2004 SESSION

044088366 1 **HOUSE BILL NO. 856** 2 AMENDMENT IN THE NATURE OF A SUBSTITUTE 3 (Proposed by the Senate Committee on Education and Health 4 5 6 7 on February 26, 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. 8 Be it enacted by the General Assembly of Virginia: 9 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 10 Virginia are amended and reenacted as follows: 11 § 54.1-3200. Definitions. 12 As used in this chapter, unless the context requires a different meaning: 13 "Board" means the Board of Optometry. 14 "Optometrist" means any person practicing the profession of optometry as defined in this chapter and 15 the regulations of the Board. "Practice of optometry" means the examination of the human eye to ascertain the presence of defects 16 17 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 18 19 determine the accommodative or refractive states of the human eye or range or power of vision of the 20 human eye; the use of testing appliances for the purpose of the measurement of the powers of vision; 21 the examination, diagnosis, and optometric treatment in accordance with this chapter, of conditions and 22 visual or muscular anomalies of the human eye; the use of diagnostic pharmaceutical agents set forth in 23 § 54.1-3221; and the prescribing or adapting of lenses, prisms or ocular exercises, visual training or 24 orthoptics for the correction, relief, remediation or prevention of such conditions. An optometrist may 25 treat certain diseases or abnormal conditions of the human eye and its adnexa with certain therapeutic 26 pharmaceutical agents only as permitted under this chapter. 27 "TPA-certified optometrist" means an optometrist who is licensed under this chapter and who has 28 successfully completed the requirements for TPA certification established by the Board pursuant to 29 Article 5 (§ 54.1-3222 et seq.) of this chapter. Such certification shall enable an optometrist to prescribe 30 and administer Schedule III through VI controlled substances and devices as set forth in the Drug 31 Control Act (§ 54.1-3400 et seq.) to treat certain diseases, including abnormal conditions, of the human 32 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 33 34 limited to, laser surgery or other invasive modalities, except for treatment of emergency cases of 35 anaphylactic shock with intramuscular epinephrine. 36 The foregoing shall not restrict the authority of any optometrist licensed or certified under this 37 chapter for the removal of superficial foreign bodies from the human eye and its adnexa or from 38 delegating to personnel in his personal employ and supervised by him, such activities or functions as are 39 nondiscretionary and do not require the exercise of professional judgment for their performance and 40 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 41 42 functions is assumed by such optometrists. 43 § 54.1-3211. Examination. 44 The Board shall set the necessary standards to be attained in the examinations to entitle the candidate 45 to receive a license to practice optometry. The examination shall be given at least semiannually if there are any candidates who have applied to 46 47 the Board for examination at least thirty 30 days before the date for the examination. The examination shall include anatomy; physiology; pathology; general and ocular pharmacology **48** designed to test knowledge of the proper use, characteristics, pharmacological effects, indications, 49 50 contraindications and emergency care associated with the use of diagnostic pharmaceutical agents; and 51 the use of the appropriate instruments.

The Board may determine a score which that it considers satisfactory on any written examination of 52 53 the National Board of Examiners in Optometry. The Board may waive its examination for a person who 54 achieves a satisfactory score on the examination of the National Board of Examiners in Optometry.

55 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 56 57 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 58 pharmaceutical agents. After June 30, 2004, every person who is initially licensed to practice optometry 59

HB856S1

Ŋ

ENAT

Ħ

SUBSTITUTE

2 of 4

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

§ 54.1-3221. "Diagnostic pharmaceutical agents" defined; utilization; acquisition. 61

62 A. Certified optometrists may administer diagnostic pharmaceutical agents only by topical application 63 to the human eye. "Diagnostic pharmaceutical agents" shall be defined as the following drugs in 64 strengths not to exceed those stated:

65 1. Mydriatics and cycloplegics known as tropicamide in a 1.0 percent solution, phenylephrine 66 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; 67

2. Anesthetic agents known as proparacaine hydrochloride in a 0.5 percent solution, tetracaine in a 68 0.5 percent solution and benoxinate hydrochloride in a 0.4 percent solution; 69 70

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 71 in the Drug Control Act (§ 54.1-3400 et seq.) that are used for the purpose of examining and 72 determining abnormal or diseased conditions of the human eye or related structures. 73

74 B. Any optometrist who utilizes diagnostic pharmaceutical agents without being certified as required 75 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 76 77 pharmaceutical agents upon presentation of evidence of Board certification for administration of such 78 drugs.

79 § 54.1-3222. TPA certification; certification for treatment of diseases or abnormal conditions with 80 therapeutic pharmaceutical agents.

- A. The Board shall certify an optometrist to prescribe for and treat certain diseases or abnormal 81 82 conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents, if the 83 optometrist files a written application, accompanied by the fee required by the Board and satisfactory 84 proof that the applicant:
- 85 1. Is licensed by the Board as an optometrist and certified to administer diagnostic pharmaceutical 86 agents pursuant to Article 4 (§ 54.1-3220 et seq.) of this chapter;

87 2. Has satisfactorily completed such didactic and clinical training programs for the treatment of diseases and abnormal conditions of the eve and its adnexa as are determined, after consultation with a 88 89 school or college of optometry and a school of medicine, to be reasonable and necessary by the Board 90 to ensure an appropriate standard of medical care for patients; and

91 3. Passes such examinations as are determined to be reasonable and necessary by the Board to ensure 92 an appropriate standard of medical care for patients.

B. TPA certification shall enable an optometrist to prescribe and administer, within his scope of 93 practice, Schedule III through VI controlled substances and devices as set forth in the Drug Control Act 94 95 (§ 54.1-3400 et seq.) to treat certain diseases and abnormal conditions of the human eye and its adnexa 96 as determined by the Board with certain therapeutic pharmaceutical agents specified by the Board, 97 within the following conditions:

98 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 99 Control Act (§ 54.1-3400 et seq.), which are appropriate to alleviate ocular pain and (ii) other Schedule 100 VI controlled substances as defined in § 54.1-3455 of the Drug Control Act appropriate to treat diseases 101 102 and abnormal conditions of the human eye and its adnexa.

103 2. Prescriptions for oral analgesics to relieve ocular pain shall be limited to dosages for no more than 104 seventy-two hours.

3. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in 105 106 § 54.1-3455 of the Drug Control Act.

43. Treatment of glaucoma shall require prior consultation with the patient's physician or other 107 108 appropriate physician, and shall exclude treatment of congenital and infantile glaucoma. Treatment of 109 angle closure glaucoma shall be limited to initiation of immediate emergency care. 110

54. Treatment of infantile or congenital glaucoma shall be prohibited.

5. Treatment through surgery or other invasive modalities shall not be permitted, except for treatment 111 112 of emergency cases of anaphylactic shock with intramuscular epinephrine, such as that included in a bee 113 sting kit.

114 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 115 116 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 117 118 pharmaceutical agents.

A. The Board shall promulgate such regulations governing the treatment of certain diseases and 119 120 abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents by 121 TPA-certified optometrists as are reasonable and necessary to ensure an appropriate standard of medical

HB856S1

Ŋ

125 In establishing standards of instruction and training, the Board shall consult with a school or college 126 of optometry and a school or college of medicine and shall set a minimum number of hours of clinical 127 training to be supervised by an ophthalmologist. The didactic and clinical training programs may 128 include, but need not be limited to, programs offered or designed either by schools of medicine or 129 schools or colleges of optometry or both or some combination thereof.

130 The Board may prepare, administer, and grade appropriate examinations for the certification of 131 optometrists to administer therapeutic pharmaceutical agents or may contract with a school of medicine, 132 school or college of optometry, or other institution or entity to develop, administer, and grade the 133 examinations.

134 In order to maintain a current and appropriate list of therapeutic pharmaceuticals on the 135 TPA-Formulary, current and appropriate treatment guidelines, and current and appropriate determinations 136 of diseases and abnormal conditions of the eye and its adnexa which that may be treated by 137 TPA-certified optometrists, the Board may, from time to time, amend such regulations. Such regulations 138 shall be exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq.), except to 139 any extent that they may be specifically made subject to §§ 2.2-4024, 2.2-4030, and 2.2-4031; the 140 Board's regulations shall, however, comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et 141 seq.). the Board shall, however, conduct a public hearing prior to making amendments to the 142 TPA-Formulary, the treatment guidelines or the determinations of diseases and abnormal conditions of 143 the eye and its adnexa which that may be treated by TPA-certified optometrists. Thirty days prior to 144 conducting such hearing, the Board shall give written notice by mail of the date, time, and place of the 145 hearing to all currently TPA-certified optometrists and any other persons requesting to be notified of the 146 hearings and publish notice of its intention to amend the list in the Virginia Register of Regulations. 147 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 148 149 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 150 151 Registrar of Regulations. The TPA-Formulary shall be the inclusive list of the therapeutic 152 pharmaceutical agents that a TPA-certified optometrist may prescribe.

153 B. To assist in the specification of the TPA-Formulary, there shall be a seven-member 154 TPA-Formulary Committee, as follows: three Virginia TPA-certified optometrists to be appointed by the 155 Board of Optometry, one pharmacist appointed by the Board of Pharmacy from among its licensees, two 156 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 157 by the Board of Medicine shall have demonstrated, through professional experience, knowledge of the 158 159 optometric profession. In the event the Board of Pharmacy or the Board of Medicine fails to make 160 appointments to the TPA-Formulary Committee within thirty30 days following July 1, 1996the Board of Optometry's requesting such appointments, or within thirty 30 days following any subsequent vacancy, 161 162 the Board of Optometry shall appoint such members.

163 The TPA-Formulary Committee shall recommend to the Board those therapeutic pharmaceutical 164 agents to be included on the TPA-Formulary for the treatment of certain diseases and abnormal 165 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 purposesonly.

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.

175 For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a 176 practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for 177 a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide 178 practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history 179 is obtained; (ii) provide information to the patient about the benefits and risks of the drug being 180 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 181 may be transmitted electronically; except for medical emergencies, the examination of the patient shall 182

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 whichthat 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.

196 No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship.197 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.

211 F. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to 212 Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title may issue prescriptions in good faith or 213 provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within 214 the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant 215 to § 54.1-3223, which shall be limited to (i) oral analgesics included in Schedules III and through VI, as 216 defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), when which are 217 appropriate to relieve ocular pain, and (ii) other oral Schedule VI controlled substances, as defined in 218 § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the 219 human eye and its adnexa, (iii) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the 220 Drug Control Act, and (iv) intramuscular administration of epinephrine for treatment of emergency 221 cases of anaphylactic shock.

222 2. That the Board of Optometry shall promulgate regulations to implement the provisions of this 223 act to be effective within 280 days of its enactment.