



AMERICAN OPTOMETRIC ASSOCIATION

## Contact Lens Rule Compliance Toolkit



October 2020

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## Introduction

In June 2020, the Federal Trade Commission (FTC) finalized changes to the Contact Lens Rule. This toolkit includes information and guidance regarding how prescribers can comply with the updated regulations.

The June notice of updated guidelines came nearly 4 years after the FTC initially began to consider changes to regulations under the Fairness to Contact Lens Consumers Act (FCLCA). In December 2016, based on the FTC's belief that contact lens prescribers have not been complying with the FCLCA requirement to automatically provide contact lens prescriptions to patients at the completion of a contact lens fitting, the FTC proposed to finalize a requirement that would mandate that all contact lens prescribers have all patients sign a separate form acknowledging that the patient received a copy of their contact lens prescription. At that time, the FTC proposed that the signed acknowledgement form include FTC-mandated language. The form would also be required to be retained for 3 years and would need to be produced in the case of an investigation.

Since the beginning of this rule making process, the FTC has dismissed the concerns of [doctors of optometry, ophthalmologists](#), [patient health and consumer advocates](#), and [a bipartisan group of more than 100 U.S. House and Senate leaders](#) who have repeatedly shared concerns in public comments, Congressional and advocate sign-on letters, [agency oversight](#) hearings, committee directives, and reports and [public education workshops](#).

In June 2019, the FTC released the supplementary rulemaking, which included changes from the initial proposal to allow prescribers additional options for creating a paper trail to document that patients received copies of their contact lens prescriptions.

The regulation changes announced in June 2020 had an effective date of October 16, 2020.

# Contact Lens Rule Requirements

## All prescribers must:

- ✓ Provide a copy of the contact lens prescription to the patient at the end of the contact lens fitting (prescriptions must be provided, even if the patient doesn't ask for it).
- ✓ Correct any inaccuracy in the prescription, inform the seller if it's expired, and give the reason if it's invalid in response to a verification request.

## Prescribers cannot:

- ☒ Require patients to buy contact lenses from the prescriber.
- ☒ Require patients to pay additional fees or sign a waiver or release in exchange for a copy of the contact lens prescription.
- ☒ Disown liability or responsibility for the accuracy of an eye examination.

**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.<sup>1</sup>**

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<sup>1</sup> <https://www.ftc.gov/tips-advice/business-center/guidance/contact-lens-rule-guide-prescribers-sellers>

# FTC Guidance on Contact Lens Prescription Extensions

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## Contact lens prescription renewals: Prescribers still need to release that Rx

By: Alysa Bernstein | Jul 27, 2020 9:44AM

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Your patient calls you panicked because she's on her last pair of contact lenses. Perhaps due to COVID-19, she isn't able to (or doesn't want to) come into the office. You may determine, in your medical judgment, that it's appropriate to renew or extend that prescription. How do the Contact Lens Consumer Act and the Contact Lens Rule apply to that interaction?

While prescribers are likely looking out for the best interests of their patients by renewing or extending prescriptions under those circumstances, they still have to comply with the law. A renewal or extension – including one where you determine that no change in the existing prescription is required – counts as a "contact lens fitting" under the [Fairness to Contact Lens Consumers Act](#) and the [Contact Lens Rule](#). That means if you renew or extend a patient's prescription in that context, you still must provide the patient a copy of the contact lens prescription, whether or not they ask for it. If prescribers are willing to sell lenses to their patients, the fitting is complete and prescribers must automatically give their patients a copy of the prescription.

Under the Act and the Rule, you can't require payment from a patient as a condition of providing or verifying their contact lens prescription. Yes, you may require a patient to pay for the exam, fitting, or evaluation before giving them a copy of their prescription, but only if you also require immediate payment from a patient whose eye exam shows no need for glasses or contacts. Prescribers also can't require patients to buy contact lenses, or sign a waiver or release, as a condition of releasing or verifying a prescription. These prohibitions apply to prescription renewals and extensions.

So renew those prescriptions, if medically appropriate, but provide prescriptions to your patients – and compete for the sale of lenses on price and convenience.

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## 2020 Compliance Updates

### New Contact Lens Prescription Documentation Requirements

Contact lens prescribers must document that they have provided a copy of the contact lens prescription to the patient. Doctors can utilize any method outlined below:

- **Digital Copy:** Doctors can provide a digital copy of the prescription to the patient and retain documentation that the prescription was sent. The doctor would also need to get patient consent to send the prescription electronically. **Update: In August 2020 FTC clarified that consent to provide the prescription electronically can be obtained through the intake form process.**
- **Patient Signs Prescription:** Doctors can have patients sign the prescription itself and include language on the prescription noting that the prescription was received. The doctor would then need to keep a copy of the signed prescription.
- **Patient Signs Eye Exam Sales Receipt:** Doctors can have patients sign their sales receipt for the examination and on the receipt include language that the prescription was received.
- **Patient Signs Separate Form:** Doctors can have patients also choose to use a separate form that the patient signs acknowledging receipt of the prescription. The doctor is allowed to use whatever language he/she would like to on that form. Additional information/language can be included on the form.

### New Documentation Requirements

Prescribers must maintain documentation for at least three (3) years. If a prescriber provides a digital copy of the prescription, the prescriber must keep records or proof for at least three years that it was sent, received, or made accessible, downloadable and printable. If a patient refuses to sign the confirmation, the prescriber should note the refusal, sign it, and keep it.

### New Requirements for Contact Lens Retailer Requests for Prescriptions

The FCLCA has always required that prescribers provide contact lens prescription to anyone who is designated to act on behalf of the patient, including contact lens sellers.

The updated 2020 final regulations now require that physicians respond to these requests **within 40 business hours**. Prior to this rule change there was not a timeframe within which the prescription was required to be provided.

## Templates for Compliance

The following are templates to assist physicians in complying with new regulatory changes.

The template "**Contact Lens Prescription Signed Acknowledgment Form**" is an example of a form that can be used if you choose to have patients sign a separate form to acknowledge receipt of the patient's contact lens prescription. You can also create your own form. The FTC does not require specific language to be used but recommends, "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting."

The AOA has reached out to several electronic health record companies to ensure they are aware of the recent regulatory changes. These companies are working to improve functionality to ensure compliance. Contact your EHR vendor for information on approaches that may be feasible for your system.



# Contact Lens Prescription Signed Acknowledgment Form

Sign below to acknowledge that you were provided with a copy of your contact lens prescription at the completion of your contact lens fitting.

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_

# Frequently Asked Questions

## Exemptions

*FTC has indicated that doctors who do not have a direct or indirect financial interest in the sale of contact lenses do not need to request that a patient acknowledge receipt of a contact lens prescription and need not maintain records associated with patient acknowledgments. Below are frequently asked questions regarding this exemption.*

**Does a doctor need to comply with the new acknowledgement requirements if the doctor sells no medical devices in their office but they lease space from a corporate partner that does sell products? Would leasing space mean the doctor who does not sell any medical devices has an association, affiliation, or are co-located with a contact lens seller?**

Yes, a lease arrangement would qualify as an indirect financial interest such that a prescriber would need to comply with the acknowledgment and recordkeeping requirement of the Final Rule. If prescribers are ever not sure, FTC would advise them to err on the side of caution and request acknowledgments and keep records of such acknowledgments.

**Many doctors of optometry provide optometric care through the military, or at Veterans' Administration hospitals or through the Public Health Service on tribal reservations. These doctors will often prescribe contact lenses but have no direct or indirect financial interest in the sale of contact lenses. Are these doctors exempt from the new rules?**

Any prescriber who has no direct or indirect financial interest in the sale of contact does not need to request that a patient acknowledge receipt of a contact lens prescription and need not maintain records associated with patient acknowledgments. FTC has indicated, "It sounds like that may be the case with optometrists providing through the military or via the public health service."

**How do I determine if I have a direct or indirect financial interest in the sale of contact lenses, which requires that I ask my patients to confirm prescription receipt?**

FTC indicates, "If you have an association, affiliation, or are co-located with a contact lens seller, you have a financial interest in the sale of contact lenses. But there may be other ways where you have a financial interest with a contact lens seller so, if you are not sure if your interest qualifies, err on the side of caution and ask your patients to confirm receipt of their prescriptions."

## Trial Lenses and Specialty Lenses

**Are gas permeable lenses exempt from prescription release and acknowledgement requirements?**

There is unfortunately not an exemption for those lenses. FTC noted in the initial rulemaking:

“The Act thus does not permit the Commission by rule to grant an exception to the release requirement for custom-designed soft and rigid gas permeable lenses.”

The FTC did clarify:

*“Specialty” or custom-made lenses are sometimes necessary to complete the fitting process. To the extent these lenses are necessary to complete the fitting process, prescribers may charge patients for such lenses as part of the cost of the fitting process, and as such **may condition the release of a contact lens prescription on payment of the fitting fee.**”<sup>2</sup>*

**I typically have patients try lenses at home for a few days before finalizing their prescription. Do I need to have the patient return to the office to sign the acknowledgment form?**

When doctors provide patients trial lenses to try at home there are a few options. If doctors have the ability to email or post to a patient portal a contact lens prescription that can help to ease the process. One option would be that once the prescription is finalized the doctor could email that prescription to the patient or make it available on the patient portal. The doctor would just need to ensure that when the patient came into the office for the initial visit that the patient signs a form indicating that the patient would like to have the prescription emailed or made available on the patient portal.

If you don't email or make prescriptions available on the portal, you could have the patient sign the final version of the contact lens prescription when they come to the office to pick it up. Alternatively, the doctor could have the patient sign a separate acknowledgment form when the patient returns to the office to pick up the prescription.

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

You can, but only if the trial lenses are necessary to complete the fitting process. This is sometimes the case with “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, or as a condition of renewing their prescription. (<https://www.ftc.gov/tips-advice/business-center/guidance/faqs-complying-contact-lens-rule>)

**While the FTC requires doctors to release a patient's contact lens prescription once it is finalized, what if a patient requires medically necessary specialty contact lenses that CANNOT be purchased**

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<sup>2</sup> [https://www.ftc.gov/sites/default/files/documents/federal\\_register\\_notices/contact-lens-rules-16-cfr-parts-315-and-456/040702contactlensrule.pdf](https://www.ftc.gov/sites/default/files/documents/federal_register_notices/contact-lens-rules-16-cfr-parts-315-and-456/040702contactlensrule.pdf) (p. 13)

**online? In order to determine a final prescription, the patient MUST purchase the first pair of lenses from their prescribing doctor.**

Thank you for your question. If the contact lens is required in order to determine a final prescription, such as in the situation you describe regarding specialty lenses, you can charge the patient for the lenses. The FTC has indicated:

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

You can, but only if the trial lenses are necessary to complete the fitting process. This is sometimes the case with "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, or as a condition of renewing their prescription.

(<https://www.ftc.gov/tips-advice/business-center/guidance/faqs-complying-contact-lens-rule>)

## **Affirmative Consent to Provide Prescriptions Electronically**

**Are doctors prohibited from verbally asking the patient for their consent to send the prescription electronically. Does the doctor actually need to have the patient sign something or record the patient providing consent?**

A doctor would need to have the patient sign a form to provide consent to send the prescription electronically. The doctor should specify the method that will be used for sending the prescription electronically. There is no time frame provided in the Rule for when the verifiable affirmative consent needs to be given. FTC indicated, "For a new patient, for instance, this could be part of the intake forms. How would you like your prescription? On paper? Electronic? If electronic, email or portal? Please sign. Then the prescriber could keep that form on file and the prescriber could ask on subsequent visits if the patient wishes to change their election or a patient could initiate a change."

## **HIPAA and The Contact Lens Rule**

**Is it a HIPAA violation to send a prescription through email that is not encrypted?**

Sending patient information securely is a best practice. However, if the doctor does not have the ability to send the prescription securely or via encrypted email, they can make the patient aware of that when the patient consents to receiving their prescription electronically. With regard to unencrypted email, HHS previously clarified, "covered entities are permitted to send individuals unencrypted emails if they have advised the individual of the risk, and the individual still prefers the unencrypted email." So sending the prescription via unencrypted email would be acceptable, but the doctor should inform the patient that the prescription would be sent via unencrypted email and make sure the patient understands the situation. Again, using secure communications would be the best practice.

## **Penalties**

### **What is the penalty for non-compliance?**

Doctors should also be aware that failure to comply with Contact Lens Rule regulations can result in legal action including civil monetary penalties of up to \$42,530 per violation.

## **Patient Refusals**

### **What should I do if a patient refuses a copy of their contact lens prescription?**

If a patient refuses a copy of their contact lens prescription, you should document the refusal and sign the documentation.

### **What should I do if a patient refuses to sign the prescription acknowledgement form?**

If a patient refuses to sign the acknowledgment form following receipt of the contact lens prescription, the FTC indicates that physicians should note the refusal, sign it, and retain the documentation for three years.

## **Additional Copies of Prescriptions**

### **Do I need to have an acknowledgement form signed if I provide a patient with an additional copy of their contact lens prescription?**

No, you do not need an additional acknowledgement. You should document the request and the data you provided the additional copy in the patient record. By regulation, physicians are supposed to reply to these requests within 40 business hours.

## **Patient Acknowledgement by Minors**

### **Can minors sign prescription acknowledgement forms?**

The FTC has indicated, for the purpose of the contact lens rule, FTC would consider an acknowledgment form signed by a minor patient to satisfy the Rule's requirements. A signature from the minor's parent or guardian would also be satisfactory. You should also confirm your state law with regard to signatures from minors.

## **Retailer Requirements**

The 2020 updates to the Contact Lens Rule institute new requirements on contact lens retailers.

## **Robocalls**

If a seller verifies prescriptions through calls that use, in whole or in part, an automated message, the seller must:

- (1) Record the entire call;
- (2) Commence the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule;
- (3) Deliver the information required in a slow and deliberate manner and at a reasonably understandable volume; and
- (4) Make the information repeatable at the prescriber's option.

## **Alteration of Prescriptions**

- A seller may not alter a contact lens prescription. In the context of prescription verification, alteration includes, but is not limited to, providing the prescriber with the name of a manufacturer or brand other than that specified by the patient's prescription, unless such name is provided because the patient entered or orally provided it when asked for the manufacturer or brand listed on the patient's prescription.
- For private label contact lenses, a seller may substitute for contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

## **Accepting Prescriptions**

- A seller is required to provide a prominent method, and a clear and prominent disclosure of that method, for the patient to present the seller with a copy of the patient's prescription.
- Such method and the disclosure must be provided prior to requesting a prescriber's contact information for verification of the prescription

## **Reporting Contact Lens Retailer Concerns to AOA**

Unfortunately, many retailers are illegally selling contact lenses or using regulatory loopholes to circumvent requirements designed to ensure the safety of our patients.

Although the AOA is not a regulatory body or an enforcement agency, we regularly meet with government agencies and policymakers to inform them of illegal business practices and threats to our patients' safety. The more informed we can be, the better we can advocate for improved laws and regulations that better protect our patients.

Therefore, we encourage that you complete the survey at: [www.aoa.org/stopillegalcls](http://www.aoa.org/stopillegalcls) if you encounter a concerning retailer practice.

## Reporting Contact Lens Retailer Violations to the FDA and FTC

To ensure that enforcement agencies and policymakers are aware of illegal and unsafe contact lens sales, it is important for doctors of optometry, paraoptometrists, and the public to report these sales directly to the FTC and/or the FDA. Please use the following links and instructions to report violations to the appropriate agencies. If you have any questions, please feel free to email [StopIllegalCLS@aoa.org](mailto:StopIllegalCLS@aoa.org).

- o [Federal Trade Commission \(FTC\)](#)
- o [FDA's MedWatch](#)
- o [FDA's online sales violations](#)

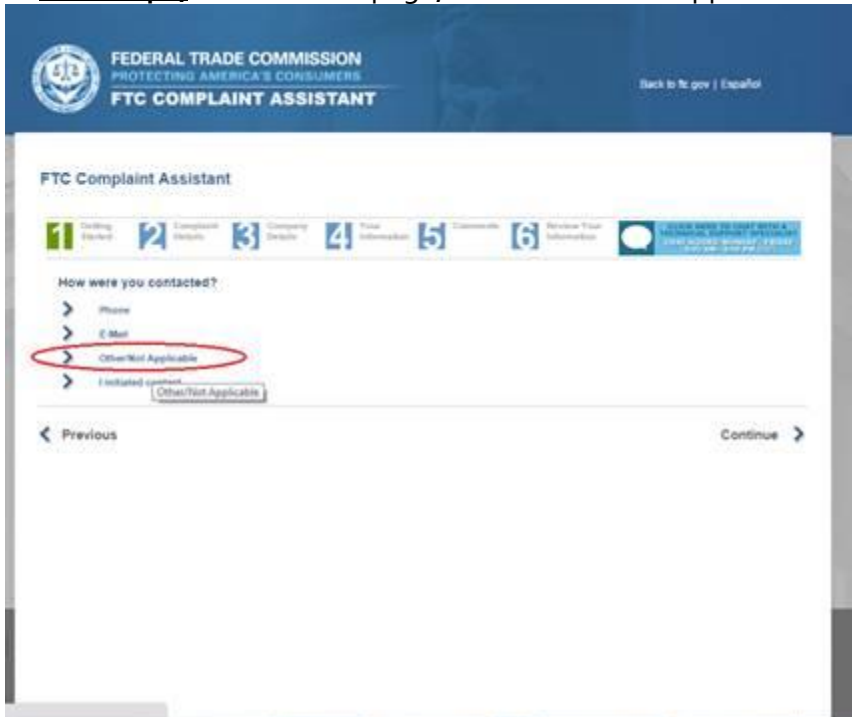
**FTC COMPLAINTS:** To report a violation to the FTC, please follow the directions below. You can report violations of the [FCLCA](#), sales of contact lenses without prescriptions, non-FDA approved CLs sales, and other violations to the FTC.

1. Go to: <https://www.ftccomplaintassistant.gov/GettingStarted#crnt>.
2. Click "Other" on the bottom left of the screen.
3. Under the "Other" menu, click "Health and Fitness," the last item.
4. On the next page, click "Other/Not Applicable."
5. Click the first selection, "Eyeglasses or Contact Lens."
6. Select the options that match your complaint until completed.

### FTC: Steps: 1-3



FTC Step 4: On the next page, click "Other/Not Applicable."





**FTC Step 5:** Click the first selection, "Eyeglasses or Contact Lens."

The screenshot shows the FTC Complaint Assistant interface. At the top, it features the FTC logo and the text "FEDERAL TRADE COMMISSION PROTECTING AMERICA'S CONSUMERS FTC COMPLAINT ASSISTANT". A navigation bar contains six numbered steps: 1. Getting Started, 2. Complaint Details, 3. Complaint Details, 4. Your Information, 5. Comments, and 6. Review Your Information. Below this, the question "Is your complaint related to:" is followed by a list of categories. The first category, "Eyeglasses or Contact Lenses", is circled in red. Other categories include "Eyeglasses or Contact Lenses - Plans", "Dietary Supplements or Herbal Remedies", "Prescriptions or Over the Counter (OTC) Drugs", "Other Medical Products, Supplies, or Treatments", and "Medical Discount Plans, Cards, or Insurance". At the bottom of the list, there are "Previous" and "Continue" buttons.

**FTC Step 6.** Select the options that match your complaint until completed.

### **FDA COMPLAINT:**

Defects, malfunctions, and contact lens related injuries/infections should be reported to FDA's MedWatch. The FDA's MedWatch Safety Information and Adverse Event Reporting Program is the initial step to take when reporting adverse events. Information may be reported to MedWatch by phone at 800.FDA.1088; by fax at 800.FDA.0178; by mail to 5600 Fishers Lane, Rockville, Maryland, 20852-9787; or online (See below for instructions for MedWatch Reporting). The FDA has also provided MedWatch Learn as a web-based learning tool that teaches students, health professionals, and consumers how to complete the forms necessary to report problems to FDA

1. Visit the MedWatch webpage.
2. Click "Report a Problem."
3. Begin Report as "Health Practitioner" or "Consumer/Patient" by clicking the respective button
4. Respond to questions.
5. Review and submit data.

## FDA MedWatch Step 1-2

The screenshot shows the FDA MedWatch homepage. At the top, there is a navigation bar with the FDA logo and the text 'U.S. FOOD & DRUG ADMINISTRATION'. Below this is a search bar and a menu with categories like Home, Food, Drugs, Medical Devices, etc. The main heading is 'MedWatch: The FDA Safety Information and Adverse Event Reporting Program'. There are social media sharing options (Share, Tweet, LinkedIn, Pin It, Email, Print) and a search bar for the MedWatch section. A red circle highlights the 'Report a Problem' button, which is a red button with a white arrow icon. Other buttons include 'Safety Information' and 'Stay Informed'.

## FDA MedWatch Step 3

The screenshot shows the 'MedWatch Online Voluntary Reporting Form' page. The header includes the FDA logo and navigation links. The main heading is 'MedWatch Online Voluntary Reporting Form'. Below this is a 'Welcome' message and a 'Frequently Asked Questions' link. The section 'Begin report as a:' has two options: 'Health Professional (FDA Form 3500)' and 'Consumer/Patient (FDA Form 3500B)'. Both options are circled in red.

**FDA Online Sales** If your report is related to an online retailer that is selling contact lenses that you are concerned with, you can report the internet retailer to the FDA's "Report a Problem."

1. Go to <https://www.fda.gov/Safety/ReportaProblem/ucm059315.htm>
2. Complete the survey
3. Submit the form