

Tupelo Eye Clinic

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Federal Trade Commission
Office of the Secretary
Room 159-H (Annex A)
600 Pennsylvania Avenue Northwest
Washington DC 20580



Re: Contact Lens Rule, Project #R411002

TO WHOM IT MAY CONCERN:

The purpose of having contact lens as a prescription item is that there is significant risk of blindness from wearing them. The risk is low and the benefits are great, but a prescription is appropriate because often the wearer is only minimally aware of the dangers and must be protected.

The contact lens rule presents some practical problems for the prescriber.

- 1) The prescriber has 8 business hours to respond to a request from a seller for contact lenses. Holidays are defined as federal holidays. Since many, if not most, prescribers of contact lenses are solo practitioners, this requirement is not practical. Many solo practitioners close their office entirely for vacations, illness, and religious holidays that are not federal holidays. Their patients may be told to seek emergency care at another practitioner's office, or an emergency room, but those practitioners do not have access to their office records. In this case under the proposed rule, the prescriptions would be "passively verified." (Section 315.5.C.3)

I do not believe it is the intent of the law to regulate the times a practitioner's office is open. I certainly do not feel the intent of the law is to regulate the manner in which a practitioner may observe or not observe religious holidays.

My suggestion would be that the supplier determine that the prescriber's office is open and that the prescriber will be present in the office during the next eight hours. This should be done when the request for verification is made. This could be as simple as calling the office. Unless the office is open and the prescriber will be present in the office during the next eight hours, then verification

would be delayed until the office is open.

- 2) Passive verification (Section 315.5.C.3) also raises liability issues. A prescriber may for any number of reasons **not** want a patient to continue to wear contact lenses. (A medical condition that if the contact lenses are worn will result in blindness, an expired prescription, a patient who because of poor contact lens care and hygiene, is exposing themselves to high risk of eye damage.) A prescriber may not be able to be present in the office every business day and in solo offices the office may be closed. (Vacations, illness, work at satellite clinics, religious holidays not the same as federal holidays.) The prescriber is therefore not always available every business day to verify prescriptions.

A liability issue arises, if the seller requests verification and none is received in eight hours. Lenses are sold to the patient without the prescriber's consent, the patient loses vision or becomes blind as a result of contact lens wear, and the patient sues the prescriber. The patient could argue that since the prescriber knows the prescription will be filled in eight hours, if they do not respond to the seller, then the prescriber has the duty to respond in eight hours to prevent lenses from being sold. It is unfair for the prescriber to be held accountable for the selling of a contact lens which the prescriber feels should not be prescribed simply because he is unable to respond to the seller within eight hours.

Recommendation:

In the event a contact lens is dispensed without authorization of the prescriber, (passive verification), the prescriber may **not** be held liable for damage to the patient from the contact lens.

- 3) **Statue of Limitations.** Practitioners are required to keep medical records in accordance with State and Federal law. In our State, it is longer than three years and in the case of a minor it does not even start until the patient is 21-years-old. In the event of litigation involving injury or blindness from a contact lens, it could be

critically important to establish what contact lenses were provided, who provided the lenses, and the circumstances under which the lenses were provided.

Recommendation:

Sellers of contact lenses should be required to be in compliance with all Federal law related to the maintenance of medical records. In addition, they should be required to be in compliance with State laws in the State in which they are located, in the State in which the patient is located, and in the State the prescriber is located. Consumer records should be maintained by sellers just as they are by prescribers.

- 4) Section VI of the Proposed Rule (Paragraph 3) estimates a prescriber will spend an average of one minute providing each patient or authorized party a prescription. When a request from a seller arrives by phone or by fax, it is much more time consuming. The phone must be answered, details recorded, patients identified, chart located, information presented to the prescriber, a decision made, the information communicated to the seller, and the chart refilled. All of this takes **much more** than one minute.

Recommendation:

That the cost factor stated for the prescriber be amended to more accurately reflect the true cost.

- 5) Compliance With Health Insurance Portability and Accountability Act (HIPAA) requires written authorization from a patient before any medical information may be released, and that authorization is specific as to who may receive the information. The law is very strict and has high penalties for unauthorized release of medical information. Telephone and fax requests that are currently being received do not have a patient's signed written authorization for release of information. In order to be in compliance with HIPAA, prescribers may not release the contact lens information to a third party without the patient's signed authorization. Under the passive verification provision of the contact lens rule, these prescriptions are being filled because the practitioner may not give the seller any information

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without being in violation of federal HIPAA law. Thus, the consumer safeguards provided by having contact lenses being regulated as a prescription item are being defeated.

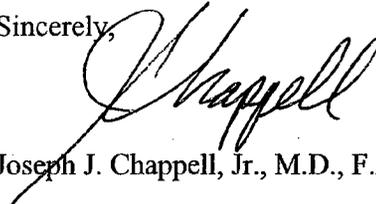
Recommendation:

That any request for verification of a contact lens prescription be treated the same as any other request for medical information; namely, that it be accompanied by a signed authorization from the patient to release the medical information. This signature could then be compared to the signature on file in the chart and verification could be accomplished in accordance with HIPAA guidelines. The consumer does and should have the right to have their medical information safeguarded under HIPAA, even extending to their contact lens prescription.

I appreciate your consideration of the above items. These are filed in accordance with the hearing which is now in progress for public comment on the contact lens rule project #R411002.

Thank you.

Sincerely,



Joseph J. Chappell, Jr., M.D., F.A.C.S.

JJC:vlj