Virginia Department of
Health Professions
Board of Optometry

Agenda
Virginia Board of Optometry
TPA-Formulary Committee Meeting

August 19, 2019
Board Room 3
1:00 p.m.

Call to Order – Fred E. Goldberg, O.D., Chair
- Welcome
- Emergency Egress Procedures

Introductions – Dr. Goldberg

Ordering of Agenda – Dr. Goldberg

Public Comment – Dr. Goldberg
The Board will receive all public comment related to agenda items at this time. The Board will not receive comment on any regulatory process for which a public comment period has closed or any pending or closed complaint or disciplinary matter.

Discussion Items – Elaine Yeatts/Leslie Knachel **Page 2-13**
Exclusion of Schedule V Controlled Substances from TPA-Formulary (18VAC105-20-47(B))

New Business – Dr. Goldberg

Meeting Adjournment – Dr. Goldberg

This information is in **DRAFT** form and is subject to change.

Regulations of the Virginia Board of Optometry

18VAC105-20-46. Treatment guidelines for TPA certified optometrists.

A. TPA-certified optometrists may treat diseases and abnormal conditions of the human eye and its adnexa which may be treated with medically appropriate pharmaceutical agents as referenced in 18VAC105-20-47. The adnexa is defined as conjoined, subordinate or immediately associated anatomic parts of the human eye, including eyelids and eyebrows.

B. In addition, the following may be treated:

1. Glaucoma (excluding the treatment of congenital and infantile glaucoma). Treatment of angle closure shall follow the definition and protocol prescribed in subsection C of this section.

2. Ocular-related post-operative care in cooperation with patient's surgeon.

3. Ocular trauma to the above tissues as in subsection A of this section.

4. Uveitis.

5. Anaphylactic shock (limited to the administration of intramuscular epinephrine).

C. The definition and protocol for treatment of angle closure glaucoma shall be as follows:

1. As used in this chapter, angle closure glaucoma shall mean a closed angle in the involved eye with significantly increased intraocular pressure, and corneal microcystic edema.

2. Treatment shall be limited to the initiation of immediate emergency care with appropriate pharmaceutical agents as prescribed by this chapter;

3. Once the diagnosis of angle closure glaucoma has been established by the optometrist, the ophthalmologist to whom the patient is to be referred should be contacted immediately;

4. If there are no medical contraindications, an oral osmotic agent may be administered as well as an oral carbonic anhydrase inhibitor and any other medically accepted, Schedule III, IV or VI, oral antiglaucomic agent as may become available; and

5. Proper topical medications as appropriate may also be administered by the optometrist.

D. An oral Schedule VI immunosuppressive agent shall only be used when 1) the condition fails to appropriately respond to any other treatment regimen; 2) such agent is prescribed in consultation with a physician; and 3) treatment with such agent includes monitoring of systemic effects.

18VAC105-20-47. Therapeutic pharmaceutical agents.

A. A TPA-certified optometrist, acting within the scope of his practice, may procure, administer and prescribe medically appropriate therapeutic pharmaceutical agents (or any therapeutically appropriate combination thereof) to treat diseases and abnormal conditions of the human eye and its adnexa within the following categories:

1. Oral analgesics - Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedule III, IV and VI narcotic and nonnarcotic agents.

2. Topically administered Schedule VI agents:

a. Alpha-adrenergic blocking agents;

b. Anesthetic (including esters and amides);

c. Anti-allergy (including antihistamines and mast cell stabilizers);

d. Anti-fungal;

e. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

f. Anti-infective (including antibiotics and antivirals);

g. Anti-inflammatory;

h. Cycloplegics and mydriatics;

i. Decongestants; and

j. Immunosuppressive agents.

3. Orally administered Schedule VI agents:

a. Aminocaproic acids (including antifibrinolytic agents);

b. Anti-allergy (including antihistamines and leukotriene inhibitors);

c. Anti-fungal;

d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

e. Anti-infective (including antibiotics and antivirals);

f. Anti-inflammatory (including steroidal and nonsteroidal);

g. Decongestants; and

h. Immunosuppressive agents.

B. Schedule I, II and V drugs are excluded from the list of therapeutic pharmaceutical agents.

C. Over-the-counter topical and oral medications for the treatment of the eye and its adnexa may be procured for administration, administered, prescribed or dispensed.

Optometry Specific Statutes

§ 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 diseases or abnormal conditions of the human eye and its adnexa with therapeutic pharmaceutical agents (TPAs), 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.);

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, 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.

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.

1996, cc. 152, 158; 2004, c. 744; 2015, c. 355; 2018, c. 280.

§ 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 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, 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 that 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 that 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 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.

(1996, cc. 152, 158; 2004, c. 744.)

§ 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.

(1996, cc. 152, 158.)

Drug Control Act

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

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;

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;

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. (Effective until July 1, 2020) 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.

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.

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. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department and is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, the examination required by clause (iii) shall not be required.

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, provided that, in cases in which the practitioner has performed the examination required pursuant to clause (iii) by use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship 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; and (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. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. 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.

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.

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; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, for the close contact except for the physical examination required in clause (iii) of subsection B; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability. 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, a nurse practitioner, 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.).

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.

§ 54.1-3401. (Effective until July 1, 2020) Definitions.

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

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

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or 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 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

§ 54.1-3453. Placement of substance in Schedule V.

The Board shall place a substance in Schedule V if it finds that:

1. The substance has low potential for abuse relative to the controlled substances listed in Schedule IV;

2. The substance has currently accepted medical use in treatment in the United States; and

3. The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

§ 54.1-3454. Schedule V.

The controlled substances listed in this section are included in Schedule V:

1. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter and such substances so excepted may be dispensed pursuant to § 54.1-3416.

2. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Pyrovalerone.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB-34714; Briviact);

Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester]-2779;

Gabapentin [1-(aminomethyl)cyclohexaneacetic acid];

Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide];

Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].