

FTC FACTS for Business

Complying with the Contact Lens Rule

INTRODUCTION

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

- **I’m an optician. Am I considered a “prescriber” under the Contact Lens Rule?**

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.”

- **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?**

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.

- **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?**

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.

- **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?**

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.

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

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

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

The Contact Lens Rule applies to contact lenses that require a prescription.

2. The Prescription

- **When am I required to give my patients their contact lens prescriptions?**

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.

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

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.

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

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.

- **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?**

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.

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

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.

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

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.

- **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?**

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.

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

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

- **As a contact lens seller, I’ve called a lot of eye care providers to find out whether they have Saturday business hours. What records do I keep to show I have “actual knowledge” of their Saturday business hours?**

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.

- **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?**

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.

- **As a seller, can I depend on information a customer gives me about an eye care provider’s Saturday business hours?**

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.

- **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”?**

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 eye care provider’s Saturday hours some other way.

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4. “Eight business hours” for Verification

- **I’m a prescriber. How much time do I have to verify a prescription?**

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.

- **How is the “eight business hour” period calculated if the seller’s verification request is received during business hours?**

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.

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

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

- **When is a direct communication “completed” under the Contact Lens Rule?**

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.

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

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.

- **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?**

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

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

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.

- **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?**

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

- **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?**

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.

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- **I've received a seller's verification request via an automated telephone message but I can't understand it. What can I do?**

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.

- **Sometimes I can't get my calls or faxes through to the sellers. What can I do?**

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.

The FTC works for the consumer to prevent fraudulent, deceptive and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint or to get free information on consumer issues, visit ftc.gov or call toll-free, 1-877-FTC-HELP (1-877-382-4357); TTY: 1-866-653-4261. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

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.

FEDERAL TRADE COMMISSION	ftc.gov
1-877-FTC-HELP	FOR THE CONSUMER