



FEDERAL TRADE COMMISSION

PROTECTING AMERICA'S CONSUMERS

THE CONTACT LENS RULE: A GUIDE FOR PRESCRIBERS AND SELLERS

TAGS: [Advertising and Marketing](#) | [Health Claims](#)

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

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

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

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

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

For Prescribers

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

All prescribers must:

give a copy of the contact lens prescription to the patient at the end of the contact lens fitting – even if the patient doesn't ask for it. You may provide the prescription digitally if the patient agrees to get it digitally instead of on

paper, and if the patient also agrees to the specific method (for example, e-mail, text, or portal), *and* if the electronic means can be accessed, downloaded, and printed by the patient. You also must keep records or proof that a patient agreed to digital delivery for at least three years.

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

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

if you provided a digital copy of the prescription, keep records or proof for at least three years that it was sent, received, or made accessible, downloadable and printable.

give the contact lens prescription to anyone who is designated to act on behalf of the patient, including contact lens sellers, within 40 business hours.

In any response to a verification request, you have to correct any inaccuracy in the prescription, inform the seller if it's expired, and give the reason if it's invalid.

You cannot require patients to:

buy contact lenses

pay additional fees or

sign a waiver or release in exchange for a copy of the contact lens prescription.

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

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

Prescription expiration

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

For Sellers

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

What is direct communication?

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

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

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

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

Verification

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

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

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

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

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

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

Record-keeping

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

The Fine Print

What practices are not allowed?

You must not:

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

fill a prescription if the prescriber tells you by direct communication within eight business hours after getting a complete verification request that the prescription is inaccurate, expired, or otherwise invalid

alter prescriptions. If you submit a verification request for a brand that is not the customer's prescribed brand, you may be violating the Rule by altering the prescription. The only exception is if you've submitted a verification request for a brand that the customer told you is listed on their prescription. To qualify for this exception, you must ask the customer to give you the manufacturer or brand listed on their prescription, and the customer must have told you that information. For private label lenses, however, you can substitute identical contact lenses made by the same manufacturer and sold under a different name

suggest or state that customers can get contact lenses without a prescription

What's a business hour?

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

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

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

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

Your Opportunity to Comment

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

June 2020



ftc.gov



Lisa Martin <lmartin@utah.gov>

Re: Board Authorized Procedures

2 messages

Robert Wooldridge OD <rpwod@aol.com>

Tue, Aug 25, 2020 at 5:02 PM

Reply-To: Robert Wooldridge OD <rpwod@aol.com>

To: "alyssa@utaheyedoc.org" <alyssa@utaheyedoc.org>, "DCarey@AOA.ORG" <DCarey@aoa.org>

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Daniel,

In response to your question to Alyssa White, the Utah State Board has specifically discussed and approved the procedures indicated below. This is not intended to be an all inclusive list. These are only the procedures that have been specifically discussed. Other procedures occasionally arise for review by the Board and approval or denial by DOPL. I will copy my fellow Board members and Larry Marx of the Dept. of Occupational and Professional Licensing in case I forget a procedure or state something in error.

Procedures discussed and approved

Chalazion incision and cuttorage

"Lump and Bump" excision or biopsy eg papilloma, nevus, etc

Cyst drainage/excision

Punctal cautery

Intraocular injections into the anterior chamber or vitreal cavity eg Durysta into AC and Anti-VEGF medications into the vitreous

Ocular or periocular injections, eg subconjunctival injections of 5-FU after trabeculectomy

Botox in periocular areas and adnexa for therapeutic or cosmetic purposes

Intravenous injection of fluorescein for fluorescein angiography

Laser suture lysis ie cutting a suture with a laser, not laser surgery involving cutting of ocular tissue

Corneal and conjunctival foreign body removal have been previously approved for many years. Suture removal would be included in this category.

In general, if the Optometry Practice Act does not exclude a treatment, it is generally allowed though this is subject to Board review and DOPL approval, hence the recent discussions and decisions. Procedures specifically denied include ocular surgery that must be performed in an operating room such as cataract surgery and laser surgery such as LASIK, SLT, retinal laser treatments.

The exclusion of laser surgery does not apply to certain cosmetic treatments of the skin that are frequently performed by Master Estheticians, nurses, etc

Larry and Board members, please correct me if I have made any errors or omissions.

Rob

Robert P. Wooldridge, OD, FFAO

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Carey, Daniel <DCarey@aoa.org>

Tue, Aug 25, 2020 at 5:43 PM

To: Robert Wooldridge OD <rpwod@aol.com>

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Excellent information, thank you very much for this thorough overview.

On Aug 25, 2020, at 7:02 PM, Robert Wooldridge OD <rpwod@aol.com> wrote:

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Lisa Martin <lmartin@utah.gov>

Board agenda item

3 messages

Robert Wooldridge OD <rpwod@aol.com>

Thu, Aug 20, 2020 at 3:39 PM

Reply-To: Robert Wooldridge OD <rpwod@aol.com>

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Hi Everyone,

I would like to put vaccinations on the agenda for our next meeting. That is, I believe that it would be reasonable for optometrists to administer vaccines such as for the flu. I discussed this briefly with Larry after a meeting a year or so ago and he said we cannot do these injections. Larry, is this something we can discuss?

I believe there will be a huge demand for the flu vaccine this Fall and the COVID vaccine when it becomes available. Many of our patients do not have a PCP or see a MD on a regular basis. Making such vaccines available in optometrists offices will greatly improve access to these medications for Utah citizens. We know that pharmacists can give the shots; I think that optometrists are certainly qualified to do so as well.

Rob

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Larry Marx <lmarx@utah.gov>

Thu, Aug 20, 2020 at 3:50 PM

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I believe it is a scope of practice issue we should discuss. I personally would very feel comfortable having an optometrist give me a vaccination, since you can inject substances into the eye the arm would be easy. Optometrist are healthcare providers and well qualified. I will research what other states allow. It will be critical for people to get flu, pneumonia and if it becomes available Covid vaccinations.

Larry

[Quoted text hidden]

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Larry Marx, Bureau Manager

State of Utah Department of Commerce
Division of Occupational
and Professional Licensing

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Robert Wooldridge OD <rpwod@aol.com>

Thu, Aug 20, 2020 at 4:25 PM

Reply-To: Robert Wooldridge OD <rpwod@aol.com>

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Thank you Larry!

Rob

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(A) An [optometrist/doctor of optometry/optometric physician] may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(B) In order to initiate and administer an immunization described in subdivision (A), an [optometrist/doctor of optometry/optometric physician] shall do all of the following:

- (1) Complete an immunization training program endorsed by the CDC or the injections course approved by the National Board of Examiners in Optometry or similar equivalent, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.
- (2) Be certified in basic life support.
- (3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the [Insert Appropriate State Agency].

(C) An [optometrist/doctor of optometry/optometric physician] administering immunizations pursuant to this section, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.