Virginia Department of Health Professions
Board of Optometry

# Agenda
**Virginia Board of Optometry**
**Full Board Meeting**

**October 16, 2020**
**Board Room 4**
**10:30 a.m.**

**Call to Order – Fred E. Goldberg, O.D., Board President**
- Welcome
- Emergency Egress Procedures
- Mission Statement

**10:35 a.m. Public Hearing – Dr. Goldberg** **Pages 2-6**
To receive public comments on the proposed changes to the *Regulations of the Virginia Board of Optometry* to add alpha-adrenergic agonists the TPA formulary.

**Public Hearing Adjournment – Dr. Goldberg**

**Business Meeting of the Board**

**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.

**Approval of Minutes – Dr. Goldberg** **Pages 7-17**
- July 13, 2020 – Virtual Board Member Training
- July 17, 2020 – Virtual Full Board Meeting
- September 14, 2020 – Virtual TPA Formulary Committee Meeting

**Director's Report – Dr. Barbara Allison-Bryan**

**Regulatory Actions – Elaine Yeatts** **Pages 18-23**
- Adoption of Proposed Regulations for Waiver of Electronic Prescribing (pages 19-20; action required)
- Repeal of 18VAC105-20-50. Professional Designations (effective 10/29/2020)
- Adoption of Exempt Action on Addition to the TPA-Formulary (pages 21-23; action required)

**Discussion Items** **Pages 24-41**
- Amendments to the Federal Contact Lens Rule (effective 10/16/2020) – **Leslie Knachel**

**Board Counsel Report – Charis Mitchell**

**President's Report – Dr. Goldberg**

**Board of Health Professions Report – Dr. Clayton-Jeter**

**Staff Reports** **Pages 42-45**
- Executive Director's Report – **Leslie Knachel**
  - Statistics (page 42-44)
  - Outreach – TPA Formulary Notification
  - NBEO Update (page 45)
- Discipline Report – **Kelli Moss**

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| **New Business** – **Dr. Goldberg** |
| **Next Meeting –** February 12, 2021 |
| **Meeting Adjournment – Dr. Goldberg** |

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

Virginia Department of Health Professions
Board of Optometry

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# MISSION STATEMENT

Our mission is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.

**BOARD OF OPTOMETRY**

**Addition to TPA formulary**

**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. Alpha-adrenergic agonists;

~~b.~~c. Anesthetic (including esters and amides);

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

~~d.~~e. Anti-fungal;

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

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

~~g.~~h. Anti-inflammatory;

~~h.~~i Cycloplegics and mydriatics;

~~i.~~j. Decongestants; and

~~j.~~k. 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 with the exception of controlled substances in Schedule II consisting of hydrocodone in combination with acetaminophen and gabapentin in Schedule V.

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.

Virginia Society of Eye Physicians and Surgeons

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*EYE MDs of VIRGINIA*

September 29, 2020

Virginia Board of Optometry
Attention: Leslie Knachel, Executive Director

Members of the Board of Optometry:

Dr. Nicole Langelier and I were appointed by the Board of Medicine to serve on the Board of Optometry's TPA Formulary Committee, which held a virtual meeting on September 14, 2020. As the committee's ophthalmologist members and on behalf of the Virginia Society of Eye Physicians and Surgeons (VSEPS), we submit the following comment to support and augment the committee's discussion and the Board of Optometry's deliberations. VSEPS applauds the work of the committee and supports its decision to recommend the addition of alpha-adrenergic agonists, to include the drug Upneeq, to the TPA Formulary.

In addition, we support and emphasize the remarks made by Dr. Langelier during the meeting in regard to drug and patient safety concerns, specifically with the condition ptosis and the prescribing of drugs like Upneeq to treat ptosis. Dr. Langelier outlined Upneeq's package insert and highlighted possible contraindications. She stressed that the etiology of ptosis needs to be definitively determined, as it could be due to a serious or life-threatening condition if left untreated.

**Drug Indications and Precautions**
Upneeq can be absorbed systemically. The package insert provides warnings and precautions surrounding cardiovascular disease and vascular insufficiency as well as potential drug interactions. The medication cannot be used in patients with anatomically narrow angles as it may cause pupillary dilation and induce angle closure glaucoma.

**Causes of Ptosis – Involutional, Myogenic, Neurogenic, Mechanical, Traumatic**
There are many causes of ptosis. It is crucial to understand the etiology of an individual patient's ptosis, as it may be life threatening.

Ptosis may be involutional, or natural "wear and tear," from age, contact lens use, sleeping on one side, or prior eye surgery. Involutional ptosis is commonly seen after intraocular surgery due to the stress of the speculum on the levator muscle, as well as the effect of topical prednisolone. Involutional ptosis is the most common cause of ptosis, and Upneeq may be helpful for patients with mild involutional ptosis.

Ptosis may be myogenic, a problem inherent to muscle tissue, which may or may not be isolated the orbital anatomy. Mitochondrial myopathies such as chronic progressive external ophthalmoplegia (CPEO) can cause ptosis. CPEO can also be associated with heart conditions that can be deadly if not diagnosed and treated.

Most seriously, ptosis can be caused by a neurologic problem such as a third nerve palsy, Horner's syndrome, or myasthenia gravis. One possible cause of a third nerve palsy is a posterior communicating artery (PCOM) aneurysm. The traditional "triad" is blown pupil, ptosis, and a "down and out" eye with poor motility accompanied by headache. In reality, the limitation of motility can be subtle and the pupil may not

be involved until very late in the presentation (i.e., after loss of consciousness from a ruptured aneurysm). When it ruptures, mortality is very high and thus this is considered an emergent clinical finding.

Horner's syndrome arises from damage to the nerves in the sympathetic trunk of the head and neck, and can cause ptosis, miosis, and anhidrosis. Extremely serious or fatal conditions can cause Horner's syndrome, such as carotid artery dissection, lung cancer, and brain tumors. However, the presentation of Horner's syndrome can be very subtle because it affects the Mullers muscle of the eyelid, which is the weaker of the two eyelid opening muscles. Ptosis may be quite mild and the pupil asymmetry can be missed if not checked in a dark room. *Due to denervation supersensitivity, a patient with Horner's will respond well to Upneeq and may not seek additional medical care or have their underlying condition diagnosed or treated.*

Myasthenia gravis is an autoimmune disease that attacks the acetylcholine receptors, resulting in neuromuscular weakness. It can cause ptosis, double vision, generalized weakness, and difficulty swallowing or difficulty breathing. Ptosis is often the earliest symptom, so early identification and treatment is important to prevent complications of the disease. Aspiration pneumonia from difficulty swallowing and respiratory complications can be fatal. Specific exams and testing, such as in-office levator excursion measurements, fatigability of the muscle, and ice testing can be performed. Lab tests are not always accurate, so if there is a high suspicion of the condition but the patient is still testing negative, neurology consultation is warranted.

Other concerning causes of ptosis include orbital malignancy. While other orbital signs such as proptosis, motility restriction, and double vision may be present, ptosis may be the presenting sign. Orbital malignancy without orbital signs is seen in invasive and infiltrative tumor types including malignancies with perineural spread such as lymphoma, squamous cell carcinoma, and some primary lacrimal gland malignancies. Lymphoma is a common orbital malignancy that can invade the levator muscle and cause ptosis with decreased levator function without other clinical findings on exam.

**Recommendations for Prescribing Upneeq**

Upneeq is appropriate for a patient with *mild involutional* ptosis. Any other cause of ptosis needs to be identified and managed appropriately. Patients with moderate to severe involutional ptosis (upper eyelid margin to light reflex distance of 2mm or less (MRD1≤2) that also affects daily function such as ability to read or drive will likely qualify for insurance coverage of surgical ptosis repair. This is a common outpatient surgery done by an oculoplastic surgeon, and it typically has minimal discomfort and relatively quick and easy recovery. This surgery, which is often covered by health insurance, should be recommended first instead of Upneeq, a new drug not likely currently covered by insurance, for moderate to severe involutional ptosis. If the patient elects to forego surgery after being fully informed about the procedure, including the risks and benefits of surgery, Upneeq may be a good option.

Patients with concerning features including anisocoria, motility deficits, double vision, headache, pain, eyelid swelling, or sudden onset ptosis should be referred to ophthalmology immediately or referred to urgent imaging as appropriate.

Virginia Society of Eye Physicians and Surgeons

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*EYE MDs of VIRGINIA*

**Board of Optometry Guidance and Education**
*Given the serious drug and patient safety concerns associated with Upneeq and ptosis as described above, VSEPS strongly recommends that the Board of Optometry offer prescribing guidance and education to licensees in conjunction with the addition of Upneeq to the TPA Formulary.*

VSEPS stands ready to assist in the development of such guidance and education.

We thank you for the opportunity to serve on the TPA Formulary Committee and for your attention and consideration.

Sincerely,

Michael Keverline, MD
President, VSEPS

Cc: Dr. William Harp, MD, Virginia Board of Medicine
Caroline Juran, Virginia Board of Pharmacy
Nicole Langelier, MD, MBE
Mark Hickman and Cal Whitehead, Commonwealth Strategy Group

**BOARD OF OPTOMETRY**
**WEBEX TRAINING SESSION**
**July 13, 2020**

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| **TIME AND PLACE:** | The Virginia Board of Optometry (Board) WebEx training meeting was virtually called to order at 2:01 p.m. |
| **PRESIDING OFFICER:** | Fred E. Goldberg, O.D. President |
| **MEMBERS PRESENT:** | Lisa Wallace-Davis, O.D. Vice-President<br>Steven A. Linas, O.D.<br>Clifford A. Roffis, O.D. |
| **MEMBERS NOT PRESENT:** | Devon Cabot, Citizen Member<br>Helene Clayton-Jeter, O.D. |
| **STAFF PRESENT:** | Leslie L. Knachel, Executive Director<br>Kelli Moss, Deputy Executive Director<br>Charis Mitchell, Assistant Attorney General, Board Counsel<br>Anthony C. Morales, Operations Manager<br>Celia Wilson - Administrative Assistant<br>Me-Lien Chung, Discipline Case Specialist<br>Matt Treacy – Media Production Specialist |
| **QUORUM:** | With four members of the Board present, a quorum was established. |
| **CALL TO ORDER:** | Ms. Knachel welcomed the participants to the training session and took roll call |
| **TRAINING SESSION:** | Celia Wilson, Matt Treacy and Ms. Knachel went over the expectations and procedures for the upcoming virtual board meeting to be conducted on July 17, 2020. |
| **ADJOURNMENT:** | The meeting adjourned at 2:24 p.m. |

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Fred Goldberg, O.D.
Chair

Leslie L. Knachel, M.P.H.
Executive Director

**BOARD OF OPTOMETRY**
**VIRTUAL FULL BOARD MEETING**
**JULY 17, 2020**

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|---|---|
| **TIME AND PLACE:** | The Virginia Board of Optometry (Board) meeting was called to order at 9:01 a.m. |
| **PRESIDING OFFICER:** | Fred E. Goldberg, O.D. President (On-Site) |
| **MEMBERS PARTICIPATING ON-SITE:** | Steven A. Linas, O.D. |
| **MEMBERS PARTICIPATING VIRTUALLY:** | Lisa Wallace-Davis, O.D. Vice-President<br>Devon Cabot, Citizen Member<br>Helene Clayton-Jeter, O.D.<br>Clifford A. Roffis, O.D. |
| **MEMBERS NOT PRESENT:** | All Members were present. |
| **STAFF PRESENT ON-SITE:** | Leslie L. Knachel, Executive Director<br>Kelli Moss, Deputy Executive Director<br>Celia Wilson, Administrative Assistant<br>Matt Treacy, Media Production Specialist |
| **STAFF PARTICIPATING VIRTUALLY:** | David Brown, D.C., Agency Director<br>Charis Mitchell, Assistant Attorney General, Board Counsel<br>Elaine Yeatts, Senior Policy Analyst<br>Barbara Allison-Bryan, M.D., Agency Deputy Director<br>Anthony C. Morales, Operations Manager<br>Tamara Farmer, Administrative Assistant<br>Yetty Shobo, Deputy Executive Director, Healthcare Workforce Data Center<br>Me-Lien Chung, Discipline Case Specialist |
| **OTHERS PRESENT:** | Bo Keeney, Virginia Optometric Association<br>Christine Markus, King and Spalding, LLC<br>Robert Bohannon |
| **CALL TO ORDER QUORUM** | Dr. Goldberg welcomed attendees and requested that Ms. Knachel take a roll call of the board members present. With six members of the Board present, a quorum was established. Ms. Knachel introduced new staff member, Me-Lien Chung, Disciplinary Case Specialist. Dr. Goldberg read the Board's mission statement. |
| **ORDERING OF AGENDA:** | There were no changes to the agenda |
| **PUBLIC COMMENT:** | There was no public comment. |
| **APPROVAL OF MINUTES:** | Dr. Linas moved to approve the meeting minutes for the February 7, 2020 - Full Board Meeting. |

The motion was properly seconded. A roll call vote was taken. The motion carried with an unanimous aye vote.

**DIRECTOR'S REPORT:**

Dr. Brown reported on agency measures to ensure the safety of agency staff and other individuals in the building during the COVID-19 pandemic and to keep the boards functioning in a telework environment.

**LEGISLATIVE/REGULATORY UPATE:**

**2020 Legislative/Regulatory Update**

Ms. Yeatts presented the following information to the Board:

- 2020 legislative session overview
- Consideration of Board recommendation for resubmission of clean-up bill for Chapter 32, Optometry Law.

  The Board discussed the need for the proposed legislation.

  Ms. Cabot moved to resubmit the proposed legislation as presented for the 2021 legislative session..

  The motion was properly seconded. A roll call vote was taken.

  The motion carried with an unanimous aye vote.

- HB 967 – Consideration of any waiver of experience requirements for the spouse of an active duty military or veteran

  The Board discussed the options for addressing the waiver.

  Dr. Linas moved to delegate decisions related to waiver requests to be handled on a case-by case basis by the Executive Director in consultation with the Board's President.

  The motion was properly seconded. A roll call vote was taken.

  The motion carried with an unanimous aye vote.

  Dr. Linas requested that legislation related to sending an email to notify patients of transfer or medical records when closing or relocating. Ms. Yeatts indicated that this applied to all boards within DHP and consideration would be given for resubmission.

- Regulations for E-prescribing waiver is under view by the administration.
- Repeal of regulations for Professional Designation is under review by administration.
- Regulations for handling fees became effective on 03/05/2020
- Regulations for inactive licenses became effective on 03/04/2020
- Petition for Rulemaking – Consideration of Haine petition to restrict number of contact lenses per prescription.

  The Board discussed the petition.

Ms. Cabot moved to reject the petition for rulemaking because the Board concurred with the comment from the National Association of Optometrists and Opticians that it is contrary to the spirit of Federal Trade Commission law and rules and the regulation would be very difficult to monitor or enforce.

The motion was properly seconded. A roll call vote was taken.

The motion carried with an unanimous aye vote.

- Federal Contact Lens Rule amendments are in process of being finalized, but are not yet effective. Once effective the Board may need to take regulatory action to include the changes. This topic will be included on the agenda for the next board meeting.

**DISCUSSION ITEMS:**

**Healthcare Workforce Data Center (HWDC) Presentation**
Dr. Shobo presented the results of the HWDC's 2020 survey of Virginia's optometrists.

Dr. Clayton-Jeter moved to accept the HWDC data as presented by Dr. Shobo.

The motion was properly seconded. A roll call vote was taken.

The motion carried with an unanimous aye vote.

**Continuing Education (CE)**
Ms. Knachel requested that the Board consider not conducting a CE audit of licensees for the licensure period of January 1, 2019 – March 31, 2020, so that staff resources could be focused on the current discipline caseload.

Dr. Linas moved to not conduct a CE audit of licensees for the licensure period of January 1, 2019 – March 31, 2020.

The motion was properly seconded. A roll call vote was taken.

The motion carried with an unanimous aye vote.

Ms. Knachel stated that she has received numerous inquiries about whether the Board will change any of its current CE requirements because of the COVID-19 pandemic. The consensus of the Board is that it is too early in the licensure period to make changes and there are opportunities for licensees to attend online courses where the licensee and the lecturer may communicate with one another as required by the regulations.

No action was initiated at this time, but the Board asked for this issue to be placed on the next agenda for further consideration.

Ms. Knachel presented a draft Telepractice Guidance Document for the Board's consideration.

The Board discussed the guidance document.

Dr. Wallace-Davis moved to accept the guidance document as submitted.

The motion was properly seconded. A roll call vote was taken.

The motion carried with an unanimous aye vote.

**BOARD COUNSEL REPORT:** Ms. Mitchell provided a general update of the Attorney General's office and the effects of the pandemic.

**PRESIDENT'S REPORT:** Dr. Goldberg reported provided a report on the effects of the pandemic on optometry practice. Additionally, he provided comments on attending the Association of Regulatory Boards of Optometry's virtual meeting.

**BOARD OF HEALTH PROFESSION'S REPORT:** Dr. Clayton-Jeter reported the activities of the Board of Health Professions.

**ASSOCIATION OF REGULATORY BOARDS ANNUAL MEETING REPORT:** Dr. Goldberg included his comments during the President's Report.

**STAFF REPORTS:**

**Executive Director's Report**

Ms. Knachel reported on the following:

- Licensee Statistics
- E-Prescribing Waiver Requests
- Outreach activities
- Updated licensing forms
- Board calendar for 2021

**Discipline Report**

Ms. Moss provided an overview of the discipline caseload.

**NEW BUSINESS:**

**Elections**

Dr. Goldberg asked for nominations for President of the Board.

Dr. Linas moved to nominate Dr. Goldberg for President.

The motion was properly seconded. No other nominations were received. A roll call vote was taken.

The motion carried with an unanimous aye vote.

Dr. Goldberg asked for nominations for Vice-President of the Board.

Dr. Wallace-Davis moved to nominate Ms. Cabot for Vice-President.

The motion was properly seconded. No other nominations were received. A roll call vote was taken.

The motion carried with an unanimous aye vote.

Dr. Goldberg asked if there was any other new business. Ms. Knachel requested the Board consider an inquiry that was received the day before the meeting regarding a newly approved drug named UPneeq. The Board discussed whether this drug could be prescribe under current regulations. Ms. Mitchell indicated that there is a statutory process to determine what is included in the TPA-Formulary and following this process will allow for adequate research and public comment. Ms. Knachel asked the Board to consider convening the TPA-Formulary Committee to review the drug and make recommendations to the Board.

The Board discussed the issue.

Dr. Clayton-Jeter moved to convene the TPA-Formulary Committee to review the existing structure of the formulary. The motion was not seconded. After further discussion, Dr. Clayton-Jeter withdrew her previous motion.

Dr. Clayton-Jeter moved to convene the TPA-Formulary Committee to review 18VAC105-20-47(A)(2), Topically Administered Schedule VI Agents, of the regulations and make recommendations to the Board at its next meeting.

The motion was properly seconded. A roll call vote was taken. The motion carried with an unanimous aye vote.

**NEXT MEETING:** Dr. Goldberg stated that the next board meeting is scheduled for October 16, 2020.

**ADJOURNMENT:** The meeting adjourned at 12:08 p.m.

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Fred Goldberg, O.D.
Chair

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Leslie L. Knachel, M.P.H.
Executive Director

**BOARD OF OPTOMETRY**
**VIRTUAL TPA FORMULARY COMMITTEE**
**MEETING MINUTES**
**September 14, 2020**

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| **TIME AND PLACE:** | A virtual meeting via Webex of the TPA Formulary Committee, (Committee) meeting was called to order at 1:00 p.m. |
| **PRESIDING OFFICER:** | Fred Goldberg, O.D. (Virtual Participation) |
| **MEMBERS PARTICIPATING ONSITE:** | Steven Linas, O.D. |
| **MEMBERS PARTICIPATING VIRTUALLY:** | Michael Keverline, M.D.<br>Nicole Langelier, M.D.<br>Cheryl Nelson, Pharmacist<br>Jonathan Noble, O.D.<br>Lisa Wallace-Davis, O.D. |
| **OTHERS PRESENT VIRTUALLY:** | Mark Hickman, Virginia Society of Eye Physicians and Surgeons<br>Christina Markus, King & Spalding<br>Caitlyn Ozier, King & Spalding<br>David Jacobs, M.D. Medical Director, Osmotica |
| **STAFF PARTICIPATING ONSITE:** | Leslie L. Knachel, Executive Director<br>Elaine Yeatts, Senior Policy Analyst<br>Amy Davis, Executive Assistant<br>Celia Wilson, Operations Administrative Assistant<br>Me-Lien Chung, Discipline Case Specialist |
| **STAFF PARTICIPATING VIRTUALLY:** | Kelli Moss, Deputy Executive Director |
| **ORDERING OF AGENDA:** | No changes or additions were made to the agenda. |
| **PUBLIC COMMENT:** | Ms. Knachel read the written comment submitted by Commonwealth Eye Care Associates in support of optometrists being able to prescribe supporting approval of the oxymetazoline hydrochloride. (See Attachment A)<br><br>Christina Markus, regulatory lawyer from King & Spalding presented oral comment asking the TPA-Formulary Committee to recommend to the Board of Optometry a regulatory amendment that will allow the Board to agree that UPNEEQ is legally appropriate for optometrists to prescribe to their patients. (See Attachment B) |
| **DISCUSSION ITEMS:** | Ms. Knachel reviewed the information from the minutes of the July 17, 2020, Board of Optometry meeting which voted to convene the TPA-Formulary Committee to review 18VAC-105-20-47(A)(2) of the Regulations of the Virginia Board of Optometry, Topically Administered Schedule VI Agents and make recommendations to the Board at its next meeting scheduled for October 16, 2020. |

The Board discussed the addition of alpha-adrenergic agonists to the TPA-Formulary.

Dr. Wallace-Davis moved to add Alpha-adrenergic agonists to the regulations as item (b) of 18VAC-105-20-47(A)(2). The motion was properly seconded by Dr. Noble.

A roll call vote was taken by Ms. Knachel. The motion carried with an unanimous aye vote.

**NEXT STEPS:** Dr. Goldberg reviewed the next steps required Pursuant to §54.1-3223 of the *Code of Virginia*.

**ADJOURNMENT:** The meeting adjourned at 1:34 p.m.

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Fred Goldberg, O.D.. Leslie L. Knachel, M.P.H

Committee Chair Executive Director

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Date Date

Attachment A

# Commonwealth Eye Care Associates


**Dr. Andrew J. Michael, MD**
*Ophthalmic Consultation and Co-Management*
*Glaucoma Consultation & Surgery*
*Cataract Surgery*

**Dr. Shawn H. Hobbs, OD**
*Comprehensive Consultation and Co-Management*
*Treatment of Eye Diseases*
*Pre and Post Surgical Care*

**Dr. Joseph D Iuorno, MD**
*Ophthalmic Consultation and Co-Management*
*Cornea Consultation & Surgery*
*Refractive Consultation & Surgery*

**Dr. Tami A. Flowers, MD**
*Ophthalmic Consultation and Co-Management*
*Cataract Surgery*
*External Disease*

**Dr. Meredith L. Diehl, MD**
*Ophthalmic Consultation and Co-Management*
*Ophthalmic Neurological Consultation*

**Dr. Jonathan R. Noble, OD**
*Comprehensive Consultation and Co-Management*
*Treatment of Eye Diseases*
*Pre and Post Surgical Care*

**Dr. Drew D. Munro, MD**
*Ophthalmic Consultation and Co-Management*
*Oculoplastic Consultation & Surgery*
*Orbital & Reconstructive Surgery*

**Dr. Matthew T. Young, MD**
*Ophthalmic Consultation and Co-Management*
*Glaucoma Consultation & Surgery*
*Cataract Surgery*

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Virginia Board of Optometry TPA
Committee

September 11, 2020

RE: 0.1% Oxymetazoline HCL solution (Trade name: Upneeq)
Public Comment

Dear Madams and Sirs:
Thank you for soliciting written public comment in anticipation of your Committee's consideration related to this novel formulation of oxymetazoline. Our ophthalmic practice in Central Virginia has specialized in referral care of the full range of ocular pathology for the past 20 years. We receive referrals from over 120 actively practicing Doctors of Optometry, as well as other ophthalmologists and medical practitioners in many disciplines, who see patients in our region and beyond. As a result, we are well-qualified to comment on what is within the reasonable scope of knowledge and practice of optometrists in the Commonwealth of Virginia.

We strongly support approving this formulation of oxymetazoline (Upneeq) for prescription use by Doctors of Optometry. This medication, available in other strengths and formulations, for other indications, is already available over the counter, without prescription, and is often recommended to patients by optometrists and other doctors. This medication has an excellent safety profile. It is well within the purview of optometry and already within their scope of practice to be familiar with this medication. Patients will benefit from their optometrist having the ability to prescribe this medication when indicated. We are fully in favor of your approving this medication for prescription use and management of indicated conditions by Doctors of Optometry in the Commonwealth of Virginia.

Please contact our practice directly if you have questions or if we can be of further assistance.

Respectfully submitted,

Doctors Andrew J. Michael, MD and Joseph D. Iuorno, MD
Commonwealth Eye Care Associates, PC

**Attachment B**

My name is Chris Markus, and I am a regulatory lawyer with the law firm King & Spalding. I am here today representing Osmotica Pharmaceuticals and its affiliated company RVL Pharmaceuticals.

In July 2020, the companies received FDA approval of a new drug product bearing the brand name UPNEEQ™ and the generic name oxymetazoline hydrochloride solution, 0.1%. This product is a locally-acting, topical eyedrop that FDA approved for the treatment of acquired blepharoptosis – also called ptosis or droopy eyelid – in adults. The FDA approval letter and product prescribing information have been included in your briefing materials for today. Essentially, UPNEEQ interacts with the Mueller muscle in the eyelid, and causes the lid muscle to contract and the eyelid to raise – opening the field of vision for affected patients. UPNEEQ is approved for administration once each day to the affected eye or eyes. Before the approval of this product, the primary treatment available for acquired blepharoptosis was surgery.

On the line with me today is David Jacobs, M.D., who served as the Medical Director for Osmotica and RVL Pharmaceuticals during the time the pivotal clinical trials were conducted to demonstrate the safety and effectiveness of UPNEEQ. These trials supported FDA's approval, and Dr. Jacobs can address any questions that the TPA-Formulary Committee may have concerning UPNEEQ or its safety or efficacy profile in patients.

We appreciate your attention today to this first-in-class drug approval to treat acquired blepharoptosis in adults.

We recently asked the Virginia Board of Optometry to affirm that UPNEEQ is within the scope of prescribing authority for qualified Virginia optometrists. The governing statute for the practice of optometry (Va. Code § 54.1-3222.B.) states that: "TPA certification shall enable an optometrist to prescribe and administer … Schedules III through VI controlled substances … to treat diseases and abnormal conditions of the human eye and its adnexa as determined by the Board, within the following conditions: …2. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act…."

However, the regulation that you are reviewing today establishes limitations – via the exclusive enumeration of covered categories – that does not appear currently broad enough to recognize UPNEEQ. Some of the categories are defined by mechanism of action; for example, one authorizes optometrists' prescription of "alpha adrenergic antagonists" – however, UPNEEQ is an alpha adrenergic agonist. Other categories are defined by therapeutic purpose; however, UPNEEQ does not fit appear to fit within any of the listed therapeutic categories. We respectfully request today that the Committee develop a recommendation for how the Board of Optometry can amend its regulation and facilitate patient access through optometrist prescribing of UPNEEQ.

We would like to share with the Committee that we have reviewed optometrist prescribing laws covering the United States. In the majority of states, the legal provisions do not impose exclusive limitations affecting this product. We have had to seek clarification in a handful of jurisdictions (Connecticut, the District of Columbia, Illinois, Kansas, New Hampshire, Oregon, and Virginia), but those respective Boards of Optometry or their staffs to date have generally confirmed that UPNEEQ is within the authorized scope of optometrist prescribing authority. We are awaiting feedback from Connecticut, Illinois, and Virginia.

Again, we ask the TPA-Formulary Committee to recommend to the Board of Optometry a regulatory amendment that will allow the Board to agree that UPNEEQ is legally appropriate for optometrists to prescribe to their patients. This could be accomplished by a product-specific or a general regulatory clarification.

Thank you.

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KING & SPALDING

## Agenda Item: Regulatory Actions - Chart of Regulatory Actions
## (As of September 25, 2020)

**Board of Optometry**

| Chapter | | Action / Stage Information |
|---|---|---|
| [18 VAC 105 - 20] | Regulations of the Virginia Board of Optometry | Waiver for e-prescribing [Action 5438]<br>Emergency/NOIRA – Comment on NOIRA from 9/14 to 10/14<br>Board to adopt proposed regulations to replace emergency regulations on 10/16/20 |
| [18 VAC 105 - 20] | Regulations of the Virginia Board of Optometry | Repeal of professional designation rules and fees [Action 5426]<br>Fast-Track - *Register Date: 9/14/20*<br>*Effective: 10/29/20* |

**Agenda Item: Adoption of Proposed Regulation for Waiver of Electronic Prescribing**

Included in agenda package:

Copy of emergency regulations currently in effect until 2/11/22 with one amendment (highlighted) as recommended by the Department of Planning and Budget

Staff note:

There were no comments on the Notice of Intended Regulatory Action to replace emergency regulations.

Board action:

Motion to adopt the proposed regulations for optometrists to replace emergency regulations for a temporary waiver for e-prescribing of opioids

**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.

D. Beginning July 1, 2020, a prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia, unless the prescription qualifies for an exemption as set forth in subsection C of that section. Upon written request, the board may grant a one-time waiver of the requirement for electronic prescribing, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

**Agenda Item: Adoption of Exempt Action on addition to the TPA Formulary**

Included in agenda package:

Copy of minutes of the TPA Formulary Committee – September 14, 2020

Copy of Statutes relating to the TPA Formulary (54.1-3222 and 54.1-3223)

Copy of regulation as recommended by the Committee

Staff note:

There was a public hearing on the proposal

This is an exempt action as specified in the Administrative Process Act

§ 2.2-4002. Exemptions from chapter generally.

A. Although required to comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et seq.), the following agencies shall be exempted from the provisions of this chapter, except to the extent that they are specifically made subject to §§ 2.2-4024, 2.2-4030, and 2.2-4031:

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

Board action:

Adoption of addition to TPA formulary in 18VAC105-20-47 as recommended by the TPA Formulary Committee

**BOARD OF OPTOMETRY**

**Addition to TPA formulary**

**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. Alpha-adrenergic agonists;

~~b.~~c. Anesthetic (including esters and amides);

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

~~d.~~e. Anti-fungal;

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

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

~~g.~~h. Anti-inflammatory;

~~h.~~i Cycloplegics and mydriatics;

~~i.~~j. Decongestants; and

~~j.~~k. 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 with the exception of controlled substances in Schedule II consisting of hydrocodone in combination with acetaminophen and gabapentin in Schedule V.

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.

**Excerpt from the *Regulations of the Virginia Board of Optometry***

**18VAC105-20-45. Standards of practice.**

A. An optometrist shall legibly document in a patient record the following:

1. During a routine or medical eye examination:

a. An adequate case history, including the patient's chief complaint;

b. The performance of appropriate testing;

c. The establishment of an assessment or diagnosis; and

d. A recommendation for an appropriate treatment or management plan, including any necessary follow-up.

2. During an initial contact lens examination:

a. The requirements of a routine or medical eye examination as prescribed in subdivision 1 of this subsection;

b. Assessment of corneal curvature;

c. Evaluation of contact lens fitting;

d. Acuity through the lens; and

e. Directions for the wear, care, and handling of lenses.

3. During a follow-up contact lens examination:

a. Evaluation of contact lens fitting and anterior segment health;

b. Acuity through the lens; and

c. Such further instructions as necessary for the individual patient.

4. In addition, the record of any examination shall include the signature of the attending optometrist and, if indicated, refraction of the patient.

B. The following information shall appear on a prescription for ophthalmic goods:

1. The printed name of the prescribing optometrist;

2. The address and telephone number at which the patient's records are maintained and the optometrist can be reached for consultation;

3. The name of the patient;

4. The signature of the optometrist;

5. The date of the examination;

6. If an expiration date is placed on a prescription for ophthalmic goods, the date shall not be less than one year unless the medical reason for a shorter expiration date is documented in the patient record; and

7. Any special instructions.

C. Contact lens.

1. Sufficient information for complete and accurate filling of an established contact lens prescription shall include (i) the power, (ii) the material or manufacturer or both, (iii) the base curve or appropriate designation, (iv) the diameter when appropriate, and (v) medically appropriate expiration date.

2. An optometrist shall provide a patient with a copy of the patient's contact lens prescription at the end of the contact lens fitting, even if the patient doesn't ask for it. An optometrist may first require all fees to be paid, but only if he requires immediate payment from patients whose eye examinations reveal no need for corrective eye products.

3. An optometrist shall provide or verify the prescription to anyone who is designated to act on behalf of the patient, including contact lens sellers.

4. An optometrist shall not require patients to buy contact lenses, pay additional fees or sign a waiver or release in exchange for a copy of the contact lens prescription.

5. An optometrist shall not disclaim liability or responsibility for the accuracy of an eye examination.

D. Spectacle lens.

1. A licensed optometrist shall provide a written prescription for spectacle lenses immediately after the eye examination is completed. He may first require all fees to be paid, but only if he requires immediate payment from patients whose eye examinations reveal no need for corrective eye products.

2. An optometrist shall not require patients to buy ophthalmic goods, pay additional fees or sign a waiver or release in exchange for a copy of the spectacle prescription.

3. An optometrist shall not disclaim liability or responsibility for the accuracy of an eye examination.

E. Practitioners shall maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

1. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or his personal representative; or

2. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

F. Practitioners shall post information or in some manner inform all patients concerning the time frame for record retention and destruction. Patient records shall only be destroyed in a manner that protects patient confidentiality.

G. For the purpose of prescribing spectacles, eyeglasses, lenses, or contact lenses to a patient, a licensee shall establish a bona fide provider-patient relationship in accordance with requirements of § 54.1-2400.01:2 of the Code of Virginia.

# THE CONTACT LENS RULE: A GUIDE FOR PRESCRIBERS AND SELLERS

**TAGS:** Advertising and Marketing Health Claims

Consumers have the right to shop around when buying contact lenses – and prescribers and sellers have specific legal obligations. Are you complying with the Contact Lens Rule?

**Changes to the Rule go into effect October 16, 2020.**

The Fairness to Contact Lens Consumers Act gives people certain rights, including the right to shop around when buying contact lenses. The Act also imposes duties on contact lens prescribers and sellers, and requires the Federal Trade Commission (FTC) to develop and enforce implementing rules. In 2004, the FTC issued the Contact Lens Rule to spell out the Act's requirements. In 2020, the FTC amended the Rule, which you can find here.

The Contact Lens Rule requires prescribers to give patients a copy of their contact lens prescriptions at the end of a contact lens fitting, even if the patient doesn't ask for it. A patient who wants to buy contact lenses from another seller may give the prescription to that seller. If a patient doesn't give his prescription to that seller, the seller must get that information from the patient and send it to a prescriber to verify before selling the lenses.

The verification process works like this: the patient gives information about her prescription (e.g., the manufacturer or brand, power, diameter) to the seller, who then submits it to the prescriber in a request to verify that information. The prescriber has eight business hours to respond. If the prescriber does not respond within that time, the prescription is verified automatically, and the seller may provide contact lenses to the consumer.

## FOR PRESCRIBERS

According to the Rule, "prescriber" refers to anyone permitted under state law to issue prescriptions for contact lenses – including ophthalmologists, optometrists, and licensed opticians who also are permitted under state law to fit contact lenses (sometimes called "dispensing opticians").

### All prescribers must:

- give a copy of the contact lens prescription to the patient at the end of the contact lens fitting – even if the patient doesn't ask for it. You may provide the prescription digitally if the patient agrees to get it digitally instead of on paper, and if the patient also agrees to the specific method (for example, e-mail, text, or portal), *and* if the electronic means can be accessed, downloaded, and printed by the patient. You also must keep records or proof that a patient agreed to digital delivery for at least three years.

In addition, if you are a prescriber who sells lenses or with a direct or indirect financial interest in the sale of contact lenses, you have to:

- ask patients to sign a statement confirming they got their prescription. They'd confirm by signing an acknowledgment of receipt, a prescriber-retained copy of a contact lens prescription, or a prescriber-retained copy of the examination receipt. Keep those confirmations for at least three 3 years. If a patient refuses to sign the confirmation, note the refusal, sign it, and keep it.

- if you provided a digital copy of the prescription, keep records or proof for at least three years that it was sent, received, or made accessible, downloadable and printable.
- give the contact lens prescription to anyone who is designated to act on behalf of the patient, including contact lens sellers, within 40 business hours.
  In any response to a verification request, you have to correct any inaccuracy in the prescription, inform the seller if it's expired, and give the reason if it's invalid.
  **You cannot** require patients to:
- buy contact lenses
- pay additional fees or
- sign a waiver or release in exchange for a copy of the contact lens prescription.

**You may** require a patient to pay for the eye exam, fitting, and evaluation before giving them a copy of the contact lens prescription, but only if you also require immediate payment from a patient whose eye exams show no need for glasses, contact lenses, or other corrective eye care products. Proof of valid insurance coverage counts as payment for purposes of this requirement.

**You cannot** disown liability or responsibility for the accuracy of an eye examination.

## Prescription expiration

The Rule sets a floor, or minimum, expiration date of one year unless there is a legitimate medical reason for setting a shorter expiration date. If a prescriber's state law specifies an expiration date of more than one year, that law would govern for those prescribers. Even if a prescriber's state law does not set an expiration date of more than the one-year minimum required by the Rule, prescribers are free to set a date of more than one year if they feel it is appropriate. The Rule merely prohibits prescribers from setting an expiration date of less than a year unless there is a medical justification for a shorter duration. If the prescriber has such a medical justification, the prescriber must document the medical reason for the shorter expiration date with enough detail to allow for review by a qualified medical professional, and maintain the records for at least three years.

## For Sellers

You may provide contact lenses only when the customer presents his prescription in person, by fax, or by email if the prescription has been scanned and attached to the email. The customer also can give you permission to verify the prescription by "direct communication" with the prescriber.

**What is direct communication?**

It's a completed communication by phone, fax, or email.

**Direct communication by phone** requires reaching and speaking to the intended recipient, or leaving an electronic voice message for the intended recipient.

**Direct communication by fax or email** requires that the intended recipient actually get the fax or email message.

For more details about compliance, see FAQs: Complying with the Contact Lens Rule at business.ftc.gov.

## Verification

When verifying a contact lens prescription, you have to give this information to the prescriber using direct communication:

- patient's full name and address
- contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate
- quantity of lenses ordered
- date of patient order
- date and time of verification request
- a contact person for the seller, including name, fax and phone numbers, and
- a clear statement of the prescriber's regular Saturday business hours if the seller is counting those hours as business hours under the Rule.

Under the Rule, a prescription is verified if the prescriber:

- confirms its accuracy to the seller via direct communication
- informs the seller that the prescription is inaccurate and provides accurate information to the seller via direct communication, or
- fails to communicate with the seller within eight business hours of getting a complete verification request. During the eight business hour period, the seller must give the prescriber a reasonable opportunity to verify the prescription.

When using automated phone calls for verification, you have to:

- record the entire call
- begin the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule,
- deliver the information required by the Rule in a slow and deliberate manner and at a reasonably understandable volume, and
- make the information required by the Rule repeatable at the prescriber's option

## Record-keeping

You have to keep prescriptions presented to you; prescription verification requests, including the recording of automated calls containing verification requests; and prescriber responses to the verification requests. If you count a prescriber's Saturday business hours, you also have to keep a record of what those hours are and how you learned of them. Keep these records for at least three years.

# THE FINE PRINT

## What practices are not allowed?

You must not:

- fill a prescription unless you have a copy of it or have verified it, as required by the Rule

- fill a prescription if the prescriber tells you by direct communication within eight business hours after getting a complete verification request that the prescription is inaccurate, expired, or otherwise invalid
- alter prescriptions. If you submit a verification request for a brand that is not the customer's prescribed brand, you may be violating the Rule by altering the prescription. The only exception is if you've submitted a verification request for a brand that the customer told you is listed on their prescription. To qualify for this exception, you must ask the customer to give you the manufacturer or brand listed on their prescription, and the customer must have told you that information. For private label lenses, however, you can substitute identical contact lenses made by the same manufacturer and sold under a different name
- suggest or state that customers can get contact lenses without a prescription

## What's a business hour?

Prescriptions are verified automatically if the prescriber doesn't respond to the seller's verification request within eight business hours. A business hour is defined as one hour between 9 a.m. and 5 p.m., Monday through Friday, excluding federal holidays, in the prescriber's time zone. If a seller determines that a particular prescriber has regular Saturday business hours, the seller also may count those Saturday hours as business hours under the Rule.

## How is the "eight business hour" verification period calculated?

When calculating eight business hours, begin the verification period the first business hour **after** the prescriber gets a complete verification request and end it eight business hours later.

For example, if the prescriber gets a request at 10 a.m. Monday, he has to respond by 10 a.m. Tuesday. If there's no response, you can provide the contact lenses at 10:01 a.m. Tuesday. If the verification request is received at 10 p.m. Monday, the response would be due by 5 p.m. Tuesday. If there's no response, you can provide the lenses at 5:01 p.m. Tuesday.

## YOUR OPPORTUNITY TO COMMENT

The National Small Business Ombudsman and 10 Regional Fairness Boards collect comments from small businesses about federal compliance and enforcement activities. Each year, the Ombudsman evaluates the conduct of these activities and rates each agency's responsiveness to small businesses. Small businesses can comment to the Ombudsman without fear of reprisal. To comment, call toll-free 1-888-REGFAIR (1-888-734-3247) or go to www.sba.gov/ombudsman.

June 2020

**PART 315—CONTACT LENS RULE**

**Contents**



AUTHORITY: Pub. L. 108-164, secs. 1-12; 117 Stat. 2024 (15 U.S.C. 7601-7610).

Link to an amendment published at 85 FR 50717, Aug. 17, 2020.

## 16 CFR--PART 315

View Printed Federal Register page 85 FR 50717 in PDF format.

Amendment(s) published August 17, 2020, in 85 FR 50717

EFFECTIVE DATES: Oct. 16, 2020

1. The authority for part 315 is revised to read as follows:

AUTHORITY: 15 U.S.C. 7601-7610.

SOURCE: 69 FR 40508, July 2, 2004, unless otherwise noted.

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### §315.1 Scope of regulations in this part.

This part, which shall be called the “Contact Lens Rule,” implements the Fairness to Contact Lens Consumers Act, codified at 15 U.S.C. 7601-7610, which requires that rules be issued to address the release, verification, and sale of contact lens prescriptions. This part specifically governs contact lens prescriptions and related issues. Part 456 of Title 16 governs the availability of eyeglass prescriptions and related issues (the Ophthalmic Practice Rules (Eyeglass Rule)).

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### §315.2 Definitions.

Link to an amendment published at 85 FR 50717, Aug. 17, 2020.

## Amendment:

## 16 CFR--PART 315

View Printed Federal Register page 85 FR 50717 in PDF format.

Amendment(s) published August 17, 2020, in 85 FR 50717

EFFECTIVE DATES: Oct. 16, 2020

2. Amend §315.2 by adding in alphabetical order the definitions of “Provide to the patient a copy”, “Reasonably understandable volume” and “Slow and deliberate manner” to read as follows:

## §315.2 Definitions.

*Provide to the patient a copy* means giving a patient a copy of his or her contact lens prescription:

(1) On paper; or

(2) In a digital format that can be accessed, downloaded, and printed by the patient. For a copy provided in a digital format, the prescriber shall identify to the patient the specific method or methods of electronic delivery to be used, such as text message, electronic mail, or an online patient portal, and obtain the patient's verifiable affirmative consent to receive a digital copy through the identified method or methods; and maintain records or evidence of a patient's affirmative consent for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

*Reasonably understandable volume* means at an audible level that renders the message intelligible to the receiving audience.

*Slow and deliberate manner* means at a rate that renders the message intelligible to the receiving audience

For purposes of this part, the following definitions shall apply:

*Business hour* means an hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. “Business hour” also may include, at the seller's option, a prescriber's regular business hours on Saturdays, provided that the seller has actual knowledge of these hours. “Business hour” shall be determined based on the time zone of the prescriber.

“Eight (8) business hours” shall be calculated from the time the prescriber receives the prescription verification information from the seller, and shall conclude when eight (8) business hours have elapsed. For verification requests received by a prescriber during non-business hours, the calculation of “eight (8) business hours” shall begin at 9 a.m. on the next weekday that is not a Federal holiday or, if applicable, on Saturday at the beginning of the prescriber's actual business hours.

*Commission* means the Federal Trade Commission.

*Contact lens* means any contact lens for which State or Federal law requires a prescription.

*Contact lens fitting* means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include:

(1) An examination to determine lens specifications;

(2) Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and

(3) Medically necessary follow-up examinations.

*Contact lens prescription* means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

(1) The name of the patient;

(2) The date of examination;

(3) The issue date and expiration date of prescription;

(4) The name, postal address, telephone number, and facsimile telephone number of prescriber;

(5) The power, material or manufacturer or both of the prescribed contact lens;

(6) The base curve or appropriate designation of the prescribed contact lens;

(7) The diameter, when appropriate, of the prescribed contact lens; and

(8) In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.

*Direct communication* means completed communication by telephone, facsimile, or electronic mail.

*Issue date* means the date on which the patient receives a copy of the prescription at the completion of a contact lens fitting.

*Ophthalmic goods* are contact lenses, eyeglasses, or any component of eyeglasses.

*Ophthalmic services* are the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.

*Prescriber* means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration. “Other person,” for purposes of this definition, includes a dispensing optician who is permitted under State law to

issue prescriptions and who is authorized or permitted under State law to perform contact lens fitting services.

*Private label contact lenses* mean contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.

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**§315.3 Availability of contact lens prescriptions to patients.**

**Link to an amendment published at 85 FR 50717, Aug. 17, 2020.**

## Amendment:

## 16 CFR--PART 315

View Printed Federal Register page 85 FR 50717 in PDF format.

Amendment(s) published August 17, 2020, in 85 FR 50717

EFFECTIVE DATES: Oct. 16, 2020

3. Amend §315.3 by:

a. Revising paragraphs (a)(1) and (2);

b. Adding paragraph (a)(3);

c. Revising paragraphs (b)(1) through (3); and

d. Adding paragraph (c).

The additions and revisions read as follows:

## §315.3 Availability of contact lens prescriptions to patients.

(a) *In general.* When a prescriber completes a contact lens fitting, the prescriber:

(1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription;

(2) Shall, as directed by any person designated to act on behalf of the patient, verify the contact lens prescription by electronic or other means; and

(3) Shall, upon request, provide any person designated to act on behalf of the patient with a copy of the patient's contact lens prescription by electronic or other means within forty (40) business hours of receipt of the request. A prescriber shall note in the patient's record the name of the requester and the date and time that the prescription was provided to the requester.

(b) *Limitations.* A prescriber may not:

(1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(3) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;

(2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(3) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or

(3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1), (a)(2), or (a)(3) of this section.

(c) *Confirmation of prescription release.* (1)(i) Upon completion of a contact lens fitting, the prescriber shall do one of the following:

(A) Request that the patient acknowledge receipt of the contact lens prescription by signing a statement confirming receipt of the contact lens prescription;

(B) Request that the patient sign a prescriber-retained copy of a contact lens prescription that contains a statement confirming receipt of the contact lens prescription;

(C) Request that the patient sign a prescriber-retained copy of the receipt for the examination that contains a statement confirming receipt of the contact lens prescription; or

(D) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message) in compliance with paragraph (a)(1) of this section, retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable.

(ii) If the prescriber elects to confirm prescription release via paragraphs (c)(1)(i)(A), (B), or (C) of this section, the prescriber may, but is not required to, use the statement, “My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting” to satisfy the requirement.

(iii) In the event the patient declines to sign a confirmation requested under paragraph (c)(1)(i)(A), (B), or (C) of this section, the prescriber shall note the patient's refusal on the document and sign it.

(2) A prescriber shall maintain the records or evidence required under paragraph (c)(1) of this section for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(3) Paragraphs (c)(1) and (c)(2) of this section shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses, including, but not limited to, through an association, affiliation, or co-location with a contact lens seller.

(a) *In general.* When a prescriber completes a contact lens fitting, the prescriber:

(1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and

(2) Shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.

(b) *Limitations.* A prescriber may not:

(1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;

(2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or

(3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1) or (a)(2) of this section.

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**§315.4 Limits on requiring immediate payment.**

A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.

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**§315.5 Prescriber verification.**

Link to an amendment published at 85 FR 50717, Aug. 17, 2020.

## Amendment:

## 16 CFR--PART 315

View Printed Federal Register page 85 FR 50717 in PDF format.

Amendment(s) published August 17, 2020, in 85 FR 50717

EFFECTIVE DATES: Oct. 16, 2020

4. Amend §315.5 by:

a. Redesignating paragraphs (d), (e), (f), and (g) as paragraphs (e), (f), (h), and (i), respectively;

b. Adding new paragraph (d);

c. Revising newly redesignated paragraph (f);

d. Adding new paragraph (g);

e. Adding new paragraph (h)(2)(iii);

f. Revising newly redesignated paragraph (i).

The additions and revisions read as follows:

## §315.5 Prescriber verification.

* * * * *

(d) *Automated telephone verification messages.* If a seller verifies prescriptions through calls that use, in whole or in part, an automated message, the seller must:

(1) Record the entire call;

(2) Commence the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule;

(3) Deliver the information required by paragraph (b) of this section in a slow and deliberate manner and at a reasonably understandable volume; and

(4) Make the information required by paragraph (b) of this section repeatable at the prescriber's option.

* * * * *

(f) *No alteration of prescription.* A seller may not alter a contact lens prescription. In the context of prescription verification, alteration includes, but is not limited to, providing the prescriber with the name of a manufacturer or brand other than that specified by the patient's prescription, unless such name is provided because the patient entered or orally provided it when asked for the manufacturer or brand listed on the patient's prescription. Notwithstanding the preceding sentences, for private label contact lenses, a seller may substitute for contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(g) *Seller requirement to accept prescription presentation:* A seller shall provide a prominent method, and a clear and prominent disclosure of that method, for the patient to present the seller with a copy of the patient's prescription. Such method and the disclosure shall be provided prior to requesting a prescriber's contact information for verification of the prescription; provided, however, in the case of an order placed by telephone, a seller shall comply by providing a disclosure of the method prior to requesting a prescriber's contact information for verification of the prescription. The method to present the prescription shall be provided through (i) the same medium by which the order is placed, or (ii) electronic mail, text message, or file upload.

(h) * * *

(2) * * *

(iii) If the communication occurs via telephone and uses an automated message, the complete recording required pursuant to paragraph (d)(1) of this section.

* * * * *

(i) *Recordkeeping requirement—Saturday business hours.* A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for a request for a copy of the prescription specified in §315.3(a)(3) or for verification specified in paragraph (c)(3) of this section shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(a) *Prescription requirement.* A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is:

(1) Presented to the seller by the patient or prescriber directly or by facsimile; or

(2) Verified by direct communication.

(b) *Information for verification.* When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information through direct communication:

(1) The patient's full name and address;

(2) The contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate;

(3) The quantity of lenses ordered;

(4) The date of patient request;

(5) The date and time of verification request;

(6) The name of a contact person at the seller's company, including facsimile and telephone numbers; and

(7) If the seller opts to include the prescriber's regular business hours on Saturdays as “business hours” for purposes of paragraph (c)(3) of this section, a clear statement of the prescriber's regular Saturday business hours.

(c) *Verification events.* A prescription is verified under paragraph (a)(2) of this section only if one of the following occurs:

(1) The prescriber confirms the prescription is accurate by direct communication with the seller;

(2) The prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; or

(3) The prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section. During these eight (8) business hours, the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request.

(d) *Invalid prescription.* If a prescriber informs a seller before the deadline under paragraph (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified under paragraph (c)(2) of this section.

(e) *No alteration of prescription.* A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, a seller may substitute for private label contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(f) *Recordkeeping requirement—verification requests.* A seller shall maintain a record of all direct communications referred to in paragraph (a) of this section. Such record shall consist of the following:

(1) For prescriptions presented to the seller: the prescription itself, or the facsimile version thereof (including an email containing a digital image of the prescription), that was presented to the seller by the patient or prescriber.

(2) For verification requests by the seller:

(i) If the communication occurs via facsimile or e-mail, a copy of the verification request, including the information provided to the prescriber pursuant to paragraph (b) of this section, and confirmation of the completed transmission thereof, including a record of the date and time the request was made;

(ii) If the communication occurs via telephone, a log:

(A) Describing the information provided pursuant to paragraph (b) of this section,

(B) Setting forth the date and time the request was made,

(C) Indicating how the call was completed, and

(D) Listing the names of the individuals who participated in the call.

(3) For communications from the prescriber, including prescription verifications:

(i) If the communication occurs via facsimile or e-mail, a copy of the communication and a record of the time and date it was received;

(ii) If the communication occurs via telephone, a log describing the information communicated, the date and time that the information was received, and the names of the individuals who participated in the call.

(4) The records required to be maintained under this section shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(g) *Recordkeeping requirement—Saturday business hours.* A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for verification specified in §315.5(c)(3) shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

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**§315.6 Expiration of contact lens prescriptions.**

(a) *In general.* A contact lens prescription shall expire:

(1) On the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;

(2) Not less than one year after the issue date of the prescription if such State law specifies no date or specifies a date that is less than one year after the issue date of the prescription; or

(3) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

(b) *Special rules for prescriptions of less than one year.* (1) If a prescription expires in less than one year, the specific reasons for the medical judgment referred to in paragraph (a)(3) of this section shall be documented in the patient's medical record with sufficient detail to allow for review by a qualified professional in the field.

(2) The documentation described in the paragraph above shall be maintained for a period of not less than three years, and it must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(3) No prescriber shall include an expiration date on a prescription that is less than the period of time that he or she recommends for a reexamination of the patient that is medically necessary.

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**§315.7 Content of advertisements and other representations.**

Any person who engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

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**§315.8 Prohibition of certain waivers.**

A prescriber may not place on a prescription, or require the patient to sign, or deliver to the patient, a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.

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**§315.9 Enforcement.**

Any violation of this Rule shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices, and the Commission will enforce this Rule in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*

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**§315.10 Severability.**

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

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**§315.11 Effect on state and local laws.**

(a) State and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are preempted.

(b) Any other State or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency.

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# Optometry Monthly Snapshot for July 2020

Optometry has received more cases in July than closed. Optometry has closed 2 patient care cases and 3 non-patient care cases for a total of 5 cases.

| Cases Closed | |
|---|---|
| Patient Care | 2 |
| Non-Patient Care | 3 |
| Total | 5 |

The board has received 4 patient care cases and 2 non-patient care cases for a total of 6 cases.

| Cases Received | |
|---|---|
| Patient Care | 4 |
| Non-Patient Care | 2 |
| Total | 6 |

As of July 30, 2020 there are 23 patient care cases open and 17 non-patient care cases open for a total of 40 cases.

| Cases Open | |
|---|---|
| Patient Care | 23 |
| Non-Patient Care | 17 |
| Total | 40 |

There are 1,985 Optometry licensees as of August 1, 2020. The number of current licenses are broken down by profession in the following chart.

| Current Licenses | |
|---|---|
| Optometrist | 87 |
| Professional Designation | 260 |
| TPA Certified Optometrist | 1,638 |
| Total for Optometry | 1,985 |

There were 10 licenses issued for Optometry for the month of July. The number of licenses issued are broken down by profession in the following chart.

| Licenses Issued | |
|---|---|
| TPA Certified Optometrist | 10 |
| Total for Optometry | 10 |

Virginia Department of Health Professions
Cash Balance
As of June 30, 2020

| | 105- Optometry |
|---|---|
| **Board Cash Balance as June 30, 2019** | $ 352,434 |
| **YTD FY20 Revenue** | 366,940 |
| **Less: YTD FY20 Direct and Allocated Expenditures** | 376,875 |
| **Board Cash Balance as June 30, 2020** | $ 342,500 |

Virginia Department of Health Professions
Cash Balance
As of Augsut 31, 2020

| | 105- Optometry |
|---|---|
| **Board Cash Balance as June 30, 2020** | $ 342,500 |
| **YTD FY21 Revenue** | 8,290 |
| **Less: YTD FY21 Direct and Allocated Expenditures** | 79,190 |
| **Board Cash Balance as Augsut 31, 2020** | $ 271,600 |

## Leslie Knachel

**From:** Lisa Fennell <LFennell@arbo.org> on behalf of Lisa Fennell
**Sent:** Friday, August 7, 2020 12:59 PM
**To:** Lisa Fennell
**Subject:** New Information about NBEO exams
**Attachments:** OSLE Interest 2020.pdf

ARBO Member Boards:

Please see information below from the NBEO regarding new options for the Part I Exam. I know there have been some complaints from students regarding a lack of exam opportunities and the NBEO has been working to expand the options. Also, please see attached information on the NBEO's Online State Law Exam program that is an option available to you.

Regards,
Lisa

*Lisa Fennell*
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Association of Regulatory Boards of Optometry
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Charlotte, NC 28202
Phone: 704-970-2710
Fax: 888-703-4848

NATIONAL BOARD OF EXAMINERS IN OPTOMETRY

NBEO has been continually working with Pearson VUE to identify more opportunities for our examinations administered at Pearson Professional Centers during this challenging time. We would like to inform you that the **Part I Applied Basic Science (ABS) examination will additionally be offered January 25-30, 2021**. Registration for this examination will open on November 2, 2020 through our website located here. This administration is open to candidates who were at least in the third professional year of optometry school in March of 2020. This new January administration is in addition to the November 2-20, 2020 administration that is already scheduled.