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What is **The Contact Lens Rule**? A guide to the Federal Trade Commission's rules on Contact Lenses, Amended in 2020.

# Reproduced from:

https://www.ftc.gov/business-guidance/resources/contact-lens-rule-guide-prescribers-sellers

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. If you are willing to sell lenses to the patient, the fitting is complete and you must provide them with the prescription. Similarly, if you are simply renewing a patient's prescription, you must provide the prescription immediately upon completion of the examination.

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 prescription 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. If you provide the prescription via portal, access to the prescription should remain available as long as the prescription is valid.

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. You may not ask or require a patient to sign the confirmation before you give them their prescription. For example, asking for confirmation should not be part of any pre-appointment paperwork. Also, any confirmation you get before a patient receives their prescription does not comply with the Rule.

\*\*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. You may ask for a patient's permission to get a digital copy of the prescription before the examination. If the patient doesn't agree to a digital copy, you have to give them a printed copy and ask for a confirmation of receipt.

\*\*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 inform the seller if it's expired, correct any inaccuracy in the prescription, and give the reason if it's invalid. A seller may not sell the lenses after a timely denial. However, a prescriber's general denial without explanation (for example, the words "inaccurate" or "invalid" alone), violates the Rule.

### 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 quali?ed 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:

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

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

### 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

<sup>\*\*</sup>patient' s full name and address

<sup>\*\*</sup>contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate

<sup>\*\*</sup>quantity of lenses ordered

<sup>\*\*</sup>date of patient order

<sup>\*\*</sup>date and time of verification request

<sup>\*\*</sup>a contact person for the seller, including name, fax and phone numbers, and

<sup>\*\*</sup>a clear statement of the prescriber's regular Saturday business hours if the seller is counting those hours as business hours under the Rule.

<sup>\*\*</sup>confirms its accuracy to the seller via direct communication

<sup>\*\*</sup>informs the seller that the prescription is inaccurate and provides accurate information to the seller via direct communication, or

<sup>\*\*</sup>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.

<sup>\*\*</sup>record the entire call

<sup>\*\*</sup>begin the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule.

<sup>\*\*</sup>deliver the information required by the Rule in a slow and deliberate manner and at a reasonably understandable volume, and

<sup>\*\*</sup>make the information required by the Rule repeatable at the prescriber's option

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.

### 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
- \*\*fill additional shipments of lenses once the prescriber has let you know that the prescription provided in the verification request was inaccurate, expired, or invalid, without re-verifying the request or getting a copy of your patient's valid 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.

[Note: Edited December 2021 to clarify guidance on pre-appointment paperwork.]

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#### 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.