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HOUSE BILL NO. 856

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Wealth and Institutions on January 29, 2004)

(Patron Prior to Substitute—Delegate Jones, S.C.)

A BILL to amend and reenact §§ 54.1-3200, 54.1-3211, 54.1-3221, 54.1-3222, 54.1-3223 and 54.1-3303 of the Code of Virginia, relating to the practice of optometry.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3200, 54.1-3211, 54.1-3221, 54.1-3222, 54.1-3223 and 54.1-3303 of the Code of Virginia are amended and reenacted as follows:

§ 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; the use of diagnostic pharmaceutical agents set forth in § 54.1-3221; 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 this 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 *prescribe and administer Schedule III through VI controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) 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.

§ 54.1-3211. Examination.

The Board shall set the necessary standards to be attained in the examinations to entitle the candidate to receive a license to practice optometry.

The examination shall be given at least semiannually if there are any candidates who have applied to the Board for examination at least thirty days before the date for the examination.

The examination shall include anatomy; physiology; pathology; general and ocular pharmacology designed to test knowledge of the proper use, characteristics, pharmacological effects, indications, contraindications and emergency care associated with the use of diagnostic pharmaceutical agents; and the use of the appropriate instruments.

The Board may determine a score which it considers satisfactory on any written examination of the National Board of Examiners in Optometry. The Board may waive its examination for a person who achieves a satisfactory score on the examination of the National Board of Examiners in Optometry.

Those persons licensed on or before June 30, 1997, to practice optometry in this state but not certified to administer diagnostic pharmaceutical agents may continue to practice optometry but may not administer diagnostic pharmaceutical agents without satisfying the requirements of this section. Those persons licensed after June 30, 1997, shall be considered as certified to administer diagnostic pharmaceutical agents. *After June 30, 2004, every person who is initially licensed to practice optometry*

in Virginia shall meet the qualifications for a TPA-certified optometrist.

§ 54.1-3221. "Diagnostic pharmaceutical agents" defined; utilization; acquisition.

A. Certified optometrists may administer diagnostic pharmaceutical agents only by topical application to the human eye. "Diagnostic pharmaceutical agents" shall be defined as ~~the following drugs in strengths not to exceed those stated:~~

~~1. Mydriatics and cycloplegics known as tropicamide in a 1.0 percent solution, phenylephrine hydrochloride in a 2.5 percent solution and cyclopentolate hydrochloride in a 1.0 percent solution to be used only on persons three years of age or older;~~

~~2. Anesthetic agents known as proparacaine hydrochloride in a 0.5 percent solution, tetracaine in a 0.5 percent solution and benoxinate hydrochloride in a 0.4 percent solution;~~

~~3. The miotic known as pilocarpine in a 1.0 percent solution; and~~

~~4. Dapiprazole hydrochloride in a 0.5 percent solution~~*Schedule VI controlled substances as set forth in the Drug Control Act (§ 54.1-3400 et seq.) that are used for the purpose of examining and determining abnormal or diseased conditions of the human eye or related structures.*

B. Any optometrist who utilizes diagnostic pharmaceutical agents without being certified as required by this article shall be subject to the disciplinary sanctions provided in this chapter.

C. Licensed drug suppliers or pharmacists are authorized to supply optometrists with diagnostic pharmaceutical agents upon presentation of evidence of Board certification for administration of such drugs.

§ 54.1-3222. TPA certification; certification for treatment of diseases or abnormal conditions with 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 *prescribe and administer Schedule III through VI controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) 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~~*(i)* analgesics included on Schedules III ~~and~~ *through* 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 *and (ii) other Schedule VI controlled substances as defined in § 54.1-3455 of the Drug Control Act appropriate to treat diseases and abnormal conditions of the human eye and its adnexa.*

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.

3.Therapeutic pharmaceutical agents shall include certain injectable Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act for (i) the treatment of abnormal or diseased conditions of the adnexa and (ii) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

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~~.

5. Treatment of infantile or congenital glaucoma and use of injectables for cosmetic purposes shall be prohibited.

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.

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 (§ 2.2-4000 et seq.), except to any extent that they may be specifically made subject to §§ 2.2-4024, 2.2-4030, and 2.2-4031; the Board's regulations shall, however, comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 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 § 2.2-4031, 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~~*the Board of Optometry's requesting such appointments*, 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.

§ 54.1-3303. 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 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 practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner 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. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history

is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. 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. In order to determine whether a prescription which appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner 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.

No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

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 or provide manufacturers' professional samples for 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 assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for 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 controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title may issue prescriptions in good faith or provide manufacturers' professional samples 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 *(i)* oral analgesics included in Schedules III ~~and~~ *through* VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), ~~when~~ *which are* appropriate to relieve ocular pain, ~~and~~ *(ii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa, (iii)* topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act, *and (iv) certain injectable Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act, for the treatment of abnormal or diseased conditions of the adnexa and for intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.*

2. That the Board of Optometry shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.