analgesics to relieve ocular pain shall be limited to dosages for no more than seventy-two hours.

3. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act.

4. Treatment of glaucoma shall require prior consultation with the patient's physician or other appropriate physician, and shall exclude treatment of congenital and infantile glaucoma. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care.

5. Treatment through surgery or other invasive modalities shall not be permitted, except for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine, such as that included in a bee sting kit.

6. Entities permitted or licensed by the Board of Pharmacy to distribute or dispense drugs, including, but not limited to, wholesale distributors and pharmacists, shall be authorized to supply TPA-certified optometrists with those therapeutic pharmaceutical agents specified by the Board on the TPA-Formulary.

§ 54.1-3223. Regulations relating to instruction and training, examination, and therapeutic pharmaceutical agents; Board to determine TPA-Formulary; appointment of TPA-Formulary Committee.

A. The Board shall promulgate such regulations governing the treatment of certain diseases and

abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents by TPA-certified optometrists as are reasonable and necessary to ensure an appropriate standard of medical care for patients, including, but not limited to, determinations of the diseases and abnormal conditions of the human eye and its adnexa which may be treated by TPA-certified optometrists, treatment guidelines, and the drugs specified on the TPA-Formulary. In establishing standards of instruction and training, the Board shall consult with a school or college of optometry and a school or college of medicine and shall set a minimum number of hours of clinical training to be supervised by an ophthalmologist. The didactic and clinical training programs may include, but need not be limited to, programs offered or designed either by schools of medicine or schools or colleges of optometry or both or some combination thereof.

The Board may prepare, administer, and grade appropriate examinations for the certification of optometrists to administer therapeutic pharmaceutical agents or may contract with a school of medicine, school or college of optometry, or other institution or entity to develop, administer, and grade the examinations.

In order to maintain a current and appropriate list of therapeutic pharmaceuticals on the TPA-Formulary, current and appropriate treatment guidelines, and current and appropriate determinations of diseases and abnormal conditions of the eye and its adnexa which may be treated by TPA-certified optometrists, the Board may, from time to time, amend such regulations. Such regulations shall be exempt from the requirements of the Administrative Process Act (§ 9-6.14:1 et seq.), except to any extent that they may be specifically made subject to §§ 9-6.14:14.1, 9-6.14:21, and 9-6.14:22; the Board's regulations shall, however, comply with § 9-6.18 of the Virginia Register Act (§ 9-6.15 et seq.). The Board shall, however, conduct a public hearing prior to making amendments to the TPA-Formulary, the treatment guidelines or the determinations of diseases and abnormal conditions of the eye and its adnexa which may be treated by TPA-certified optometrists. Thirty days prior to conducting such hearing, the Board shall give written notice by mail of the date, time, and place of the hearing to all currently TPA-certified optometrists and any other persons requesting to be notified of the hearings and publish notice of its intention to amend the list in the Virginia Register of Regulations. During the public hearing, interested parties shall be given reasonable opportunity to be heard and present information prior to final adoption of any TPA-Formulary amendments. Proposed and final amendments of the list shall also be published, pursuant to § 9-6.14:22, in the Virginia Register of Regulations. Final amendments to the TPA-Formulary shall become effective upon filing with the Registrar of Regulations. The TPA-Formulary shall be the inclusive list of the therapeutic pharmaceutical agents that a TPA-certified optometrist may prescribe.

B. To assist in the specification of the TPA-Formulary, there shall be a seven-member TPA-Formulary Committee, as follows: three Virginia TPA-certified optometrists to be appointed by the Board of Optometry, one pharmacist appointed by the Board of Pharmacy from among its licensees, two ophthalmologists appointed by the Board of Medicine from among its licensees, and the chairman who shall be appointed by the Board of Optometry from among its members. The ophthalmologists appointed by the Board of Medicine shall have demonstrated, through professional experience, knowledge of the optometric profession. In the event the Board of Pharmacy or the Board of Medicine fails to make appointments to the TPA-Formulary Committee within thirty days following July 1, 1996, or within thirty days following any subsequent vacancy, the Board of Optometry shall appoint such members.

The TPA-Formulary Committee shall recommend to the Board those therapeutic pharmaceutical agents to be included on the TPA-Formulary for the treatment of certain diseases and abnormal conditions of the eye and its adnexa by TPA-certified optometrists.

§ 54.1-3224. Denial, etc., of TPA certification; disciplinary actions; summary suspension under certain circumstances.

A. The Board of Optometry may deny, refuse to renew, revoke, or suspend any TPA-certificate issued to a TPA-certified optometrist, or applied for by a licensed optometrist in accordance with the provisions of this article, or may discipline or reprimand any certificate holder for violations of this chapter or the Board's regulations.

B. The Board may take action summarily to suspend a TPA-certified optometrist's certification under this section by means of a telephone conference call if, in the opinion of a majority of the Board, (i) a good faith effort to convene a regular meeting of the Board has failed and (ii) there is an imminent danger to the public health or safety which warrants this action.

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, *or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician's assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et*

seq.) of Chapter 32 of this title. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide physician-patient relationship.

For purposes of this section, a bona fide physician-patient-pharmacist relationship is one in which a physician prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

B. No prescription shall be filled which does not result from a bona fide physician-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

In order to determine whether a prescription which appears questionable to the pharmacist results from a bona fide physician-patient-pharmacist relationship, the pharmacist shall contact the prescribing physician or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

C. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine authorized to issue such prescription if the prescription complies with the requirements of this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title, known as the "Drug Control Act."

D. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions for Schedule VI controlled substances and devices as set forth in Chapter 34 of this title in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

E. A licensed physician's assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions for Schedule VI controlled substances and devices as set forth in Chapter 34 of this title in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

F. A TPA-certified optometrist who is authorized to prescribe contolled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title may issue prescriptions in good faith to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to oral analgesics included in Schedules III and VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), when appropriate to relieve ocular pain, and topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act.

§ 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.

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

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

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

"Board" means the Board of Pharmacy.

"Compound" means the taking of two or more ingredients and fabricating them into a single preparation, usually referred to as a dosage form.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.1 or Title 4.1.

"Cosmetic" means all articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance, and articles intended for use as a component of any such articles except soap.

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

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

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

"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.

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

"Manufacture" means the production, preparation, propagation, compounding, conversion or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include the preparing, compounding, packaging or labeling of a controlled substance by a practitioner as an incident to his administering or dispensing of a controlled substance or marijuana in the course of his professional practice, or by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than twelve percent of tetrahydrocannabinol by weight, or the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

"Medical equipment supplier" means any person, as defined in § 1-13.19, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, and those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment.

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

derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

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

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

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

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

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

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

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

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

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician's assistant pursuant to § 54.1-2952.1, *TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title,* 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 this Commonwealth.

"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.

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

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

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

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user

or consumer. No person shall be subject to any state or local tax by reason of this definition.

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

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

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

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

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, ~~or~~ dentistry, *or veterinary medicine or* a licensed nurse practitioner pursuant to § 54.1-2957.01 ~~or~~, a licensed physician's assistant pursuant to § 54.1-2952.1, *or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title* shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

The practitioner may prescribe, on a written prescription or on oral prescription as authorized by this chapter, and administer drugs and devices, or he may cause them to be administered by a nurse or intern under his direction and supervision, or a practitioner may prescribe and cause drugs and devices to be administered 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 State Mental Health, Mental Retardation and Substance Abuse Services Board by other persons who have been trained *properly* to ~~properly~~ administer drugs and who administer drugs only under the control and supervision of the practitioner or a pharmacist.

A practitioner may authorize registered nurses and licensed practical nurses to possess epinephrine for administration in treatment of emergency medical conditions pursuant to an oral or written order or standing protocol issued by a practitioner within the course of his professional practice.

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 certified by the Board of Dentistry who has satisfactorily completed a training program for this purpose that is approved by the Board of Dentistry.

No written prescription order form shall include more than one prescription. This provision shall not apply, however, to the entry of any order on a patient's chart in any hospital or any long-term care facility, as defined in Board regulations, in Virginia or to a prescription ordered through the pharmacy operated by the Department of Corrections, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

Such a prescription shall be written, dated, and signed by the person prescribing on the day when issued, and shall bear the full name and address of the patient for whom the drug is prescribed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered.

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 physician's instructions pertaining to dosage, frequency, and manner of administration, when the drugs administered would be normally self-administered by (i) a resident of a facility licensed or certified by the State Mental Health, Mental Retardation and Substance Abuse Services Board; (ii) a resident of any adult care residence which is licensed by the Department of Social Services; (iii) a resident of the Virginia Rehabilitation Center for the Blind; (iv) a resident of a facility approved by the Board or Department of Youth and Family Services for the placement of children in need of services or delinquent or alleged delinquent youth; or (v) a program participant of an adult day care center licensed by the Department of Social Services.

This section shall not interfere with any practitioner issuing prescriptions in compliance with 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 practitioner shall be deemed to be valid prescriptions. This section shall not prohibit a practitioner from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

B. The written prescription referred to in subsection A of this section shall be written with ink or

individually typed and each prescription shall be manually signed by the practitioner. The prescription may be prepared by an agent for his signature. The prescription shall contain the name, address, telephone number, and federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand.

C. Pursuant to § 32.1-87, the prescription form shall include two boxes, one labelled "Voluntary Formulary Permitted" and the other labelled "Dispense As Written." A prescriber may indicate his permission for the dispensing of a drug product included in the Formulary upon signing a prescription form and marking the box labelled "Voluntary Formulary Permitted." A Voluntary Formulary product shall be dispensed if the prescriber fails to indicate his preference. If no Voluntary Formulary product is immediately available, or if the patient objects to the dispensing of a generic drug, the pharmacist may dispense a brand name drug. On and after July 1, 1993, printed prescription forms shall provide:

" [] Dispense As Written

[] Voluntary Formulary Permitted

.....

Signature of prescriber

If neither box is marked, a Voluntary Formulary product must be dispensed."

D. Practitioners' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard-copy form, and such facsimile copy shall be treated as a valid, original prescription order.

2. That §§ 54.1-2957.1, 54.1-2957.2 and 54.1-2957.3 of the Code of Virginia are repealed.

3. That the regulations of the Board of Medicine relating to TPA-certified optometrists as in effect on January 1, 1996, shall continue in effect and shall be deemed to be the regulations of the Board of Optometry until such time as the Board of Optometry shall adopt valid regulations pursuant to this provision and the Board of Optometry regulations shall become effective. The Board of Optometry shall have sole authority to regulate all aspects of the scope of optometry practice.

4. That, on the effective date of this act, the Board of Optometry shall be deemed to be the successor in interest to the Board of Medicine to the extent this act transfers certain powers and duties for the certification of optometrists to administer therapeutic pharmaceutical agents; all rightful title and interest in and records for such TPA-certification of optometrists vested in the Board of Medicine prior to such effective date shall be transferred to and shall be deemed to be standing in the name of the Board of Optometry.

5. That the Director of the Department of Health Professions is authorized, from the effective date of this act, to transfer funds between the Boards of Medicine and Optometry for the reimbursement of outstanding expenses associated with TPA certification of optometrists.