

Re: Contact Lens Rule, Project # R411002

From: Charles W. Kissling, O.D.

Ks.

As an optometrist practicing for nearly 20 years, I wish to provide comment on the proposed rules as regards the Fairness to Contact Lens Consumers legislation, hereafter referred to as the Act.

Sec. 315.5 (b)

This section states that the seller shall seek verification of prescription information by providing the prescriber specified information through “direct communication.”

Sec. 315.5 (c) (1)

This section allows verification if “the prescriber confirms the prescription is accurate by direct communication with the seller.”

Sec. 315.5 (c) (3)

This section allows verification to have occurred if “the prescriber fails to communicate with the seller within eight business hours after receiving from the seller the information described in paragraph (b) of this section.”

The proposed rules define direct communication to include:

1. The definition requires that the communication involve a completed communication with the intended recipient.
2. Reaching and speaking with the intended recipient or leaving a voice message on the telephone answering machine of the intended recipient.
3. Direct communication by facsimile or e-mail would require that the intended recipient receive the facsimile or e-mail.

The three sections cited above, in conjunction with the definition of direct communication, leave me with the following questions that need further clarification by the FTC in the Rules. Since section 315.5 (c) (3) of the Act states that the prescriber must communicate with the seller within eight business hours after receiving the verification request from the seller (note that it does not say within eight business hours after the seller sends the request); and it will necessarily be the seller who determines when the 8 business hour period begins and ends; I have two questions:

- 1. What, specifically, are the ways in which the prescriber will be said to have received a verification request from the seller?**

**2. How does the seller know if, and when, the prescriber has received the verification request, so the seller will know when to start the eight business hour clock?**

Prior to this Act, the seller had to prove that a valid prescription existed before selling contact lenses. Now, the information provided by the purchaser is presumed to be evidence of a valid prescription, and the prescriber has an 8 business hour window to prove the prescription invalid or incorrect. Thus, the seller no longer must prove that the prescription exists; rather, the provider must now prove that the prescription does not exist. A study of over 1,000 contact lens prescription requests, conducted by the Kansas Optometric Association, found that nearly half (46%) of the requests were invalid (not a patient, incorrect, or expired). Thus, nearly half of the patients involved in these requests were at risk for having the prescription filled inappropriately if sold without true verification, as might happen if communication is incomplete. This places these patients at greater risk for contact lens related eye health complications, some of which can be sight threatening. Are you willing to place such a large percentage of contact lens purchasers at greater risk for the sake of expediency? I do not believe that it was the intent of the Act to do so. In fact, they made it very clear that they expected complete communication.

Since the prescriber has only an eight business hour window to stop the sale of incorrect lenses, or lenses with an invalid prescription, the Rules governing this Act should make certain that the prescriber has actually received the verification request before the 8 hour clock starts. Again, I remind you, that section 315 (c) (3) states that verification response must be made “within eight business hours after receiving from the seller the information.” Plus, your own definition of direct communication requires that the communication involve a “completed communication with the intended recipient.” Your proposed definition also states that direct communication by facsimile or electronic mail would require that the “intended recipient receive the facsimile or electronic mail message.” In addition, the Congressional Committee stated that:

“It is the intent of the Committee that ‘direct communication’ means a message has been both sent and received. Transmitting the request under 5 (c) does not, in and of itself, constitute a direct communication. For instance, when a facsimile that is considered a ‘direct communication’ is sent, the direct communication does not occur until a confirmation that the facsimile transmission was successful is sent. Similarly, if, for example, a prescriber is closed on Wednesday, has a phone recording stating that the office will be open at 9:00AM on Thursday, and verification request information is left on the machine Tuesday evening after normal business hours, the direct communication would not occur, and the time period for verification of the prescription would not commence, until Thursday when the prescriber receives the request and his or her business hours resume. The Committee directs the FTC to set rules defining the time frame for verification and how it is calculated, and expects the FTC’s rules to be crafted consistent with this intent.” (Section by Section Analysis of the Legislation, House Rpt. 108-318, Fairness to Contact Lens Consumers Act)

The Rules already presume the prescription information, provided by the purchaser, to be correct and valid. **I ask you to not also presume that, just because the seller has sent a verification request, the prescriber has actually received the request. As the Committee has already stated, “transmitting the request....does not, in and of itself, constitute a direct communication.”**

Examples:

A fax machine can record that it has successfully completed transmission, but this does not assure that the recipient has received the communication. I recently faxed a prescription to a local retailer early in the morning. My fax machine showed a successful transmission. Later that afternoon, the retailer called asking why I had not yet sent the prescription to them. Subsequently, I re-sent the prescription, then followed up by phone that they had received the prescription.

Similarly, occasionally someone will tell me that they left a message on my home answering machine. However, there was no message from that individual on my machine.

My office has an answering machine that answers only. It does not record messages from the caller. No where does the answering message direct the caller to leave a message. Nevertheless, that does not prevent patients from trying to leave messages on our machine. Occasionally a patient will tell us that they left us a message on our machine. Of course we did not receive the message.

Automated phone calls may not function properly. They may be garbled and hard to understand. In addition, the response requested, i.e.; press one for yes, press two for no, may not record the response correctly. An automated phone call reaching an answering machine may be capable of leaving a recorded message, however, the automated phone call is not capable of hearing the answering message that says the office is closed until Wednesday. An automated phone call may also attempt to leave a message on an answering machine that does not record messages.

I, therefore, ask again that you further clarify the communication process by answering the following questions:

- 1. What, specifically, are the ways in which the prescriber will be said to have received a verification request from the seller?**
- 2. How does the seller know if, and when, the prescriber has received the verification request, so that the seller will know when to start the eight business hour clock?**

I offer the following suggestions relating to these questions:

1. Do not allow automated phone call prescription verification requests. Such communication is fraught with difficulty.
2. In as much as the Committee has stated that in the specific case of fax communication, the “direct communication does not occur until a confirmation that the facsimile transmission was successful is sent;” require exactly that. Do not allow the seller to rely on an indication of successful transmission from their

- machine. Stipulate that the direct communication has not occurred until the intended recipient has sent confirmation that the transmission was successful.
3. Similarly, do not allow the seller to equate a message left on an answering machine with complete communication. Stipulate that such communication is not complete until a response is received from the intended recipient.
  4. In as much as your own proposed rules require “that the communication involve a completed communication with the intended recipient,” require that:
    - a. The eight business hour time clock may not start until the communication is completed.
    - b. No communication is deemed completed until a response is received from the recipient indicating receipt of the communication.
    - c. A fax machine recording a successful communication is not adequate evidence that the intended recipient has received the communication, or adequate evidence of a completed communication.
    - d. A message left on an answering machine is not adequate evidence that the intended recipient has received the communication.
    - e. An e-mail message sent is not adequate evidence that the intended recipient has received the communication.
    - f. The seller must keep a full record of the communication, including the names of the parties who participated in the communication.

As long non-personal communication methods are utilized to verify contact lens prescriptions, we will face uncertainties. Uncertainty as to whether the communication went to the right place. Uncertainty as to what the office hours of the prescriber are. Uncertainty as to whether the office is closed for some reason such as vacation, or holiday. Uncertainty as to exactly when the intended recipient actually received the request. Uncertainty as to whether there are office hours issues that affect the eight business hour span. All of these uncertainties could be avoided if the sellers were encouraged to do one of two things.

1. Use person to person, live, real-time communication.
2. Receive the original prescription from the patient. If the seller is in possession of the original prescription, there would be no need for the seller to request verification from the prescriber. Receiving the **original** prescription from the patient will also help control the number of refills, since patients would not be able to send photocopies to multiple sellers and purchase more than the prescribed number of lenses.

Sincerely,

Charles W. Kissling, O.D.