

From: Carpentervision
Sent: Thursday, March 11, 2004 9:31 AM
To: CONTACTLENSRULE
Subject: CL rule, cl project no. R411002

February 27, 2004

To: Federal Trade Commission

From: Dr. Scott M. Carpenter

RE: CI Rule, cl project no. R411002

Dear FTC,

In review of the proposed trade rules related to the Fairness to Contact Lens Consumers Act, I have encountered several items that are of concern. I wanted to take this opportunity to pass these concerns along to the FTC as follows.

To date, we have received several computer generated telephone calls from 1-800-CONTACTS to verify contact lens prescriptions for individuals that may or may not be patients in our office. By following the prompts of the computer-generated system, we have never been successful in completing the verification process. Oftentimes, the computer generated verification system will disconnect the call prior to completion of the verification process. Having been in practice for 17 years, I have never encountered such a computer generated verification process for any of the pharmaceutical prescriptions that I have ever written. When our patients require a prescription, they are provided a written prescription and a copy of that prescription is maintained in the clinical record of the patient. The computer generated telephone verification system does not allow us to maintain appropriate medical/legal records for our patients. The inability to contact a representative for 1-800-CONTACTS when there is a problem with the verification process is another issue we constantly encounter.

The Fairness to Contact Lens Consumers Act Section 315.5 c states that the verification process must take place within eight business hours of the request. The definition of 'business hours' is cause for concern. Obviously, 'business hours' vary from business to business. Many 'e-commerce' supported businesses could state that all hours are 'business hours' as compared to an optometric practice that may offer clinic 'business hours' as 8:00am to 5:00pm Monday thru Friday. Oftentimes, through the computer generated telephone verification system, the request is made shortly after my office is closed and the request may sit, unanswered from Saturday evening until Tuesday morning. It is not our intention to be non-compliant with the request, but depending upon the timing, non-compliance becomes implied simply because of our 'business hours'. An eight-hour response time for contact lens verification seems very limiting and unreasonable. It is appropriate to remember that we are discussing a prescription for a device of convenience rather than a pharmaceutical prescription that may be medically necessary.

An additional concern involves the recently implemented HIPPA regulations. How can it be possible to protect a patients medical records and information contained within them, when required to release such information to a third party whose identity can simply be defined by a fax number or a computer generated telephone system? With the current methods of prescription verification involving fax requests that contain no telephone number to reach a representative of the requesting party, practitioners may be fully compliant with prescription verification and in violation of the HIPPA regulations at the same time. Which route to 'non-compliance' is the practitioner to choose?

We have been provided with fax requests for verification of a contact lens prescription for individuals who have never been patients in our office. Additionally, a complaint was filed on my office to the Kansas Board of Examiners in Optometry by a patient who requested a contact lens verification when the prescription was expired. The Kansas Board

of Examiners in Optometry investigation was completed and it concluded that there was no basis to conclude that my office violated any provisions of the Optometry Law. Many optometrists have experienced such filed complains with similar findings and is has been documented that such complaints are actually encouraged by many third party contact lens providers. Such activity potentially leads the patient to believe that their professional vision care provider is in some manner in violation of state and federal laws. Such belief can cause a breakdown in the professional relationship between providers and their eye doctors.

Currently, through the fax verification system utilized by 1-800-CONTACTS, the request forms provide no manner in which the number of refills can be monitored. Most of our patients are provided with an expiration date of 12 months on contact lens prescriptions. It is well documented that contact lenses, over time, can lead to permanent changes and damage to the human eye. By limiting contact lens prescriptions to a one-year expiration date, we are essentially protecting the patient from obtaining an unlimited supply of contact lenses. This limitation encourages the patient to have their ocular health evaluated for contact lens related complications. When patients obtain their supply of contact lenses from a third party such as 1-800-CONTACTS, we have no manner in which to confirm how many times a patient has had their contact lens prescription filled. Due to the lack of a refill verification system, a patient could essentially, with a valid prescription for contact lenses with a one-year expiration, obtain a lifetime supply of contact lenses by ordering their contact lenses from a number of third party contact lens providers. Any product that requires a prescription to obtain is regulated and those regulations have been put in place in order to insure that the use of that product is not abused and that the use of that product is done under the supervision of a licensed professional. Without a viable prescription refill verification system, the prescribing party is essentially removed from the role of protector and supervisor and the patient is unknowingly thrust into the role that they once entrusted only with their health care provider. My office has experienced just such a case. Our patient obtained contact lenses that were not approved by a valid prescription. Unknowingly, that patient assumed that the contact lenses were appropriate for her and she wore those lenses just as she had always worn contact lenses provided to her by our office. Our patient developed, secondary to wearing inappropriate contact lenses, a corneal ulceration that required emergency medical intervention. That patient recovered from the corneal ulcer and was left with dense scar formation on her eye as a permanent reminder to her that contact lenses and contact lens wear should always be monitored by a licensed and trained professional and not a third party who may alter a valid prescription in order to sell a product.

In order to address the above concerns, any party that provides a patient with contact lenses should provide the prescribing party with the following:

1. A telephone number to allow the prescribing party to contact a representative of the party providing the contact lenses if the request in for any reason invalid.
2. An up to date listing of the number of contact lenses provided to the patient by the third party dating back to the date that the contact lens prescription was released to the patient.
3. Verification to the prescribing party that the patient has been informed by the party providing the contact lenses of the wearing schedule and replacement schedule of the contact lenses as defined by the prescribing party
4. Written documentation clearly indicating any contact lens prescriptions that patients have attempted to fill beyond the expiration date or substitutions of properly prescribed contact lenses with alternative lenses without a valid and verified prescription written by a party licensed to prescribe contact lenses.

Most optometrists have no difficulty providing verification of valid contact lens prescriptions to appropriately regulated parties. The parties that provide contact lenses from valid prescriptions provide patients with a service and price for contacts that cannot be obtained at many optometric practices. Those parties, just as the prescribing party, need to adhere to regulations and laws that govern their services and products.

Sincerely,

Scott M. Carpenter, OD

Scott M. Carpenter, OD

Carpenter Optometry, P.A.

Kansas

Office: 785/272-5544
Fax: 785/272-0275
Voice Mail: 785/554-0063