Virginia Department of Health Professions
Board of Optometry

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October 8, 2021
Board Room 4
9:00 a.m.

Agenda

Virginia Board of Optometry
Regulatory Committee Meeting

Call to Order – Clifford Roffis, O.D., Chair

- Welcome
- Emergency Egress Procedures

Ordering of Agenda – Dr. Roffis

Public Comment – Dr. Roffis

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 – Dr. Roffis **Pages (1-43)**

Regulatory change considerations

- Delete 18VAC105-20-16(B) – **Leslie Knachel** (pages 19-21)
- Clarify 18VAC105-20-45 – **Dr. Roffis** (pages 22-23)
- Contact Lens Rule Amendments – **Elaine Yeatts/Ms. Knachel** (pages 24-43)

Next Steps – Dr. Roffis

Meeting Adjournment – Dr. Roffis

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

Commonwealth of Virginia

REGULATIONS

OF THE

VIRGINIA BOARD OF OPTOMETRY

Title of Regulations: 18 VAC 105-20-05 et seq.

Statutory Authority: § 54.1-2400 and Chapter 32 of Title 54.1 of the *Code of Virginia*

Revised Date: December 9, 2020

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18VAC105-20-5. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" means pain that occurs within the normal course of a disease or condition for which controlled substances may be prescribed for no more than three months.

"Active clinical practice" means an average of 20 hours per week or 640 hours per year of providing patient care.

"Adnexa" is defined as the conjoined, subordinate, or immediately associated anatomic parts of the human eye, including eyelids and eyebrows.

"Board" means the Virginia Board of Optometry.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" means drugs listed in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through V.

"MME" means morphine milligram equivalent.

"NBEO" means the National Board of Examiners in Optometry.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"TMOD" means the treatment and management of ocular disease portion of the NBEO examination.

"TPA" means therapeutic pharmaceutical agents.

"TPA certification" means authorization by the Virginia Board of Optometry for an optometrist to treat diseases and abnormal conditions of the human eye and its adnexa and to prescribe and administer certain therapeutic pharmaceutical agents.

18VAC105-20-10. Requirements for licensure.

A. The applicant, in order to be eligible for licensure to practice optometry in the Commonwealth, shall meet the requirements for TPA certification in 18VAC105-20-16 and shall:

1. Be a graduate of a school of optometry accredited by the Accreditation Council on Optometric Education or other accrediting body deemed by the board to be substantially equivalent; have an official transcript verifying graduation sent to the board;

2. Request submission of an official report from the NBEO of a score received on each required part of the NBEO examination or other board-approved examination;

3. Submit a completed application and the prescribed fee; and

4. Sign a statement attesting that the applicant has read, understands, and will comply with the statutes and regulations governing the practice of optometry in Virginia.

B. The board may waive the requirement of graduation from an accredited school of optometry for an applicant who holds a current, unrestricted license in another United States jurisdiction and has been engaged in active clinical practice for 36 out of the 60 months immediately preceding application for licensure in Virginia.

C. Required examinations. For the purpose of § 54.1-3211 of the Code of Virginia, the board adopts all parts of the NBEO examination as its written examination for licensure. After July 1, 1997, the board shall require passage as determined by the board of Parts I, II, and III of the NBEO examination, including passage of TMOD.

D. If an applicant has been licensed in another jurisdiction, the following requirements shall also apply:

1. The applicant shall attest that the applicant is not a respondent in a pending or unresolved malpractice claim.

2. Each jurisdiction in which the applicant is or has been licensed shall verify that:

a. The license is current and unrestricted, or if the license has lapsed, it is eligible for reinstatement;

b. All continuing education requirements have been completed, if applicable;

c. The applicant is not a respondent in any pending or unresolved board action; and

d. The applicant has not committed any act that would constitute a violation of § 54.1-3204 or 54.1-3215 of the Code of Virginia.

3. An applicant licensed in another jurisdiction who has not been engaged in active practice within the 12 months immediately preceding application for licensure in Virginia shall be required to complete 20 hours of continuing education as specified in 18VAC105-20-70.

4. In the case of a federal service optometrist, the commanding officer shall also verify that the applicant is in good standing.

18VAC105-20-15. (Repealed.)

18VAC105-20-16. Requirements for TPA certification.

A. An applicant for licensure shall meet the following requirements for TPA certification:

1. Complete a full-time, postgraduate or equivalent graduate-level optometric training program that is approved by the board and that shall include a minimum of 20 hours of clinical supervision by an ophthalmologist; and

2. Submit a passing score on the TPA certification examination, which shall be TMOD or be TPA-certified by an examination satisfactory to the board.

B. A candidate for certification by the board who fails the examination as required in subdivision A 2 of this section, following three attempts, shall complete additional postgraduate training as determined by the board to be eligible for TPA certification.

18VAC105-20-20. Fees.

A. Required fees.

Initial application and licensure (including TPA certification)	$250
Annual licensure renewal without TPA certification	$150
Annual licensure renewal with TPA certification	$200
Annual renewal of inactive license	$100
Late renewal without TPA certification	$50
Late renewal with TPA certification	$65
Late renewal of inactive license	$35
Handling fee for returned check or dishonored credit card or debit card	$50
Reinstatement application fee (including renewal and late fees)	$400
Reinstatement application after disciplinary action	$500
Duplicate wall certificate	$25
Duplicate license	$10
Licensure verification	$10

B. Unless otherwise specified, all fees are nonrefundable.

C. From October 31, 2018, to December 31, 2018, the following fees shall be in effect:

Annual licensure renewal without TPA certification	$75
Annual licensure renewal with TPA certification	$100
Annual professional designation renewal (per location)	$25

18VAC105-20-30. (Repealed.)

18VAC105-20-40. Standards of conduct.

The board has the authority to refuse to issue or renew a license, suspend, revoke, or otherwise discipline a licensee for a violation of the following standards of conduct. A licensed optometrist shall:

1. Use in connection with the optometrist's name wherever it appears relating to the practice of optometry one of the following: the word "optometrist," the abbreviation "O.D.," or the words "doctor of optometry."

2. Notify the board of any disciplinary action taken by a regulatory body in another jurisdiction.

3. Post in an area of the optometric office that is conspicuous to the public a chart or directory listing the names of all optometrists practicing at that particular location.

4. Maintain patient records, perform procedures or make recommendations during any eye examination, contact lens examination, or treatment as necessary to protect the health and welfare of the patient and consistent with requirements of 18VAC105-20-45.

5. Notify patients in the event the practice is to be terminated or relocated, giving a reasonable time period within which the patient or an authorized representative can request in writing that the records or copies be sent to any other like-regulated provider of the patient's choice or destroyed in compliance with requirements of § 54.1-2405 of the Code of Virginia on the transfer of patient records in conjunction with closure, sale, or relocation of practice.

6. Ensure his access to the practice location during hours in which the practice is closed in order to be able to properly evaluate and treat a patient in an emergency.

7. Provide for continuity of care in the event of an absence from the practice or, in the event the optometrist chooses to terminate the practitioner-patient relationship or make his services unavailable, document notice to the patient that allows for a reasonable time to obtain the services of another practitioner.

8. Comply with the provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records and related to the provision of patient records to another practitioner or to the patient or his personal representative.

9. Treat or prescribe based on a bona fide practitioner-patient relationship consistent with criteria set forth in § 54.1-3303 of the Code of Virginia. A licensee shall not prescribe a controlled substance to himself or a family member other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.

10. Comply with provisions of statute or regulation, state or federal, relating to the diversion, distribution, dispensing, prescribing, or administration of controlled substances as defined in § 54.1-3401 of the Code of Virginia.

11. Not enter into a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family to include actions that result in personal gain at the expense of the patient, a nontherapeutic personal involvement, or sexual conduct with a patient. The determination of when a person is a patient is made on a case-by-case basis with consideration given to the nature, extent, and context of the professional relationship between the practitioner and the person. The fact that a person is not actively receiving treatment or professional services from a practitioner is not determinative of this issue. The consent to, initiation of, or participation in sexual behavior or involvement with a practitioner by a patient does not change the nature of the conduct nor negate the prohibition.

12. Cooperate with the board or its representatives in providing information or records as requested or required pursuant to an investigation or the enforcement of a statute or regulation.

13. Not violate or cooperate with others in violating any of the provisions of Chapters 1 (§ 54.1-100 et seq.), 24 (§ 54.1-2400 et seq.) or 32 (§ 54.1-3200 et seq.) of Title 54.1 of the Code of Virginia or regulations of the board.

18VAC105-20-41. Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

A. Decision to delegate. In accordance with § 54.1-2400 (10) of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.

B. Criteria for delegation. Cases may be delegated to an agency subordinate upon approval by a committee of the board, except those in which an optometrist may have conducted his practice in such a manner as to endanger the health and welfare of his patients or the public.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include current or past board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

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 does not 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.

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 that may be treated with medically appropriate pharmaceutical agents as referenced in 18VAC105-20-47.

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 (i) the condition fails to appropriately respond to any other treatment regimen; (ii) such agent is prescribed in consultation with a physician; and (iii) 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 Schedules III, IV, and VI narcotic and nonnarcotic agents.
2. Topically administered Schedule VI agents:

a. Alpha-adrenergic blocking agents;

b. Alpha-adrenergic agonists;

c. Anesthetic (including esters and amides);

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

e. Anti-fungal;

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

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

h. Anti-inflammatory;

i Cycloplegics and mydriatics;

j. Decongestants; and

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. Schedules 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.

18VAC105-20-48. Prescribing an opioid for acute pain.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, a TPA-certified optometrist shall follow the regulations for prescribing and treating with opioids.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, a TPA-certified optometrist shall perform a health history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance abuse.

C. Initiation of opioid treatment for all patients with acute pain shall include the following:

1. A prescription for an opioid shall be a short-acting opioid in the lowest effective dose for the fewest number of days, not to exceed seven days as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the patient record.

2. A TPA-certified optometrist shall carefully consider and document in the patient record the reasons to exceed 50 MME per day.

3. A prescription for naloxone should be considered for any patient when any risk factor of prior overdose, substance misuse, or concomitant use of benzodiazepine is present.

D. If another prescription for an opioid is to be written beyond seven days, a TPA-certified optometrist shall:

1. Reevaluate the patient and document in the patient record the continued need for an opioid prescription; and

2. Check the patient's prescription history in the Prescription Monitoring Program.

E. The patient record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed (including date, type, dosage, strength, and quantity prescribed).

F. Due to a higher risk of fatal overdose when opioids are prescribed for a patient also taking benzodiazepines, sedative hypnotics, tramadol, or carisoprodol, a TPA-certified optometrist shall only co-prescribe these substances when there are extenuating circumstances and shall document in the patient record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

18VAC105-20-49. Prescribing an opioid for chronic pain.

If a TPA-certified optometrist treats a patient for whom an opioid prescription is necessary for chronic pain, he shall either:

1. Refer the patient to a doctor of medicine or osteopathic medicine who is a pain management specialist; or

2. Comply with regulations of the Board of Medicine, 18VAC85-21-60 through 18VAC85-21-120, if he chooses to manage the chronic pain with an opioid prescription.

18VAC105-20-50. (Repealed.)

18VAC105-20-60. Renewal of licensure; reinstatement; renewal fees.

A. Every person authorized by the board to practice optometry shall, on or before December 31 of 2018, submit a completed renewal form and pay the prescribed annual licensure fee. Beginning with calendar year 2020, the renewal of licensure deadline shall be March 31 of each year. For calendar year 2019, no renewal is required.

B. It shall be the duty and responsibility of each licensee to assure that the board has the licensee's current address of record and the public address, if different from the address of record. All changes of address or name shall be furnished to the board within 30 days after the change occurs. All notices required by law or by these rules and regulations are to be deemed to be validly tendered when mailed to the address of record given and shall not relieve the licensee of the obligation to comply.

C. The license of every person who does not complete the renewal form and submit the renewal fee each year may be renewed for up to one year by paying the prescribed renewal fee and late fee, provided the requirements of 18VAC105-20-70 have been met. After the renewal deadline, a license that has not been renewed is lapsed. Practicing optometry in Virginia with a lapsed license may subject the licensee to disciplinary action.

D. An optometrist whose license has been lapsed for more than one year and who wishes to resume practice in Virginia shall apply for reinstatement. The executive director may grant reinstatement provided that:

1. The applicant has a current, unrestricted license in another United States jurisdiction and has been engaged in active clinical practice within the 12 months immediately preceding application for reinstatement; or

2. The applicant has satisfied current requirements for continuing education as specified in 18VAC105-20-70 for the period in which the license has been lapsed, not to exceed two years; and

3. The applicant has paid the prescribed reinstatement application fee.

18VAC105-20-61. Inactive licensure; reactivation.

A. An optometrist who holds a current, unrestricted license in Virginia may, upon a request on the renewal application and submission of the required fee, be issued an inactive license. The holder of an inactive license shall not be required to maintain continuing education requirements and shall not perform any act requiring a license to practice optometry in Virginia.

B. A licensee whose license has been inactive and who requests reactivation to an active license shall file an application, pay the difference between the inactive and active renewal fees for the current year, and provide documentation of having completed continuing education hours equal to the requirement for the number of years in which the license has been inactive, not to exceed 40 contact hours.

18VAC105-20-70. Requirements for continuing education.

A. Each license renewal of an active license shall be conditioned upon submission of evidence to the board of 20 hours of continuing education taken by the applicant during the previous license period. A licensee who completes more than 20 hours of continuing education in a year shall be allowed to carry forward up to 10 hours of continuing education for the next annual renewal cycle.

1. The 20 hours may include up to two hours of recordkeeping for patient care, including coding for diagnostic and treatment devices and procedures or the management of an optometry practice, provided that such courses are not primarily for the purpose of augmenting the licensee's income or promoting the sale of specific instruments or products.

2. For optometrists who are certified in the use of therapeutic pharmaceutical agents, at least 10 of the required continuing education hours shall be in the areas of ocular and general pharmacology; diagnosis and treatment of the human eye and its adnexa, including treatment with new pharmaceutical agents; new or advanced clinical devices, techniques, modalities, or procedures; or pain management.

3. At least 10 hours shall be obtained through real-time, interactive activities, including in-person or electronic presentations, provided that during the course of the presentation, the licensee and the lecturer may communicate with one another.

4. A licensee may also include up to two hours of training in cardiopulmonary resuscitation (CPR).

5. Two hours of the 20 hours required for annual renewal may be satisfied through delivery of professional services, without compensation, to low-income individuals receiving health services

through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

B. Each licensee shall attest to fulfillment of continuing education hours on the required annual renewal form. All continuing education shall be completed prior to the renewal deadline unless an extension has been granted by the Continuing Education Committee. A request for an extension shall be received prior to the renewal deadline of each year.

C. All continuing education courses shall be offered by an approved sponsor or accrediting body listed in subsection H of this section. Courses that are not approved by a board-recognized sponsor in advance shall not be accepted for continuing education credit. For those courses that have a post-test requirement, credit will only be given if the optometrist receives a passing grade as indicated on the certificate.

D. Licensees shall maintain continuing education documentation for a period of not less than three years. A random audit of licensees may be conducted by the board which will require that the licensee provide evidence substantiating participation in required continuing education courses within 30 days of the audit notification.

E. Documentation of hours shall clearly indicate the name of the continuing education provider and its affiliation with an approved sponsor or accrediting body as listed in subsection H of this section. Documents that do not have the required information shall not be accepted by the board for determining compliance. Correspondence courses shall be credited according to the date indicated on the continuing education certificate.

F. A licensee shall be exempt from the continuing competency requirements for the first renewal following the date of initial licensure by examination in Virginia.

G. The board may grant an exemption for all or part of the requirements for circumstances beyond the control of the licensee, such as temporary disability, mandatory military service, or officially declared disasters.

H. An approved continuing education course or program, whether offered by correspondence, electronically, or in person, shall be sponsored, accredited, or approved by one of the following:

1. The American Optometric Association and its constituent organizations.

2. Regional optometric organizations.

3. State optometric associations and their affiliate local societies.

4. Accredited colleges and universities providing optometric or medical courses.

5. The American Academy of Optometry and its affiliate organizations.

6. The American Academy of Ophthalmology and its affiliate organizations.

7. The Virginia Academy of Optometry.

8. Council on Optometric Practitioner Education (COPE).

9. State or federal governmental agencies.

10. College of Optometrists in Vision Development.

11. The Accreditation Council for Continuing Medical Education of the American Medical Association for Category 1 credit.

12. Providers of training in cardiopulmonary resuscitation (CPR).

13. Optometric Extension Program.

I. In order to receive credit for continuing education courses, a licensee shall submit a certificate that shows:

1. The date, location, presenter or lecturer, content hours of the course, and contact information of the provider or sponsor for verification. The certificate of attendance shall be based on verification by the sponsor of the attendee's presence throughout the course, either provided by a post-test or by a designated monitor.

2. Whether the course was in real-time and interactive, including in-person or electronic presentations.

J. Falsifying the attestation of compliance with continuing education on a renewal form or failure to comply with continuing education requirements may subject a licensee to disciplinary action by the board, consistent with § 54.1-3215 of the Code of Virginia.

18VAC105-20-75. Registration for voluntary practice by out-of-state licensees.

Any optometrist who does not hold a license to practice in Virginia and who seeks registration to practice on a voluntary basis under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice. An incomplete application will not be considered;

2. Provide a complete list of professional licensure in each state in which he has held a license and a copy of any current license;

3. Provide the name of the nonprofit organization, the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with provisions of subdivision 2 of § 54.1-3202 of the Code of Virginia.

NBEO
NATIONAL BOARD OF EXAMINERS IN OPTOMETRY®

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Six-Time Limit Appeals Change

Released: July 14, 2021

After multiple discussions with the Association of Regulatory Boards of Optometry (ARBO), NBEO will be implementing a change to our six-time limit appeals process. Effective January 1, 2022, a member of a U.S. state or Canadian provincial regulatory board will no longer sponsor candidates who have exceeded the six-time limit. Sponsors must be a CAO or a CEO of an ACOE-accredited optometric institution. Members of NBEO's Board of Directors will not serve as sponsors.

Click here to review the Six-Time Limit Policy.

If you have any questions, click here to contact NBEO.

Advancing the Assessment of Competence®

Six-Time Limit

Six-Time Limit Policy The National Board of Examiners in Optometry (NBEO), in furtherance of its mission to protect the public by assessing the competence of candidate optometrists, must preserve the integrity of the NBEO entry-level examinations. To effectuate this critical mission, the following policy provides certain limits on candidate eligibility.

Candidates seeking optometric licensure must receive a passing score on NBEO entry-level examinations within the first six attempts. Once a candidate has reached the six-attempt limit, the candidate must utilize the following appeals process and be approved by an appointed appeals committee of NBEO's Board of Directors before the candidate is eligible to register for the exam again. Under this policy, an "attempt" includes any instance where an examinee begins to take the exam. For the avoidance of doubt, under the policy, an examinee who does not sit for any part of the exam is not deemed to have made an attempt.

1. The candidate must have a sponsor who will assist the candidate in creating a remediation plan and support the candidate in her/his next attempt if granted. The sponsor must be a CAO or CEO of an ACOE-accredited optometric institution or a member of a U.S. state or Canadian provincial regulatory board.* Members of NBEO's Board of Directors will not serve as sponsors. The remediation plan must demonstrate the additional steps the candidate will undertake to prepare to take the exam an additional time and show how such steps will make it likely that the candidate will successfully pass the exam. The remediation plan must be appropriately robust based on the candidate's exam performance history and particular circumstances.

2. The candidate will submit an appeal via NBEO's online appeals platform with the proposed remediation plan, a letter explaining the circumstances that led to the six-attempt limit being reached, why the candidate should be allowed an extra attempt, and a letter from the candidate's sponsor explaining why the sponsor supports the candidate's extra attempt.

3. The Judicial Committee of NBEO's Board of Directors or an ad hoc committee of the Board appointed by the President (the "Committee"), will timely review the appeal and all related documentation. In appointing members of the Committee, NBEO will identify and avoid any potential or perceived conflicts of interest.

4. The Committee will consider all relevant written documentation in the appeal record, then deliberate and decide whether the candidate's appeal should be granted or denied. NBEO will send a letter to both the candidate and candidate's sponsor notifying them of the decision of the Committee. That decision will constitute NBEO's final determination of the matter.

5. If the committee agrees to allow an additional attempt on the exam, the candidate will have the opportunity to register for the next examination following the completion of the agreed-upon remediation. The completion of remediation must be evidenced by a written confirmation from the sponsor and emailed to NBEOAppeals@optometry.org. Once NBEO receives that confirmation, the candidate will be eligible to register for the examination.

The six-time limit appeal has a non-refundable fee of $300.

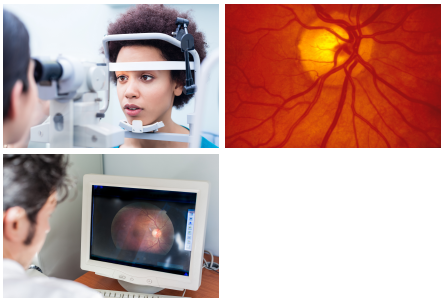
Candidates who wish to appeal once they have reached their six time limit click here.

Effective January 1, 2022, a member of a U.S. state or Canadian provincial regulatory board will no longer sponsor candidates who have exceeded the six-time limit.

P020

The TMOD exam assesses candidates' clinical thinking and decision-making with a particularly heavy emphasis on diagnosis, treatment, and management of ocular disease.

The TMOD examination is composed of 100-120 items presented as full cases, solo items, and minicases administered in a single session. Candidates will have 2.75 hours to complete the exam. The TMOD is offered as a stand-alone examination or as an embedded portion of the PAM examination. Those candidates registering to take the PAM exam do not also need to register for TMOD. Candidates who may have passed the overall PAM exam but did not pass the TMOD portion may elect to register for the stand-alone version of the TMOD.



In order to be classified as a TMOD item, the content of the item must pertain to one or more of the following:

- Formulation of most appropriate disease diagnosis which will be treated and/or managed
- Selection of treatment/management, including systemic considerations
- Dose, form, schedule, and duration of treatment
- Contraindications and side effects of medication, including systemic considerations
- Follow-up and prognosis, including reassessment of diagnosis after initiating treatment
- Treatment and management of ocular emergencies and urgencies

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Title 16

PART 456 - OPHTHALMIC PRACTICE RULES (EYEGLASS RULE)

Authority: 15 U.S.C. 57a; 5 U.S.C. 552.

Source: 57 FR 18822, May 1, 1992, unless otherwise noted.

§ 456.1 Definitions.

(a) A *patient* is any person who has had an eye examination.

(b) An *eye examination* is the process of determining the refractive condition of a person's eyes or the presence of any visual anomaly by the use of objective or subjective tests.

(c) ***Ophthalmic goods*** are eyeglasses, or any component of eyeglasses, and contact lenses.

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

(e) An *ophthalmologist* is any Doctor of Medicine or Osteopathy who performs eye examinations.

(f) An *optometrist* is any Doctor of Optometry.

(g) A *prescription* is the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.

§ 456.2 Separation of examination and dispensing.

It is an unfair act or practice for an ophthalmologist or optometrist to:

(a) Fail to provide to the patient one copy of the patient's prescription immediately after the eye examination is completed. Provided: An ophthalmologist or optometrist may refuse to give the patient a copy of the patient's prescription until the patient has paid for the eye examination, but only if that ophthalmologist or optometrist would have required immediate payment from that patient had the examination revealed that no ophthalmic goods were required;

(b) Condition the availability of an eye examination to any person on a requirement that the patient agree to purchase any ophthalmic goods from the ophthalmologist or optometrist;

(c) Charge the patient any fee in addition to the ophthalmologist's or optometrist's examination fee as a condition to releasing the prescription to the patient. Provided: An ophthalmologist or optometrist may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or

(d) Place on the 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 ophthalmologist or optometrist for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

§ 456.3 Federal or State employees.

This rule does not apply to ophthalmologists or optometrists employed by any Federal, State or local government entity.

§ 456.4 Declaration of Commission Intent.

In prohibiting the use of waivers and disclaimers of liability in § 456.2(d), it is not the Commission's intent to impose liability on an ophthalmologist or optometrist for the ophthalmic goods and services dispensed by another seller pursuant to the ophthalmologist's or optometrist's prescription.

§ 456.5 Rules applicable to prescriptions for contact lenses and related issues.

Rules applicable to prescriptions for contact lenses and related issues may be found at 16 CFR part 315 (Contact Lens Rule).

[69 FR 40511, July 2, 2004]

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Announces Final Amendments to the Agency's Contact Lens Rule

June 23, 2020

Changes will help more patients comparison shop for contact lenses

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FOR RELEASE

TAGS: contact lens | Optometry | Bureau of Consumer Protection | Consumer Protection | Advertising and Marketing

The Federal Trade Commission today announced the approval of a final rule amending the agency's Contact Lens Rule, which facilitates shopping for contact lenses by requiring prescribers to automatically provide a copy of a patient's prescription to the patient and to verify or provide prescriptions to third-party sellers.

The Final Rule requires prescribers to request that their patients confirm that they have received their prescription, and allows flexibility in the way the prescription and confirmation are provided.

"Eye doctors are required by law to provide every patient with a copy of his or her contact lens prescription, allowing patients to comparison shop for lenses," said Bureau of Consumer Protection Director Andrew Smith. "This rule change will help to ensure that eye doctors fulfill their obligations, and will facilitate FTC enforcement of these important requirements."

Issuance of the Final Rule follows an extensive review and consideration of thousands of public comments and materials received by the Commission between 2015 and 2019, including surveys, studies, analyses, and information generated at an FTC workshop devoted to the Rule and the evolving contact lens marketplace. It also incorporates changes made in response to public comments received following a supplemental notice of proposed rulemaking published in May 2019.

As detailed in a final notice of rulemaking to be published shortly, after a contact lens fitting, prescribers will be required to do one of the following to confirm that a patient received their prescription:

- request that the patient acknowledge receipt of the contact lens prescription by signing a separate confirmation statement;
- request that the patient sign a prescriber-retained copy of the prescription that contains a statement confirming the patient has received it;

request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming the patient received the prescription; or

provide the patient with a digital copy of the prescription, and retain evidence that it was sent, received, or made accessible, downloadable, and printable.

Prescribers must maintain proof that they satisfied the confirmation of prescription release requirement for at least three years. If a patient refuses to sign a confirmation, prescribers must note this and save it to record their compliance.

The Final Rule also will affect prescribers in several other ways. First, it adds a new definition of the term "provide to the patient a copy," which will allow the prescriber—with the patient's verifiable consent—to provide the patient with a digital copy of her prescription instead of a paper copy. When seeking a patient's consent, prescribers must tell the patient the specific method of electronic delivery they will use, and must keep a record of the patient's consent to that method for three years. The Final Rule will also require prescribers to provide patients or their designated agents with an additional copy of their prescriptions on request within 40 business hours.

The Final Rule includes several new requirements for sellers as well. To address concerns about sellers verifying prescriptions by leaving incomplete or incomprehensible automated telephone messages with prescribers, sellers who use automated telephone messages for verification must:

record the entire call and preserve the complete recording;

start the call by identifying it as a prescription verification request made in accordance with the Contact Lens Rule;

deliver the verification message in a slow and deliberate manner and at a volume that the prescriber can understand; and

make the message repeatable at the prescriber's option.

The Final Rule also includes modifications designed to reduce illegal prescription alterations by sellers. Under the Final Rule, sellers must make prominently available a way for consumers to present their prescriptions, and must clearly disclose that method. The method of presentation and related disclosure must be provided before requesting the prescriber's contact information to verify the prescription.

The Contact Lens Rule already prohibits prescription alteration, but the Final Rule defines "alteration" to include sellers providing, as part of a verification request, a brand or manufacturer other than that prescribed to the consumer. There are exceptions, however, for when the seller provides, as part of the verification request, the manufacturer or brand named by the consumer in response to the seller's request for the manufacturer or brand listed on the prescription. These changes should reduce the incidence of sellers selling consumers lenses other than those that were prescribed. The Final Rule also clarifies that the only permissible substitution involves private label lenses; private label and brand name lenses can be substituted for each other when they are identical lenses made by the same manufacturer.

The Rule changes go into effect 60 days after publication in the Federal Register notice.

The Contact Lens Rule

In place since August 2004, the Rule imposes obligations on both eye-care prescribers and contact lens sellers. The prescriber must automatically provide the patient with a complete copy of the contact lens prescription after completion of a contact lens fitting, and also must verify or provide the prescription to authorized third parties. The Rule also requires that contact lens vendors sell contact lenses only in accordance with a valid prescription the seller has received from either the patient or prescriber, or has verified via direct communication with the prescriber.

The Commission vote approving publication of the final notice of rulemaking in the Federal Register was 5-0, with Commissioner Rebecca Kelly Slaughter issuing a separate statement. The final notice will be published shortly.

The Federal Trade Commission works to promote competition and to protect and educate consumers. You can learn more about consumer topics and file a consumer complaint online or by calling 1-877-FTC-HELP (382-4357). For the

latest news and resources, follow the FTC on social media, subscribe to press releases and read our blogs.

PRESS RELEASE REFERENCE:

FTC Sends Warning Letters to Sellers of Cosmetic Contacts: All Contact Lens Purchases Require a Prescription from a Medical Professional

FTC Seeks Additional Public Comment on Proposed Changes to the Contact Lens Rule

FTC to Host Workshop March 7 Examining the Contact Lens Marketplace and Proposed Changes to the Commission's Contact Lens Rule

FTC Seeks Comment on Proposed Changes to Contact Lens Rule

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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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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.

(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.

(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.

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