

Federal Trade Commission (FTC) Contact Lens Rule to Take Full Effect on August 2, 2004

The new Federal Trade Commission (FTC) Contact Lens Rule implementing the Fairness to Contact Lens Consumers Act (FCLCA) will take full effect on August 2, 2004. The new FTC Contact Lens Rule closely adheres to the FCLCA, as is legally required for all rules authorized by a controlling statute. What follows is a comprehensive explanation of the new Contact Lens Rule in a user-friendly question-and-answer format.

General Issues:

1. **What is the official name of the new FTC rule?** The new FTC rule is officially called the “Contact Lens Rule.” Its official citation is 16 CFR 315. It covers eleven sections from 16 CFR 315.1 to 16 CFR 315.11.
2. **Does the rule require me to release a contact lens prescription to a patient?** YES! You must give the patient a copy of the patient’s contact lens prescription upon the completion of the fitting of the contact lens. You must do so automatically. No request from the patient is necessary and you may not require the patient to make such a request.
3. **Can I require a patient to pay for an examination and fitting before releasing the patient’s contact lens prescription to them?** YES! However, there are required circumstances that you must adhere to in order to do so. First, you can only require payment for the current examination and fitting fees, not for other past-due balances owed. Second, you must require that all your patients pay you up front – even those who do not need any ophthalmic goods. Third, the patient’s providing proof of insurance coverage is sufficient to constitute a payment. However, the FTC has expressly stated that the patient must provide proof of a current (in-force) insurance plan that covers the patient, and is an insurance plan accepted by the provider. The patient need not prove that the insurance will specifically pay the claim (for example, the insurance may be perfectly valid, but have a deductible provision). Proof of current insurance coverage for the particular patient in a plan accepted by the optometrist is all the patient need provide.
4. **Must I verify a contact lens prescription upon the request of a contact lens seller?** YES! Failure to verify the request will permit the seller to sell the lens after eight (8) business hours have elapsed. The seller must send, and you must receive, a proper and complete verification request in order to start the eight (8) hour clock running. The verification request must contain all of the following items to be proper and complete: 1) the patient’s full name and address; 2) the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; 3) the quantity of lenses ordered; 4) the date of the patient request; 5) the date and time of the verification request; 6) the name of the contact person at the seller’s company, including facsimile and telephone numbers; and 7) if the seller opts to include Saturdays as business hours, a clear statement of the prescriber’s regular Saturday business hours.

Counting Business Hours:

5. **How is a business hour defined in the new Contact Lens Rule and how does that affect me as an optometrist?** A business hour is an hour between 9:00 a.m. and 5:00 p.m. Monday through Friday, excluding federal holidays. Under the Contact Lens Rule, you have eight (8) business hours in which to respond to a contact lens seller's request for verification of a contact lens prescription. For example, if you receive a verification request at 9:00 a.m. on a Monday, you must verify by 5:00 p.m. that same day, or the seller can sell the contact lens at 5:01 p.m. that same day. Another example – if you receive a verification request at 2:00 p.m. on a Sunday, you must verify by 5:00 p.m. on Monday. Another example – if you receive a verification request at 7:00 p.m. on Wednesday, you must verify by 5:00 p.m. on Thursday. Another example – if you receive a verification request at 3:00 p.m. on Tuesday, you must verify by 3:00 p.m. on Wednesday.
6. **What about Saturdays – can they be counted as business hours under the new Contact Lens Rule?** YES! Saturdays can be counted as business hours at the option of the contact lens seller. In order for the seller to count Saturdays as business hours, the seller has to have actual knowledge of the hours that your office is open on Saturday. The seller must include in the verification request a clear statement of your regular Saturday business hours in order to count those hours as business hours. The seller must also maintain a record for not less than three years, available for inspection by the FTC, of your regular Saturday business hours and the basis for the seller's actual knowledge of those hours. If Saturdays are counted as business hours, then those actual Saturday hours must be included in the overall eight (8) hour calculation. For example – you have Saturday business hours from 11:00 a.m. to 3:00 p.m., and the seller notes in a verification request that you receive on Friday at 12:00 noon your Saturday hours – you then must verify by 2:00 p.m. on Saturday. If you had no Saturday business hours or the seller did not opt to list those Saturday hours in the verification request, then you would not have to verify until 12:00 noon on Monday in this example.
7. **What time zone is used to calculate business hours?** Only the prescriber's time zone is used to calculate business hours. For example, if a verification request is received by an optometrist at 9:00 a.m. Central Standard Time, the eight (8) business hours are calculated from that time, not the 10:00 a.m. Eastern Standard Time or the 7:00 a.m. Pacific Standard Time from where the seller may have sent the request.

Conduct of Sellers and Prescribers:

8. **Can one contact lens seller keep sending me the same verification request over and over again?** NO! The FTC has expressly stated that the new Contact Lens Rule only permits a single contact lens seller to send the exact same verification request for the same patient once. A seller can send a different verification request for the same patient (including one that alters required information or supplies missing required information from a previous request), but cannot send exactly the same request for the same prescription for the same patient more than once.

9. **Can multiple contact lens sellers send me the same verification request? YES!** As long as different contact lens sellers send the verification request, that is permitted under the new Contact Lens Rule. You would have to respond to each such verification request.
10. **What contact lenses are covered by the Contact Lens Rule?** Any contact lens for which either State or Federal law requires a prescription is covered by the new Contact Lens Rule. There are no exceptions for specialty lenses or rigid gas permeable contact lenses. The Contact Lens Rule does not cover Plano cosmetic lenses, unless State law requires a prescription for such plano cosmetic lenses. If Federal law changes to require a prescription for plano cosmetic lenses, then the Contact Lens Rule will cover them. However, current Federal law does not require a prescription for such plano cosmetic lenses and very few State laws do either.
11. **Specialty lenses are often very expensive to fit – is an optometrist prohibited from charging for those specialty lenses under the new Contact Lens Rule? NO!** The FTC has expressly stated that there is nothing improper about charging a fee for the fitting of specialty contact lenses that includes the cost of the lens used for the fitting, provided that the patient still receives a copy of their contact lens prescription upon completion of the fitting, and further provided that the release of the prescription is not contingent upon buying any other lenses from the prescribing optometrist, but merely involves payment of the fitting fee. In this scenario, the patient is not buying a lens based on the prescription, but is paying only for the lens that was necessary to determine the proper fit and, thus, help generate the proper final prescription.
12. **Must I verify as accurate a one-year prescription for a 12-month supply of contact lenses that is submitted to me by a contact lens seller in the 11th month of the validity of the prescription (in other words, the prescription would expire in one month, but the patient is seeking a full 12 month's supply of lenses)? NO!** The FTC has expressly stated that you can notify the contact lens seller that the prescription is inaccurate based on the excessive quantity of lenses being ordered. The FTC has interpreted the new Contact Lens Rule as recognizing that the purpose of requiring that the verification request state the quantity of lenses being ordered is precisely to prevent this type of overfilling that would evade the proper expiration date of the prescription. Therefore, in our example, the optometrist should notify the seller that the prescription is inaccurate and correct the quantity to only one month's supply of contact lenses.
13. **May I place the quantity of lenses and refills on the prescription itself? YES!** You are not required by the Contact Lens Rule to place this information on the actual prescription, but you have the option of doing so (and you must do so if your State law requires it). However, you may not use this as a means of artificially shortening the expiration date of the prescription. You must ensure that the quantity you list would be sufficient to last through the expiration date of the prescription.

- 14. What must be included on a contact lens prescription under the Contact Lens Rule?**
The contact lens prescription must include all the required information under both your State law and Federal law, including, but not limited to, the following: 1) the name of the patient; 2) the date of the examination; 3) the issue date and expiration date of the prescription; 4) the name, postal address, telephone number, and facsimile telephone number of the prescriber; 5) the power, material, or manufacturer or both of the prescribed contact lens; 6) the base curve or appropriate designation of the prescribed contact lens; 7) the diameter, when appropriate, of the prescribed contact lens; and 8) in the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.
- 15. What is the “issue date” of a prescription and what is the importance of this issue date?** The issue date of the prescription is the date on which the patient receives a copy of the prescription at the completion of a contact lens fitting. The FTC has expressly stated that there is only one issue date for any prescription, and the patient cannot alter the issue date by requesting additional copies of the prescription after the issue date. The issue date is important because that is the date from which the expiration period of the prescription is legally measured.
- 16. What is a private label contact lens and why should this concern me as an optometrist?** A private label contact lens is any contact lens sold under the label of a seller where the lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers. When you prescribe a private label contact lens you must include on the prescription the name of the manufacturer, the trade name of the private label brand, and, if applicable, the trade name of equivalent brand name. Also, a contact lens seller is authorized under the Contact Lens Rule to substitute for a private label brand an identical lens manufactured by the same manufacturer but sold under a different label. This is the only instance where a contact lens seller may substitute for the literal lens listed in the prescription.
- 17. Can I require a patient to pay any additional amount for releasing a copy of the patient’s contact lens prescription to the patient or for verifying a patient’s contact lens prescription? NO!** It is prohibited to charge the patient any fee for releasing the copy of the patient’s prescription to the patient, or for verifying the prescription.
- 18. Can I require a patient to sign any kind of waiver or release as a condition of releasing a copy of the patient’s contact lens prescription to the patient or for verifying a patient’s contact lens prescription? NO!** It is prohibited to have the patient sign any release or waiver for either releasing the copy of the patient’s prescription to the patient, or for verifying the prescription.
- 19. Can I require a patient to purchase lenses from me or another person as a condition for releasing a copy of the patient’s contact lens prescription to the patient or for verifying a patient’s contact lens prescription? NO!** It is prohibited to require the patient to purchase any lenses from yourself or another person as a condition for releasing the copy of the patient’s prescription to the patient, or for verifying the prescription.

However, as noted earlier, where specialty lenses are involved, you may charge the patient for the cost of the specialty lens needed to carry out the normal fitting process.

20. **Am I allowed to offer patients a package deal combining eye care services, lenses, and replacement lenses?** YES! The FTC has expressly stated that optometrists can market package deals of bundled services to patients, provided that the patient is always given the option to purchase the contact lenses elsewhere from whomever they wish.
21. **Can a contact lens seller sell a contact lens without having any prescription?** NO! There are serious penalties of up to \$11,000 per violation for a contact lens seller violating any provisions of the FCLCA. The contact lens seller must either have the contact lens prescription delivered to them directly by the patient or prescriber, transmitted to them by facsimile transmission by the patient or prescriber, or transmitted to them by a digitally imaged e-mail from the patient or prescriber – or the contact lens seller must verify the prescription by direct communication to the prescriber.
22. **Once I receive a verification request from a contact lens seller, can I just ignore that request and let eight (8) hours elapse?** YES! If the prescription is correct in all respects and is not expired, but NO if the prescription is incorrect or is expired. Why are there two different answers to this question? The first “yes” part of the answer is based on the fact that the seller will be able to sell the lenses after eight (8) hours elapse and you make no response, which is not going to cause either you or the patient any problem if the prescription is completely correct and is not expired. However, if the prescription is incorrect or expired, it would be a very dangerous mistake to fail to respond and it could put your license to practice optometry at risk and subject you to serious malpractice liability. That is why the second part of the answer is “no.” While the Contact Lens Rule does not legally force you to respond to any verification request before eight (8) hours elapses, the deliberate, knowing failure to respond to a verification request that you know to be incorrect, and that may ultimately cause harm to your patient if incorrect lenses are sold or an incorrect quantity of lenses is sold, would leave you defenseless to a malpractice lawsuit or a charge of professional misconduct by your state licensing authority. You do not want to put yourself in this position. Plus, if you correctly verify the prescription, Section 7 of the FCLCA expressly does not impose any liability on you for any ophthalmic goods and services dispensed by the seller pursuant to your correctly verified prescription. It would be nothing short of foolhardy to throw away this opportunity to immunize yourself from liability. Finally, beware of being too complacent about not responding to verification requests for completely correct, unexpired prescriptions, as you do not want to have office procedures in place that could let an incorrect or expired prescription slip through and potentially put you at risk of professional discipline or malpractice actions.
23. **What constitutes verification of a prescription?** There are three things that constitute verification of a prescription – 1) you confirm the prescription is accurate by direct communication with the seller; 2) you inform the seller through direct communication that the prescription is inaccurate; or 3) you fail to respond at all within eight (8) business hours after receiving the verification request (the seller is obligated to provide a

reasonable opportunity for you to communicate with the seller concerning the verification request within those eight (8) business hours).

24. **How do I respond to an expired prescription on a verification request?** You inform the contact lens seller that the prescription is expired. If you do not know the correct new prescription (for example, you have not examined the patient to determine the new prescription), then you are not obligated under the Contact Lens Rule to provide any other information to the contact lens seller on an expired prescription. If you do know the correct new prescription, you should advise the contact lens seller of the correct new prescription.
25. **How do I respond to an inaccurate prescription on a verification request?** You advise the contact lens seller that the prescription is inaccurate and you must specify the basis for the inaccuracy and you must correct the inaccuracy.
26. **What does direct communication mean between a seller and a prescriber?** Direct communication means a completed communication by telephone, facsimile, or electronic mail. If by telephone, it means reaching and speaking with the intended person, or leaving a voice message on the answering machine of the intended recipient. If by facsimile or electronic mail, it means that the intended recipient actually receive the message sent. However, the FTC has expressly stated that a facsimile confirmation is usually sufficient proof that the facsimile transmission was received, and confirmation that an e-mail was sent is usually sufficient proof that the e-mail was received. Consequently, sellers will begin counting the eight (8) business hours from the time they obtain these facsimile or e-mail confirmations.
27. **May a contact lens seller alter the prescription in any way? NO!** The contact lens seller is prohibited from altering the prescriber's prescription in any respect. As discussed earlier, only in the limited case of a private label contact lens for which the same manufacturer makes the identical lens, but sells the lens under another brand name, may the seller substitute the identical lens from that same manufacturer under that other brand name. In effect, this is not a true alteration of the prescription, but is designed to prevent the use of private label lenses to frustrate a patient purchasing lenses from other than the optometrist.

Expiration Dates and Recordkeeping Requirements:

28. **Are sellers required to keep records of their verification transactions? YES! Sellers** must keep extensive records of verification transaction for no less than three (3) years, and must permit the FTC access to inspect such records. Such records must consist of: 1) for prescriptions presented to the seller by the patient or the prescriber: the prescription itself or the facsimile version, or the digitally imaged e-mail version; 2) for verification requests: a copy of the verification request, including all required information on the request, and confirmation of the completed transmission of the request to the prescriber, including a record of the date and time the request was made; 3) for telephone communications: a telephone log for communications made by telephone showing the

verification information provided over the phone, the date and time the request was made, an indication of how the call was completed, and the names of all the persons who participated in the call; 4) for communications from the prescriber: how the communication was received, a copy of the communication if by e-mail or facsimile and a record of the date and time the communication was received; and if by telephone: a log describing the information communicated, the date and time the information was received, and the names of the persons who participated in the call. Sellers also must, as discussed earlier, keep records proving the Saturday business hours of prescribers with whom they count Saturday business hours. **Prescribers** are not subject to any recordkeeping requirements under the Contact Lens Rule (but see question 30 below). However, all prescribers should keep accurate patient records as a matter of normal optometric practice.

29. **How do expiration dates work for contact lens prescriptions under the Contact Lens Rule?** The answer to this depends on the state in which you write the contact lens prescription and involves three scenarios as follows: 1) if your state has no contact lens prescription expiration date law of its own, then the FCLCA imposes a minimum one year expiration date; or 2) if your state has a contact lens prescription expiration date law that is one year or longer, then your state law controls the expiration date; or 3) if your state has a contact lens prescription expiration date law that is less than one year, then the FCLCA overrides your state law and imposes a minimum one year expiration date.
30. **May I write a contact lens prescription expiration date that is less than one year under any circumstances?** YES! If in your considered medical judgment, the specific health needs of a particular patient require a less than one year contact lens prescription expiration date, then you may write a prescription with such a shorter expiration date. However, you must then also do three things: 1) you must document in the patient's medical record the specific reasons for your medical judgment in sufficient detail to allow for review by another qualified professional in the field; 2) you must maintain this documentation for no less than three (3) years and have it available to the FTC for inspection; and 3) the shorter expiration date can never be less than the time period you recommend for a medically necessary reexamination of the patient.

Miscellaneous Items:

31. **Does the Contact Lens Rule impose any advertising restrictions on sellers?** YES! It is prohibited for any person who manufactures, processes, assembles, sells, offers for sale, or distributes any contact lenses to represent, whether by advertising, making a sales presentation, or any other means, that contact lenses may be obtained without a prescription.
32. **How will the Contact Lens Rule be enforced?** The FTC has enforcement authority over the Contact Lens Rule. Any violation of the rule by either a seller or a prescriber is treated as a violation of Section 18 of the FTC Act regarding unfair or deceptive acts or practices, and can subject the violator to penalties up to \$11,000 per violation. The FTC has broad enforcement powers under the FTC Act and is not an agency to be trifled with.

33. **Does the Contact Lens Rule preempt state laws and rules? YES!** But only under certain circumstances! Like all federal laws and rules, the Contact Lens Rule would preempt any state law or rule that directly contradicted a provision of the Contact Lens Rule. In addition, the Contact Lens Rule specifically preempts any state law or rule that requires active verification of a contact lens prescription, that restricts contact lens prescription release, that establishes a prescription expiration date of less than one year, or that would be inconsistent with the FCLCA or the Contact Lens Rule to the extent of the inconsistency.

34. **Do the patient privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) interfere with my complying with the contact lens prescription verification requirements of the Contact Lens Rule? NO!** The FTC has expressly stated that HIPAA does not conflict with or override the obligations of the Contact Lens Rule. That is entirely consistent with the official opinion of the Office of Civil Rights (OCR) of the United States Department of Health and Human Services, which enforces the HIPAA privacy provisions. OCR has already ruled that the verification of a contact lens prescription to a contact lens seller is a protected, permissible transmission of health care information that does not require any separate written authorization from the patient.

Reporting Seller Violations to the FTC:

35. **Should I report seller violations of the Contact Lens Rule to the FTC? YES!** IT IS IMPERATIVE THAT YOU DO SO! The Contact Lens Rule will only work to help patients and optometrists if both sellers and prescribers obey the rule and the FTC properly enforces the rule. Instances of seller violations should be well documented by the prescriber and immediately reported to the FTC with a request for FTC investigation and action. You can file the violation report with the FTC electronically through the AOA Web site at www.aoa.org or you can directly file it with the FTC via their Web site www.ftc.gov by clicking on the "File A Complaint" option there. In either case, you need to also send an e-mail copy of your complaint to the AOA at: FTCcomplaint@aoa.org so that we can maintain a record of all complaints filed with the FTC.

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