

**From:** Spwagner02  
**Sent:** Saturday, April 03, 2004 6:22 PM  
**To:** CONTACTLENSRULE  
**Cc:**  
**Subject:** Re: Contact Lens Rule, Project No. R411002

FTC/Office of the Secretary  
Room 159-H, (Annex A)  
600 Pennsylvania Avenue, NW.,  
Washington, DC 20580

Re: Contact Lens Rule, Project No. R411002

I am an ophthalmologist in a small practice, and I fit and prescribe contact lenses. I am writing to comment on several aspects of the new contact lens rule and ophthalmic practice rule 16 CFR Parts 315 and 456. I will address each comment in separate sections for clarity. Thank you for the opportunity to provide comments.

I. Access to patient records and response time.

In the proposed rule, "the Commission does not believe that the proposed rule will impose a significant economic impact on a substantial number of small businesses." This is stated in reference to writing out prescriptions, stating medical reasons not to fill a prescription and verifying prescriptions to other sellers. I wish to report a significant economic impact for my practice and other like practices.

The requirement to respond within eight (8) business hours is problematic for certain small practices with satellite offices. These types of satellite offices can be found in many rural and under-served medical areas. They are often remote from a practice's main office. For myself it is a 40 minute round trip by car. The satellite office may only be open manned and being used one day or only a few days a week. Sometimes there are several satellite offices spread over a wide area. Due to the distances involved, patient records are usually kept at the satellite (remote) location. These records may not be accessible within the eight business hours required for response under the rule, unless a special trip is made to get the records. This takes support staff away from the office where patients are being seen, at a cost of mileage and work time at the totally random occurrence of a fax printing out. This is an unacceptable imposition on a small office.

As for my practice, we have located our contact lens patients' charts at our central office to allow us to quickly respond to a patients request for ordering contact lenses. The problem comes in that in the past, before the enactment of the rule, if the patient requested a prescription, and did not order contacts from our practice, their chart likely was kept at the remote location, because quick access for ordering was not needed, since the patient was taking care of that by taking the prescription elsewhere themselves. Now, if a request for verification comes in, I don't have any way of knowing if I have prescribed contact lenses for the patient, unless the chart is retrieved from the remote office. Another problem arises from the patient that I may have seen for a general eye exam, without providing any contact lens fitting services. They may have gone to a different practitioner for a contact lens fitting, but put my name on the request for the prescription to be filled by the seller. The chart is at the remote office--I have no way of knowing if I have ever seen the patient regarding contact lenses if I do not have the chart.

I think that a reasonable way to address this problem is to follow the spirit of the rule by responding to the faxed request in kind within the eight (8) business hours with a specific statement that the patient's records are at a remote location, and that the records will be available for review at such and such a date (a time certain) For most purposes, this will be within one business week. For example, a fax comes in Monday at 10 AM for a patient who's chart is at my remote location. That office is not open until Thursday at 9 AM. I should be able to follow the spirit of the rule by faxing back within eight hours that the prescription will be able to be reviewed and if OK, be verified on Thursday, stating the date that I can respond. This will protect the safety of the patient by permitting proper review of the chart, and not disrupting the ability of the office to see scheduled patients in the medical office because staff would have to leave to retrieve a chart.

These instances should be few, but are real, as this very circumstance occurred in my office two days ago. We had no record in our computer of the patient ever receiving any contact lens services in our office. Trying to inform 1-800 Contacts that I would be able to verify the request three days later, on Thursday, I repeatedly received faxes stating that my response was in violation of the Fairness to Contact Lens Consumers Act of 2003. I was not allowed to talk to any real person at 1-800 Contacts to explain the situation, but was repeatedly dumped into voice mail, assured that a response would come "if deemed appropriate." This caused me great concern. It turned out after a 40 minute drive to the

remote location and back, that the patient had never been evaluated for contacts, and no prescription had ever been issued by our office. Without the chart, my only other recourse in this case would have been to invalidate the prescription, because I had no other information. If the prescription was really valid, this would be wrong. If the seller followed the rule, and implied that I had not provided a valid response within the eight (8) business hours they would have dispensed the contacts in my name, even though I had never prescribed them, and attempted to tell them I could not verify it until the other office opened. This would be a worse wrong.

I do not think this unfairly causes the patient to wait. If a patient really has an "emergency," that they have no contacts and truly need them right away, they should be encouraged to contact the physician's or optometrist's office who prescribed them directly, as this can expedite getting the prescription--this communication is part of the doctor-patient relationship. Otherwise we would not know if it was just a routine request. If a request is urgent, and the chart is unavailable, special arrangements can be made. Often if I have a contact lens patient in that situation, I may provide a sample lens until they can get the prescription filled. Another safety encouragement for patients is that they have a pair of glasses for back up that they can wear in such a time, or if their eyes become irritated and they have to take the lenses out.

II. Contact lens services are not included in an eye exam--comments re: 315.2 and 315.3.

An important thing to remember, especially in light of all of the consumer comments on the FTC comment site, is that **CONTACT LENS PRESCRIPTIONS ARE NOT INCLUDED IN A REGULAR EYE EXAM**. Wording of the rule should reflect that an ophthalmologist or optometrist may bill for a contact lens fitting and evaluation in addition to a regular eye exam, and are individual and itemizable services.

I request that the commission include 456.2(c) wording in 315 to clarify what an eye care provider can bill for contact lens services, when then initial fit was done by another practitioner. I have included the appropriate section below:

Federal Trade Commission, Part 456, Ophthalmic Practice Rules  
456.2 Separation of examination and dispensing.

It is an unfair act or practice for an ophthalmologist or optometrist to:

(c) Charge the patient any fee in addition to the ophthalmologist's or optometrist's examination fee as a condition to releasing the prescription to the patient. Provided: An ophthalmologist or optometrist may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or...

This should be clarified in Section 315.2 under the definition of contact lens fitting. To prevent a contact lens evaluation for a new patient who has contacts from a previous eye doctor from being interpreted as a renewal, which it is not, 456.2 (c) can be referenced, or included. The wording from 456.2(c) provides that an ophthalmologist or optometrist can charge for evaluation of ophthalmic goods from another provider. This is an important statement, as the proposed contact lens rule is unclear regarding this issue. The new provider must perform a service to verify if the patient's current fit is still valid and is correct. If a service must be performed to issue a prescription, a charge must be allowed, or the federal government would be mandating that a physician perform free services.

It should also be clarified that a charge may be made for the medically necessary follow up exams, as defined in the Act. This would ensure that a physician can bill for the ongoing care of the contact lens patient when the prescriptions need be evaluated at the time of renewal.

III. Proper prescription requirements--comments re: Section 315.5(c).

In order to prevent unnecessary duplication of work for the physician, Section 315.5(c) of the rule should be amended to include that proper verification of a contact lens prescription can include a physician specifying to a seller that "a proper and valid written contact lens prescription was issued to the patient, and the patient is to be contacted for a copy of the prescription for verification." Otherwise the path of least resistance will be for the large contact lens seller to just fax a verification request to the doctor, instead of asking the patient for a copy of the prescription that was issued to them. Please protect the integrity of a written contact lens prescription. If a patient can type the information from their contact lens prescription into a web page to order contacts, they can certainly scan in the prescription from the doctor and e-mail it, or fax it to the internet seller, as specified in the Act. If the patient has a written prescription, it should be their responsibility to present it to get their contact prescription filled. That is how it works for all other types of prescriptions. Please put the emphasis on presentation of a prescription as the preferred method, not the verification by direct communication.

The proposed contact lens rule requires that an ophthalmologist or optometrist write out a prescription. However, it also

requires them to respond immediately to faxed requests to verify the prescription. This amounts to twice the work (or more) for the doctor. No where else, for any type of prescription is this type of verification required. If I write out a prescription for eyeglasses, I don't suddenly get a fax asking me to verify the prescription before the optical shop will make the glasses. If I write out a prescription for eye drops, or antibiotic pills, I do not then receive a fax asking me to verify my prescription before it is filled. If I write out a prescription for a blood test or an x-ray, I don't get a fax to verify it before the test is done. Why then must we write a prescription if we then have to redo it again for every fax received? This is senseless duplication of work.

The pharmacist collects the original written prescription for a medication and has to keep it on file for seven years. The optician also collects the eyeglasses prescription for the file. Why shouldn't the seller of contact lenses have to collect a prescription in order to fill an order for contacts? If the eye doctor has to write out a prescription for contact lenses, and the patient is not getting contacts through that doctor, then the responsibility should be on the patient to take the prescription and get it filled without any further input required by the doctor. That is not what the rule says. The rule requires work above and beyond that for any other type of prescription issued, including eyeglasses prescriptions. If a written prescription is required, put the responsibility on the patient for getting it filled, not the prescriber.

An analogous example can be found in the instance of a patient getting a prescription for an eye drop—say for treatment of glaucoma, with a year's worth of refills. The patient may be on this drop for life. A written prescription for the glaucoma drop is given to the patient, and they take it to the pharmacy. The pharmacist reads the prescription, and give the patient the appropriate medication. The patient then goes back each time they need a refill. Input from the physician is not required until the following year. How does this pertain to internet orders—say from 1-800 Contacts? Take the same example of the patient above, but now have them ordering their drop from an internet or mail-order pharmacy. The prescription may have to be written to allow them to get a three months supply at a time. The patient \*mails\* or faxes the prescription to the mail-order pharmacy, and then this prescription is read, filed, and filled, usually without any fax being sent to the doctor. Why can't the contact lens patient be responsible for providing the prescription--that was already written out by the doctor—to 1-800 contacts or a like seller. Why is the responsibility being placed on the physician to have to communicate to the seller, when we have already communicated it to the patient in written form?

The larger contact lens sellers may counter that asking the patient to provide a copy of the prescription may delay them getting contacts. Having to send in the prescription for medications to a mail order pharmacy seems to work for many people. Why should contact lenses be any different? Having to respond to a fax to verify a prescription I have already spent the time writing out delays my seeing patients. Waiting for a copy of the prescription from the patient probably delays 1-800 Contacts from charging a contact lens wearer's credit card, too.

IV. Some contact lenses that are fit must be purchased. Please clarify that lenses such as RGP or warranted soft lenses that must be purchased by the eye doctor in order to complete a fitting for the patient may be billed to the patient at the completion of the fit, in addition to issuing a prescription. Otherwise the practitioner would not be able to procure these lenses for fitting, if the patient didn't buy them at the end of the completed fit. RGP lenses must be ground specially for the patient like glasses lenses. Some daily wear soft lenses are special orders because of the patient's prescription, or are not available as trials for the fitting. These charges should be able to be passed along to the patient as part of the determination of fit and prescription.

V. Comments re: Section 315.4: Some services not covered by insurance are charged up front, and in advance, such as LASIK or cosmetic procedures--the patient pays and then the service is done--to prevent someone getting away without payment. Section 315.4 should be modified to allow for a contact lens fitting, \*\*which is separate from an eye exam\*\*, to be billed up front, before the service is rendered. THIS SITUATION IS NOT ADDRESSED SPECIFICALLY IN THE ACT. This does not affect the release of a prescription, since the bill must be payed before any contact lens is fit. It also doesn't affect the eye exam, since that is a separate entity. Whether or not an eye exam leads to an indication for glasses or contact lenses has nothing to do with the fitting. It is an entirely separate, and arguably, for most people, a cosmetic procedure. It is billed entirely separately from an eye exam, and may in many instances be done on a different day. If it is known in advance that the patient is going to be coming back in for the fitting, it should be entirely allowed to inform that patient (giving them advance notice) that the contact lens service is payable at the time of service. Congress may not have realized this distinction when they passed the Act. The wording of the Act sounds like Congress is referring to billing for something that has already been done.

Thank you,

Stephen Wagner, MD

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