Contact Lens Rule Compliance Toolkit

July 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 will go into effect on 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; 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.¹

¹ https://www.ftc.gov/tips-advice/business-center/guidance/contact-lens-rule-guide-prescribers-sellers
FTC Guidance on Contact Lens Prescription Extensions

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.
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. Consent to send the prescription electronically cannot be part of standard intake forms.
- **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.
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.” Additional language can be included on the form.

A template CONTACT LENS PRESCRIPTION form is also available. This customizable contact lens prescription pad includes a carbon copy second sheet to facilitate record keeping and can be ordered from the AOA Marketplace.

If you choose to add language to your eye examination receipts to comply with the revised regulations, the FTC recommends the language “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

Included below is important information to review prior to receiving your contact lens prescription.

The Centers for Disease Control and Prevention (CDC) makes clear, “Contact lenses can provide many benefits, but they are not risk-free—especially if contact lens wearers don’t practice healthy habits and take care of their contact lenses and supplies. If patients seek care quickly, most complications can be easily treated by an eye doctor. However, more serious infections can cause pain and even permanent vision loss, depending on the cause and how long the patient waits to seek treatment.”

The CDC recommends the following for contact lens wearers:

✓ Schedule a visit with your eye doctor at least once a year.
✓ Take out your contacts and call your eye doctor if you have eye pain, discomfort, redness, or blurry vision.
✓ Understand that eye infections that go untreated can lead to eye damage or even blindness.

The Food and Drug Administration (FDA) indicates:

✓ “To be sure that your eyes remain healthy you should not order lenses with a prescription that has expired or stock up on lenses right before the prescription is about to expire. It’s safer to be re-checked by your eye care professional.”

Symptoms of Eye Infection include:

- Irritated, red eyes
- Worsening pain in or around the eyes—even after contact lens removal
- Light sensitivity
- Sudden blurry vision
- Unusually watery eyes or discharge

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:__________________________________________________________

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3 https://www.fda.gov/medical-devices/contact-lenses/buying-contact-lenses
4 https://www.cdc.gov/contactlenses/germs-infections.html
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 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 of 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.

- Federal Trade Commission (FTC)
- FDA’s MedWatch
- 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."

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 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](https://www.fda.gov/Safety/ReportaProblem/ucm059315.htm)
2. Complete the survey
3. Submit the form