25100364D

SENATE BILL NO. 1081

Offered January 8, 2025

Prefiled January 7, 2025

A BILL to amend and reenact §§ 54.1-3222, 54.1-3223, 54.1-3301, and 54.1-3303 of the Code of Virginia, relating to Optometry; TPA-Formulary; TPA-Formulary Committee; dissolution.

Patron—Hashmi

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3222, 54.1-3223, 54.1-3301, and 54.1-3303 of the Code of Virginia are amended and reenacted as follows:

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

TPA certification shall enable an optometrist to prescribe and administer, within his scope of practice, Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedules III through VI controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) to treat diseases and abnormal conditions of the human eye and its adnexa as determined by the Board, within the following conditions:

1. Treatment with oral therapeutic pharmaceutical agents shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen, and analgesics included on Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act, 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. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.).

3. Administration of therapeutic pharmaceutical agents by injection shall be limited to the treatment of chalazia by means of injection of a steroid included in Schedule VI controlled substances as set forth in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.). A TPA-certified optometrist shall provide written evidence to the Board that he has completed a didactic and clinical training course provided by an accredited school or college of optometry that includes training in administration of TPAs by injection prior to administering TPAs by injection pursuant to this subdivision.

4. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care.

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

6. Treatment through surgery or other invasive modalities shall not be permitted, except as provided in subdivision 3 or for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine.

7. 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 therapeutic pharmaceutical agents.

~~A.~~ The Board shall promulgate such regulations governing the treatment of diseases and abnormal conditions of the human eye and its adnexa with 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 that may be treated by TPA-certified optometrists~~,~~ *and* treatment guidelines~~, and the drugs specified on the TPA-Formulary~~.

~~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 that may be treated by TPA-certified optometrists, the Board may, from time to time, amend such regulations.~~ Such regulations *and amendments thereto* 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 that may be treated by TPA-certified optometrists. Thirty days prior to conducting such hearing, the Board shall give written notice by mail or electronic means 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~~ *regulations* 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 30 days following the Board of Optometry's requesting such appointments, or within 30 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 diseases and abnormal conditions of the eye and its adnexa by TPA-certified optometrists.~~

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

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

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

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

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

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

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

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

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

9. Interfere with any licensed advanced practice registered nurse with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe;

10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription

drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

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

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

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

§ 54.1-3303. 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, a licensed advanced practice registered nurse pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32.

B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship. If a practitioner is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, then a bona fide practitioner-patient relationship shall not be required.

A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be 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; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances

to that patient via telemedicine if such prescribing is in compliance with federal requirements for the practice of telemedicine and, in the case of the prescribing of a Schedule II through V controlled substance, the prescriber maintains a practice at a physical location in the Commonwealth or is able to make appropriate referral of patients to a licensed practitioner located in the Commonwealth in order to ensure an in-person examination of the patient when required by the standard of care.

A prescriber may establish a bona fide practitioner-patient relationship for the purpose of prescribing Schedule II through VI controlled substances by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations; (h) the establishment of a bona fide practitioner-patient relationship via telemedicine is consistent with the standard of care, and the standard of care does not require an in-person examination for the purpose of diagnosis; and (i) the establishment of a bona fide practitioner patient relationship via telemedicine is consistent with federal law and regulations and any waiver thereof. Nothing in this paragraph shall apply to (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

C. A prescription shall only be issued for a medicinal or therapeutic purpose in the usual course of treatment or for authorized research. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription. A practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than for medicinal or 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.

D. No prescription shall be filled unless a bona fide practitioner-patient-pharmacist relationship exists. A bona fide practitioner-patient-pharmacist relationship shall exist in cases in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to a patient for a medicinal or therapeutic purpose within the course of his professional practice.

In cases in which it is not clear to a pharmacist that a bona fide practitioner-patient relationship exists between a prescriber and a patient, a pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed.

Any 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.

E. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe

Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, with the diagnosed patient and (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.

F. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, an advanced practice registered nurse, or a physician assistant authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).

G. A licensed advanced practice registered nurse 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 the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

H. 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 the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

I. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 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) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III 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 relieve ocular pain; (iii) 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; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

J. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

K. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.