

A Practical Guide to Oregon Law for Optometric Physicians

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Author: Gregory G. Kautz, OD, FAAO

Sponsor: Pacific University, College of Optometry

Introduction

During the first 20 years after I was licensed to practice optometry in Oregon, it was not required for me to show any degree of competence in the laws that define the practice of optometry. It was like getting a driver's license when I was 16. Back then, one did not need to show driving competence to anyone for the rest of their lives after receiving the initial license. However, laws change and requirements are added or subtracted. This is very true for the practice of optometry and health care in general.

In addition to the requirement to attend a class or take an online course in the Oregon laws as it pertains to your practice of optometry, the Oregon Board of Optometry also add a requirement to take a class or online course that discusses ethics. As a practicing optometrist who had to show attendance at 18 hours of continuing education each year, I thought "Oh, boy. More requirements." But, I have grown to appreciate the requirement. I do not remember the first year I authored a course in Oregon law, but the person who recruited me was Bob Yolton, OD, PhD, venerable professor at Pacific University. I'm still not sure how he talked me into it.

As Benjamin Franklin said, "We are all born ignorant, one must work hard to be stupid." William Arthur Ward said, "The pessimist complains about the wind; the optimist expects it to change; the realist adjusts the sails." Change is inevitable, and the OBO wants you to be aware of the changes to allow you to practice within the law and provide high quality, ethical and legal services to your patients. "Ignorantia juris non excusat", or "Ignorance of the law is no excuse".

Source of Law for Practicing Optometry

The laws that govern the practice of optometry are found in the Oregon Revised Statutes (ORS). A link to these laws or statutes can be found on the website of the Oregon Board of Optometry (OBO) or directly at www.oregon.gov/obo/licensing/Pages/laws-rules.aspx. The ORS chapters defining the practice of optometry are found in chapters 683.010 through 683.340.

As we know, laws can be interpreted to specify how a law affects a situation or act. The State of Oregon has the Oregon Administrative Rules (OAR) as its interpretive rule making documentation. The chapter dealing with optometry is Chapter 852. The link to the specific chapters for optometry is <https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=17>. The optometric rules are in Divisions 1, 5, 10, 20, 50, 60, 70 and 80.

Practice of Optometry

What is the practice of optometry? The specific definition says:

“...the use of any means other than invasive or laser surgery, or the prescription of Schedule I and II drugs or pharmaceutical agents that are not on the optometric non-topical formulary, for diagnosis and treatment of the human eye, for the measurement or assistance of the passers or range of human vision or the determination of the accommodative and refractive states of the human eye or the scope of its functions in general or the adaptation of lenses or frames for the aid thereof, subject to the limitations of ORS 683.040 (Qualifications of applicants for licensure)”¹

The practice of optometry also includes:

“... the prescription of Schedule II hydrocodone-combination drugs for the purposes listed in this subsection.”¹

The practice of optometry is further outlined in OAR. Optometrists may perform procedures in addition to refractive services. Optometrists may perform procedures such as corneal foreign body removal, punctal plugs, epilation and more. The tests an optometric physician must ask him or herself are outlined in the OAR, Chapter 852. The procedures optometrists may not perform are those utilizing therapeutic lasers, invasive procedures, sub-Tenon, retrobulbar, intraocular or botulinum injections. If the procedure cannot be performed without using a suture, it is also not allowed. While procedures that require deep or conscious sedation or general anesthesia is prohibited, one may prescribe intermediate-acting medications such as benzodiazepines (BZD) 2 (lorazepam) or BZD3's (diazepam) to help patients relax.² These medications, as an example, are schedule IV medications.³ I have used Ativan as a relaxing medication for patients who are anxious prior to a procedure or a refractive exam.

Notifying the Board Where You Are Practicing

This may be intuitive for many of us, but there are a surprising number of doctors who do not provide an address to the OBO in a timely fashion. One must inform the board in writing prior to practicing at a given location. This should make sense. It is the OBO's responsibility to keep track of practicing optometrists' locations. This includes those who do fill-in work, practicing as locum tenens. If you are going to help an optometrist out by filling in, notify the board *prior* to working in that location. It is also important to include a statement about the physical location of the charts that result from your exams. The OBO is also responsible to track the location of the charts of optometrists for the citizens of Oregon.

I recommend your statement be similar to the following template:

1 April 2018

*TO: The Oregon Board of Optometry
1500 Liberty St. SE
Ste 210
Salem, OR. 97302
RE: Practice Location*

This letter of notice to the OBO is to inform the Board I will be practicing optometry as a fill-in doctor at:

*1800 Pennsylvania Ave.
Portland, OR. 97302*

I will be practicing at that location 15 April 2018 through 30 April 2018.

The records and charts of my examinations will remain at that location. The owner of the practice and the charts is Howard Beatle, OD.

Sincerely,

*Gregory G. Kautz, OD, FAAO
License 1545 ATI*

The Board also has a form available on their website to update your practice and mailing addresses in the system. You can complete the form and then fax or email it to the Board. You may also update your information by using the online system. It is for updating your information. The link is on the OBO web site under [Updating your License Record online](#). Be sure you follow the instructions to gain access to your information. When typing in your license, use the format ATI-1545. Do not forget the dash.

Your mailing address for OBO notices may be different than your practice location. The mailing address is the physical address that the Board will use for any legal notices or services. It is important the address is a physical location, NOT a post office box. My official mailing address is my home address. I have practiced in a number of practices as a locum tenens doctor. Therefore, I have asked the OBO to send official notifications to my home address.⁴

License Renewal

As we all know, all professionals who practice in a number of licensed professions, no license, no work. The OBO may suspend your license if you do not renew your license by their deadline. The current due date is the first day of your birth month and the license expiration corresponds to the last day of the month of the doctor's birth. Notifications are emailed (or mailed if there is not an email address on file) 45 days prior to the due date for each optometrist. There is plenty of time to renew your license prior to the deadline. If you are late within 30 days of your deadline, you may still keep your license IF you include a late fee with your licensing fee. If you are more than 30 days late, your license is automatically suspended. And IF you are more than 60 days late, you may be required to take an examination to be licensed.⁵

It should be noted, the renewal notices sent to optometrists are courtesy notices. If the notice is not received by the licensee, it does not relieve the licensee from responsibility to renew the license by the deadline.

There is also a requirement to have completed an OBO approved course about the law as it pertains to the practice of optometry OR an approved course about ethics. A course in either subject must be completed every two years. The licensee must also have an up-to-date BLS CPR for Health Care Providers certification. Licensees must complete Board approved CPR courses. A list is available on the Board's website. If you complete a course you believe meets the requirements, you can request the Board approve it and add it to the website. The information that lists your status of these course requirements can be found on in your personal information, accessed at the [License Record](#) link on the web site of the OBO.⁶

Continuing Education Requirements

The OBO is responsible to the Oregon public to assure competency of the licensees they oversee. Optometric physicians are required to have 18 hours of continuing education per year. As stated previously, completion of one hour in ethics or Oregon law is required every two years. The ethics/law requirement can be satisfied by attending at least one hour of an OBO public meeting.^{7,8}

The key requirements for approvable CE hours are:

1. 18 hours per year
2. If the licensee has more than 18 hours in a given year, excess hours, as approved by the OBO, can be carried over to the next year. You must request this carryover. It is part of the process when you renew your license on line. Licensees may check the carryover box in the license renewal system to designate which course they wish to carry-over to the next license renewal.
3. Each year, at least nine hours must be in the area of diagnosis, treatment management of ocular disease.
4. No more than five hours of credit per year will be allowed for live observation in an approved surgical facility.
5. The hours of CE must be of different course content. If there is more than one course in a given subject with similar course content, only one will be approved.
6. Credit will be given to no more than 2 hours for each publication of a qualifying article or paper.

7. The number of hours utilizing correspondence or on-line courses is not limited.
8. The courses must be Council on Optometric Practitioner Education (COPE) approved or approved by the OBO. There is a list of OBO approved courses on their web site. ^{9, 10}

Sidebar

You may be interested in the CE requirements of other health care professionals. Medical, Osteopathic and Podiatric Physicians and Physician Assistants are required to have 30 hours of CE per year.¹¹ Naturopathic Physicians are required to have 50 hours of CE per license renewal.¹² Dentists have licenses that expire every two years and must have 40 hours per biennium.¹³ Chiropractic physicians are required to have 20 hours of CE.¹⁴ All boards have specific requirements for their professions. Interestingly, all the listed Boards require at least one hour of pain management per year.

Licensees enter their CE hours into the license renewal system. No certificates are required at license renewal. If selected for CE/CPR audit or otherwise requested by the Board, licensees are required provide CE certificates. The Board no longer requires original certificates. Copies, scans or ARBO OE tracker certificates are acceptable documentation. If selected for an audit, licensees are notified by email and U.S. mail and have 21 days to respond. Not responding to a CE/CPR audit within 21 days can lead to a \$250 civil penalty, which is a reportable discipline. Not responding at all or completing required CE in the time designated by the Board can lead to a \$500 civil penalty and a license suspension.

Standards of Practice

The OBO has the responsibility and authority to discipline optometric physicians if the licensee is guilty of offenses as outlined in the ORS.¹⁵ Primary offenses are unprofessional conduct, gross ignorance or inefficiency in the profession.¹⁶ Given the board's authority, one should be aware of offenses that lie within the definition of what is unprofessional conduct, gross ignorance or inefficiency in the profession. The areas are specified in the OAR Chapter 852, Board of Optometry. As a reminder, the Oregon Revised Statutes (ORS) states the laws governing our practice, but the Oregon Administrative Rules (OAR) outlines the specific requirements and interpretation of the law. The Statutes can be changed by legislative action. The Administrative Rules can be changed, with certain requirements (public hearings) by the OBO.

Records

Let's talk records. It still amazes me my generation still calls anything with recorded songs a record. Or my grandchildren who call an LP record a "very big DVD".

The OBO exists to protect the citizens of Oregon from unsavory practices. One has to admit, if left to our devices, many doctors would be using 5 X 8 cards for charts with personal short cut handwriting. This is hardly fair to patients of optometric physicians. Not to mention optometrists who request records from another provider and cannot make heads or tails what the chart is saying. Or us trying to interpret our own handwriting. Our charts should be clear for the sake of continuity of care for our patients. Because there were too many incidents of indecipherable charts, rules were made to assure there is a standard for records. The OBO has defined many of those standards.

Characteristics of a complete and accurate record must include the following:

- Case History
- Examinations
- Diagnostic and therapeutic services
- Prescriptions (glasses, contact lenses, medicines)
- Instructions for home therapies
- Referral recommendations
- Other information to make the record complete
- Records must be legible and detailed to allow continuity of care

It must be noted the OBO considers incomplete or inaccurate records as unprofessional conduct. ¹⁷

A patient's record must be kept in an *accessible* print or electronic format. They must be kept for a minimum of 7 years or in the case of a minor, until the patient is 21 years of age, whichever is longer. ¹⁸ Accessibility is a critical component for continuity of care. There are challenges when switching electronic record programs from one format to a different one. However, the records must be accessible, nonetheless.

Optometric physicians must provide copies of records or detailed summaries within 14 *calendar* days of a written request of the attention one holding a valid release from the patient. A recommended sample can be found in ORS 192.566. It is reprinted in Appendix A of this course. ¹⁹ It has been my experience most optometrists release records after a written request has been sent within a few working days. If you have requested records and they have not been received within 14 calendar days, you may want to send this quote to uncooperative optometric provider.

Sometimes I have problems getting timely responses from medical providers. According to the OMB, providers have not more than 30 calendar days to respond to a request for records. ²⁰ This is neither timely nor patient centric.

The last critical area for review is the conditions an optometric provider may release records. Basically, the only condition is the patient signs an appropriate request. A provider may not withhold the release of patient records or additional copies of prescriptions for lack of payment for services or goods. This includes finalized glasses prescriptions, finalized contact lens prescriptions and medical prescriptions. ²¹ Back in the olden days, I either balked or withheld records from patients who owed me for services. It made no sense to release copies of my records to a patient who owed me money. The law is now very clear, federal and state, you must release the records regardless of patients' balance of accounts with you.

You may charge for the copies of your records. I have included a copy of ORS 192.521, Health Care Provider and State Health Plan Charges in Appendix B of this course. It outlines the rules for charging for record copies and transmitting via electronics or post service.

Contact Lens Prescriptions

The question I receive the most from providers are about the release of contact lens prescriptions. Most of the questions are asked with incredulity that a completed prescription must be given to a patient upon the finalization of the fitting process and the patient has a balance owed.

The steps are quite simple. When you have completed an examination and you have a finalized refractive or contact lens prescription, you print the prescription at that visit and hand it to the patient. Done. Compliant with federal and state law. Federal law, enforced by the Federal Trade Commission (FTC) and the OBO is quite clear.

The law has not really changed in over a decade. I have placed a Q and A from the FTC in Appendix D of this course. It is quite informative. The FTC is considering changing its rule to require patients sign a receipt they have received their contact lens prescription and to maintain a copy of that receipt for three years. It is also considering removing the language about “private label” contact lenses.²² This change is being driven by corporate contact lens companies who have convinced the FTC the new rule would increase competition and benefit the consumer.

The laws do not require a contact lens or refractive prescription to be released until the provider has completed the necessary tests to determine a prescription. How many times have patients seen you for an examination and expected a glasses and contact lens prescription at the end of the refractive only examination?

What can and should the contact lens prescription? The FTC gives rules about this. A contact lens prescription will include the following areas:²³

- The name of the patient
- The date of examination
- The issue date and expiration date of prescription
- The name, postal address, telephone number, a facsimile telephone number of prescriber
- The power, material or manufacturer or both of the prescribed contact lenses
- The diameter, when appropriate, of the prescribed contact lens
- 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

I also give the number of lenses per eye per year that is allowed in the prescription. 12 lenses per eye per year for monthly lenses, etc.

In addition, the rule requires:

- The contact lens prescription will be given to the patient upon completion of fitting process, whether or not the patient requests the prescription
- A prescriber may not
 - Require the patient to purchase the contact lenses from the prescriber
 - Require a “Prescription” fee
 - Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription

The OAR of prescriptions has the same rules with slightly more specificity when giving prescriptions for glasses or contact lenses. ²⁴

The expiration dates of glasses and contact lenses is generally defaulted to one year in the FTC rules. Eye care providers may require expiration dates less than a year or more than a year. However, if the expiration date is less than a year, the doctor must specify a medical reason for having a shorter expiration time. On occasion, I have prescribed glasses or contact lenses for less than a year. A patient who has accelerated increases in myopia, cataract formation or a less-than-compliant patient wearing contact lenses, may not have a prescription with a 12-month expiration date. A patient whose contact lens prescription has expired, has run out of contact lenses and has appointment with a month or so, I will give a temporary, short time extension of the patient's contact lens expiration date.

Prescribing Medications

Medications are dispensed in the offices of most if not all medical providers. Usually in the form of a sample medication. Rules for the dispensing and writing prescriptions are very specific.

- To patients, if a doctor has a bona fide doctor-patient relationship, optometric physicians may use, prescribe, dispense or administer controlled substances in Schedules III through V and Schedule II hydrocodone-combination drugs.
- An optometric physician may not prescribe medications to him or herself
- Optometric physicians may not prescribe to immediate family members, including in-laws, for whom an optometric physician's personal or emotional involvement may render the doctor unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.

When a drug is dispensed by you, there are requirements for dispensing directly to the patient. As one who dispenses sample medication to patients, I believe the rules are in the best interest of appropriate communication to and for the patient. All dispensed drugs must follow all applicable Oregon Board of Pharmacy rules governing dispensing. All dispensed drugs must be labeled with the following information: ^{25, 26}

- Name, address and telephone number of the optometric physician
- Date
- Name of patient for which the drug is dispensed
- Direction for use
- Required precautionary information
- An expiration date after which the patient should not use the drug. Any rug bearing an expiration date may not be dispensed beyond the said expiration date of the drug

When I dispense a sample medication to a patient, I use the part of the EHR for drug prescriptions, write a prescription as if I am sending it to the pharmacy. However, I use words in English instead of medical short cut terminology. I print the prescription and give it to the patient. It has the medication, the amount dispensed and the period of time to take the medication. I always check the expiration date o the sample. I also use a multi-medication instruction form if the patient is using more than one medication. As you know, this is especially important when treating glaucoma patients. In addition to the above required information, I write down the color of the cap of the medication to help the patient identify which medication is to be used how often and on which eye.

I hope this course gives you pragmatic help and understanding for your compliant practice in delivering care to your patients. If you have questions, please feel free to ask the OBO or write to me at gregk2020@comcast.net.

Gregory G. Kautz, OD, FAAO
Optometric Physician

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23. Electronic Code of Federal Regulations, Title 16, Chapter 1, Subchapter C, Part 315.
24. OAR 852-020-0029, Standards of Optometric Practice, Prescription Content.
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Appendix A: 2017 ORS 192.566¹

Authorization form

A health care provider may use an authorization that contains the following provisions in accordance with ORS 192.558 (Use or disclosure by health care provider or state health plan):

I authorize: _____(Name of person/entity disclosing information) to use and disclose a copy of the specific health information described below regarding: _____(Name of individual) consisting of: (Describe information to be used/disclosed)

to: _____ (Name and address of recipient or recipients) for the purpose of: (Describe each purpose of disclosure or indicate that the disclosure is at the request of the individual)

If the information to be disclosed contains any of the types of records or information listed below, additional laws relating to the use and disclosure of the information may apply. I understand and agree that this information will be disclosed if I place my initials in the applicable space next to the type of information.

- _____ HIV/AIDS information
- _____ Mental health information
- _____ Genetic testing information
- _____ Drug/alcohol diagnosis, treatment, or referral information.

I understand that the information used or disclosed pursuant to this authorization may be subject to redisclosure and no longer be protected under federal law. However, I also understand that federal or state law may restrict redisclosure of HIV/AIDS information, mental health information, genetic testing information and drug/alcohol diagnosis, treatment or referral information.

You do not need to sign this authorization. Refusal to sign the authorization will not adversely affect your ability to receive health care services or reimbursement for services. The only circumstance when refusal to sign means you will not receive health care services is if the health care services are solely for the purpose of providing health information to someone else and the authorization is necessary to make that disclosure.

You may revoke this authorization in writing at any time. If you revoke your authorization, the information described above may no longer be used or disclosed for the purposes described in this written authorization. The only exception is when a covered entity has taken action in reliance on the authorization or the authorization was obtained as a condition of obtaining insurance coverage.

To revoke this authorization, please send a written statement to _____ (contact person) at _____ (address of person/entity disclosing information) and state that you are revoking this authorization.

I have read this authorization and I understand it. Unless revoked, this authorization expires _____ (insert either applicable date or event).

By: _____

(individual or personal representative)

Date: _____

Description of personal representative's authority:

Appendix B: 2017 ORS 192.563

Health care provider and state health plan charges

A health care provider or state health plan that receives an authorization to disclose protected health information may charge:

- (1)(a) No more than \$30 for copying 10 or fewer pages of written material, no more than 50 cents per page for pages 11 through 50 and no more than 25 cents for each additional page; and
- (b) A bonus charge of \$5 if the request for records is processed and the records are mailed by first class mail to the requester within seven business days after the date of the request;

- (2) Postage costs to mail copies of protected health information or an explanation or summary of protected health information, if requested by an individual or a personal representative of the individual; and

- (3) Actual costs of preparing an explanation or summary of protected health information, if requested by an individual or a personal representative of the individual. [Formerly 192.521]

Appendix C: Food and Drug Administration

Contact Lens Prescription

When you get an eye exam, you have the right to get a copy of your prescription. You can use this prescription at another vendor or to order contact lenses on the Internet, over the phone, or by mail. See Buying Contact Lenses.

As defined by the Federal Trade Commission (FTC) regulations, a prescription should contain sufficient information for a seller to completely and accurately fill the prescription. This includes the following items:

- Patient's name
- Examination date
- Date patient receives prescription after a contact lens fitting (issue date) and expiration date of prescription
- Name, address, phone number and fax number of prescriber
- Power
- Material and/or manufacturer of the prescribed contact lens
- Base curve or appropriate designation of the prescribed contact lens
- Diameter, when appropriate, of the prescribed contact lens
- For 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

The FTC enforces the requirement that eye care professionals are to give patients a copy of their contact lens prescriptions. Go to FTC's website to read:

FTC Consumer Alert: The Eyes Have It – Get Your Prescription
Federal Trade Commission (FTC)
<http://www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt143.shtm>

FTC Facts for Business: The Contact Lens Rule: a Guide for Prescribers and Sellers
Federal Trade Commission (FTC)
<http://www.ftc.gov/bcp/edu/pubs/business/health/bus62.shtm>

Appendix D: Complying with the Contact Lens Rule

TAGS: Advertising and Marketing Health Claims

As an eye care provider, you must give patients a copy of their contact lens and eyeglass prescriptions. These Q&As can help you learn more about your duties.

[application/pdf icon View PDF \(109.25 KB\)](#)

The Federal Trade Commission enforces both the Contact Lens Rule and the Eyeglass Rule. These Rules require that eye care providers give their customers copies of their prescriptions: Contact lens prescriptions must be given to the customers once the lens fitting is complete; eyeglass prescriptions must be given to customers at the end of the eye exam. Here are questions and answers to help eye care providers comply with the Contact Lens Rule.

1. WHO — AND WHAT — THE RULE COVERS

Q: I'm an optician. Am I considered a "prescriber" under the Contact Lens Rule?

A: Under the Contact Lens Rule, opticians are prescribers if state law permits them to fit contact lenses and to issue prescriptions. Sometimes opticians are called "dispensing opticians."

Q: I'm a prescriber. What if I verify a prescription and then something is wrong with the contact lenses the consumer bought from another seller? Am I liable?

A: The Fairness to Contact Lens Consumers Act and the Contact Lens Rule don't impose liability on a prescriber for problems with contact lenses sold by someone else. Traditionally, state law determines the liability.

Q: I'm a prescriber. If I don't act on a verification request, the prescription is verified passively. The consumer gets the contacts from another seller. Am I liable if something is wrong with the contact lenses?

A: Neither the Act nor the Rule imposes liability on a prescriber for problems with contact lenses. State law determines who would be liable if problems arise.

Q: I'm a prescriber. What if I'm unable to verify my patient's prescription during the "eight business hours" period, and later learn that the prescription was inaccurate, expired, or invalid? Am I required to contact the seller?

A: Neither the Act nor the Rule addresses this situation. However, it would be in your patient's best interest to contact the seller and the patient to alert them to a possible error in the prescription.

Q: Does the Contact Lens Rule apply to contact lens sellers located beyond U.S. borders?

A: The Contact Lens Rule applies to all sellers who provide contact lenses to consumers who live in the U.S.

Q: Does the Contact Lens Rule apply to non-corrective “cosmetic” or “decorative” contact lenses?

A: Both contact lenses that correct users' vision and decorative, cosmetic, or plano lenses require a valid contact lens prescription.

2. THE PRESCRIPTION

Q: When am I required to give my patients their contact lens prescriptions?

A: You must give your patients a copy of their contact lens prescription when the lens fitting is complete. Some patients may require follow-up visits after the initial exam before their contact lens fitting is complete. All follow-up exams must be medically necessary, and eye care providers should use sound professional judgment — based on appropriate and objective standards of care — to make that call.

Q: What if my patient asks for a copy of the contact lens prescription before the lens fitting is complete?

A: The Act and the Rule do not require that you provide the contact lens prescription to the patient before the fitting is complete. If you are prepared to sell your patients contact lenses, however, you cannot refuse to give them a copy of their prescription on the grounds that their fitting isn't complete. If you're willing to sell them the lenses, that means their fitting is complete, and you must give them a copy of the prescription.

Q: In my state, a contact lens prescription expires two years after it's written. Does the Contact Lens Rule change that?

A: No. If state law specifies an expiration date of one year or more from the prescription's issue date, the prescription expires on that date. But if state law specifies an expiration date of less than one year from the prescription's issue date, the expiration date is determined by the Rule. Under the Rule, a prescription expires one year from its issue date, unless there's a legitimate medical reason for setting a shorter expiration date.

Q: In my state, the law says I have to provide contact lens prescriptions to patients only if they ask for them. But the Contact Lens Rule says I have to provide the prescriptions regardless. Which law applies?

A: The Contact Lens Rule applies. You must give your patients their contact lens prescription at the completion of the contact lens fitting, whether the patient asks for it or not.

Q: As an eye care provider, can I charge a patient for trial lenses or require a patient to buy them?

A: You may, but only if the trial lenses are necessary to complete the fitting process. This is sometimes the case with some “specialty” or custom-made lenses. You may not require a patient to buy contact lenses — such as a six-month supply of disposable lenses — as a condition of giving them a copy of their prescription.

Q: I'm a contact lens seller. Can I substitute one brand of contact lenses for another brand under the Rule?

A: You can substitute one brand of contact lenses for another if:

- the prescription specifies private label lenses, and
- the substitute lenses are identical to the prescribed lenses.

Example: TekViz, Inc. manufactures and sells contact lenses under both the "TekViz" brand and the "Dr. Jones" brand. If the prescription specifies "Dr. Jones" brand lenses, the seller may substitute "TekViz" brand lenses. The seller may not substitute non-identical lenses manufactured by TekViz, Inc., or lenses manufactured by another company.

Q: The Contact Lens Rule says prescribers must provide or verify contact lens prescription information "as directed" by a third party designated by a patient. But according to HIPAA (Health Insurance Portability and Accountability Act of 1996), don't I have to get written authorization from a patient before providing or verifying his contact lens prescription to a seller?

A: No. HIPAA permits covered entities to use or disclose protected health information without patient authorization if the use or disclosure is for "treatment" or "required by law." Providing, confirming, correcting, or verifying a contact lens prescription to a seller designated by the patient constitutes treatment or is required by the Act and the Rule.

Q: As the eye care provider, may I include a specific number of refills on a contact lens prescription?

A: The Contact Lens Rule doesn't require or prohibit you from including refill quantities on contact lens prescriptions. Follow your state law if it requires — or prohibits — such information. Note that the Rule does not allow you to use refill quantities to shorten a prescription expiration period to less than a year unless there are legitimate medical reasons.

3. RECORD-KEEPING REQUIREMENTS FOR SELLERS

Q: As a contact lens seller, I've called a lot of eye care providers to find out whether they have Saturday business hours. Which records do I keep to demonstrate I have "actual knowledge" of their Saturday business hours?

A: As a seller, you must keep a record of the eye care provider's regular Saturday hours and how you know those are the hours. If you call eye care providers to learn their actual business hours, keep your notes from those calls for record-keeping purposes. You must include Saturday business hours on a verification request if you want to include those hours in the "eight business hour" verification period.

Q: Can my verification request form state that I assume that all prescribers' offices have Saturday business hours unless the prescriber's office tells me otherwise?

A: No. A seller may count a prescriber's Saturday business hours as part of the "eight business hour" verification period only if the seller knows that the prescriber has Saturday business hours. Assuming that a prescriber has Saturday business hours unless the prescriber tells you otherwise does not constitute actual knowledge for purposes of the Rule.

Q: As a seller, can I depend on information a customer gives me about an eye care provider's Saturday business hours?

A: Depending on the circumstances, information you get from a customer may be acceptable under the Rule. For example, if a customer gives you the prescriber's business card, which states that the office is open from 9 a.m. to 3 p.m. on Saturdays, you may rely on it. Remember to document that this information is the basis for your determination.

Q: What if the customer tells me, "I think my eye doctor's office is open from 9 a.m. to 5 p.m. on Saturdays"?

A: Don't rely on a customer's statement alone as a basis for your actual knowledge of a prescriber's regular Saturday hours. Verify an eyecare provider's Saturday hours some other way.

4. "EIGHT BUSINESS HOURS" FOR VERIFICATION

Q: I'm a prescriber. How much time do I have to verify a prescription?

A: The Act and the Rule give prescribers "eight business hours" to verify a prescription regardless of when the prescriber receives a properly completed verification request. "Eight business hours" is not the same as "eight hours." A "business hour" is an hour during the period from 9 a.m. to 5 p.m., Monday through Friday (excluding federal holidays), plus hours on Saturday that the seller actually knows the prescriber is regularly open for business. Business hours are calculated based on the prescriber's time zone.

Q: How is the "eight business hour" period calculated if the seller's verification request is received during business hours?

A: If you receive the verification request during business hours, the "eight business hour" period starts when the prescriber receives the request from the seller and ends when "eight business hours" have elapsed.

For example, say the verification request is received at 4 p.m. on Monday. The "eight business hour" period begins at 4 p.m. on Monday and ends at 4 p.m. on Tuesday. If the eye care provider doesn't respond, the seller can ship at 4:01 p.m. on Tuesday.

But say the verification request is received at 11 a.m. on Friday. The seller has documented actual knowledge that the eye care provider's office is regularly open from 10 a.m. to 4 p.m. on Saturday. In this case, the "eight business hour" period would begin at 11 a.m. on Friday and end at noon on Saturday. If the eye care provider doesn't respond, the seller can ship at 12:01 p.m. on Saturday.

What if you get a verification request at 11 a.m. on Friday, but the eye care provider's office isn't regularly open Saturdays? The "eight business hour" period begins at 11 a.m. on Friday and ends at 11 a.m. on Monday. If the eye care provider doesn't respond, the seller can ship at 11:01 a.m. on Monday.

Or suppose you get a verification request at 2 p.m. on Monday, July 3. The “eight business hour” period begins at 2 p.m. on Monday and ends at 2 p.m. on Wednesday, because Tuesday is July 4, a federal holiday. If the eye care provider doesn’t respond, the seller can ship at 2:01 p.m. on Wednesday.

Q: How is the “eight business hour” period calculated if the seller’s verification request is received outside business hours?

A: If the verification request is received outside of business hours, the “eight business hour” period starts at 9 a.m. the next weekday that isn’t a federal holiday (or on Saturday, if appropriate). It ends “eight business hours” later.

For example, say the verification request is received at 7 p.m. on Tuesday. The “eight business hour” period begins at 9 a.m. on Wednesday and ends at 5 p.m. the same day. If the eye care provider doesn’t respond, the seller can ship at 5:01 p.m. on Wednesday.

Or, the verification request is received at 2 p.m. on Saturday. The eye care provider’s office isn’t open Saturdays, and Monday is July 4. In this case, the “eight business hour” period begins at 9 a.m. on Tuesday and ends at 5 p.m. on Tuesday. If the eye care provider doesn’t respond, the seller can ship at 5:01 p.m. on Tuesday.

5. DIRECT COMMUNICATION

Q: When is a direct communication “completed” under the Contact Lens Rule?

A: A direct communication is completed when the recipient gets all the required information. For example, direct communication by telephone requires reaching and speaking with the intended recipient, or leaving a clear voice message, including all the required information, on the recipient’s telephone answering machine. Similarly, a direct communication by fax or email is completed when the intended recipient receives the fax or email message.

Q: How do I know that a direct communication by fax or email has been completed?

A: A fax confirmation sheet showing that a fax was transmitted is sufficient to conclude that the communication is completed.

Confirmation that an email was sent generally is sufficient to conclude that it was received. Of course, if the sender has reason to believe that an email message was not transmitted instantly (such as an electronic notice stating that the email could not be sent), the communication is not considered completed until it is successfully transmitted to the recipient’s account.

Q: I’m a seller who uses the telephone for direct communication with eye care providers. Do I have to keep a written log of all communications, or can I store this information electronically?

A: The Rule allows you to store the required information electronically, and the information can be made available for review by the Commission, if necessary.

6. AUTOMATED TELEPHONE SYSTEMS

Q: My company sells contact lenses to consumers. Can I use an automated telephone system to send a verification request to an eye care provider?

A: The Act expressly authorizes sellers to send verification requests by telephone, including automated telephone systems, as long as the requests comply with the Rule. That is, the verification request must provide all the information required, and sellers must wait “eight business hours” before selling contact lenses to the consumer.

A request delivered by an automated telephone system doesn’t comply with the Rule if: it isn’t delivered in a volume and cadence that a reasonable person can understand; it contains incomplete verification information; or it requires the prescriber’s office to provide an immediate response.

Q: When I respond to a verification request, I’d like to get some confirmation — a call, email or fax — indicating that the seller received my response. Does the Rule require that?

A: Neither the Act nor the Rule requires sellers to provide confirmation to prescribers, although they may choose to do so.

Q: My calls to the seller are answered by an automated response system or by their contact person’s voicemail. Does the Rule require sellers to have a person available to respond to my calls?

A: The Rule requires sellers to provide “a reasonable opportunity” for prescribers to communicate with them, but it doesn’t require them to have a person available to respond to calls. Nevertheless, sellers may choose to have someone available. If you have left a response on a seller’s verification response line indicating that the prescription has expired or is otherwise invalid, the seller is not permitted to ship the lenses.

Q: I’ve received a seller’s verification request via an automated telephone message, but I can’t understand it. What can I do?

A: Automated telephone verification messages must be delivered in a volume and cadence that a reasonable person can understand. If you are unable to hear or understand an automated verification request, FTC staff attorneys encourage you to contact the seller directly. If you cannot contact the seller, file a complaint with the FTC at ftc.gov.

Q: Sometimes I can’t get my calls or faxes through to the sellers. What can I do?

A: If some attempts to contact the seller are unsuccessful, try other methods of communication. For example, if your fax transmission fails, try contacting the seller via telephone or email. If you cannot contact the seller, file a complaint with the FTC at ftc.gov. Document your attempts; details make complaints more helpful.

7. FILING A COMPLAINT WITH THE FTC

You can file a complaint with the FTC online or by phone. To file a complaint online, visit ftc.gov, click “File a Complaint,” and enter your information into the form. At the section entitled, “Subject of Your

Complaint,” click on “Health.” In the final section, “Explain Your Problem,” include as many details as possible. Click “Submit Complaint” to complete the process.

To file a complaint by phone, call 1-877-FTC-HELP (1-877-382-4357); TTY: 1-866-653-4261. A counselor will record your information and enter it directly into the agency’s complaint database.

The complaint should include specific details, for example, the date and time your call was made or the reason the call you received wasn’t understandable. Prescribers with evidence, such as an audiotape of a call or the recording left on an answering machine, should keep the evidence because it may be very helpful.

While the FTC doesn’t resolve individual complaints, your complaints help the agency investigate Rule violations and may lead to enforcement action.