

April 5, 2004

Re: Contact Lens Rule, Project # R411002

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Drs. Hawks, Besler & Rogers

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I strongly support contact lens prescription release and I applaud the spirit of the 'Fairness to Contact Lens Consumers Act' (FCLCA). I thank the FTC for considering my concerns during the rulemaking process.

Assumption that a valid, unexpired prescription exists:

The challenge with this legislation is it assumes a valid, unexpired prescription exists and there is an assumption that the patient knows the parameters of their particular prescription. In my office, we have found that nearly fifty percent of the verification requests were for expired, incorrect contact lens parameters, or were for non-patients of my office. To avoid patients receiving incorrect contact lenses and potential unnecessary ocular health compromise, it is paramount that direct, two-way communication be established between seller and prescriber. For this to work, the seller must communicate with the prescriber when questions arise concerning the prescription. The prescriber needs to be notified of all sales from passive verification where the prescriber does not respond to the request for a prescription. This is needed for a complete medical record and allows the prescriber to monitor the appropriate number of refills for the duration of the prescription. Contact lenses are medical devices that warrant care in ensuring the patient receives the appropriate devices. The prescriptive nature of contact lenses must be protected. Sellers need to play an integral role in this system.

Lack of two way communication with seller:

Considering my office's experience during the last three years, two-way communication from the seller has been minimal at best. We have spent an enormous amount of staff time trying to communicate with the seller when questions about the prescription arise. There are a number of routine questions that come up that require communication and the only time we have been successful in getting any of them answered is by repeatedly calling and asking the same question to a supervisor. The seller's operators are not informed to answer these questions. On numerous occasions they have been unable to provide assistance when given the patient name and the customer number provided on the verification request and could not find an outstanding order for the patient or my office. Multiple times we were told to leave a message in a provider relations voice mail box and that someone will get back to us if they deem it necessary. We have yet to hear back from any of the messages we left. We have not received confirmation of corrections to verification requests. We never know if the order was changed to the appropriate prescription. Patients need to be protected from such behavior since it may directly affect their eye health.

This lack of communication persists despite the passage of the FCLCA. On March 29, 2004, we received a live operator request on our answering machine from 1800Contacts. The operator spoke in a very fast cadence making it difficult to understand. The patient name was a name common to two of our patients. We faxed back a request for more information, such as date of birth, to determine the correct patient. We did not hear back from 1800Contacts. On March 30, 2004, we contacted 1800Contacts by phone to check on the status of our request. At first we were told there were no open orders for our office. Since we practice on a state border, we mentioned it could possibly be a Missouri patient. We were then told they did receive our request but did not respond since they had a valid prescription in their system. If that was the case, why did they contact us in the first place? This type of activity borders on harassment and should be disallowed.

As a solution to the ongoing problem of poor communication, sellers must provide timely communication within eight business hours to the request for information. Once the prescriber sends in a request for information to the seller, the seller must not sell the contact lenses until all the concerns or questions of the prescriber have been resolved.

Sellers charging patients for lenses before the prescription is verified: An angry patient called our office stating that we had not responded to a request from 1800Contacts. She was even more concerned since 1800Contacts had already cashed her check. 1800Contacts told the patient we had not responded to three requests. We had no record of a request. My office called 1800Contacts and we were told they had called our office three times with a live operator and our phone was busy. The behavior of telling our patients we are not responding to their request when it is a busy phone signal is not appropriate. It only serves to breakdown the doctor patient relationship and places us in an adversarial role with our patient. Because of the misinformation given to the patient, the patient assumed we were being antagonistic and we may lose the patient over this incident. How can we measure the patient's loss in trust? The practice of charging before the prescription is verified needs to be disallowed since the prescription may be different than what the patient has requested, or does not exist at all thereby creating a need for a refund. This parallels a pharmacy charging for a drug and then telling the person they need to find a doctor to prescribe that drug. This further erodes the doctor patient relationship and is an aggressive business tactic to sell a product without consideration of potential ocular health consequences. Patients need to be protected from this type of behavior.

Self prescribing problems: My experience has demonstrated that patients do self prescribe contact lenses. Certainly, some have been blatant attempts to obtain contact lenses when a prescription does not exist and others have been innocent attempts. A patient that had never been fitted with, or prescribed, contact lenses presented to my clinic wearing a contact lens in one eye. She scheduled an examination since she was not seeing well enough to perform her occupational duties. When asked about how she was obtaining the contact lenses, she replied 'you can get anything online.' Unfortunately, the poorly fit contact lens caused swelling in her cornea. Fortunately, she is expected to make a recovery with appropriate medical treatment. Patients have also requested a contact lens prescription when they have not completed the fitting and adapting process. Others have requested a contact lens that is being offered for a special sale price rather than the contact lens that was prescribed. Another case involved a patient requesting to return to a previous contact lens type when the patient was fit into a

different design due to complications caused by their previous design. Again, improving communication between seller and prescriber will help eliminate ocular consequences from wearing inappropriate contact lenses. The prescriber must be informed of the passive sale of contact lenses in order to monitor and determine the lenses patients are actually wearing.

Automated phone requests should be prohibited: Our office has two receptionists that answer the telephone. They are not trained to answer questions about prescriptions. The automated phone requests force whoever answers the phone to immediately go through a series of prompts and verify the prescription information. This is not practical since they are not trained, and in a busy office they have to drop what they are doing and handle the automated request leaving patients standing in front of them or must let the telephone go unanswered. This is very intrusive, disrupts patient flow in our office, and has a negative effect on patients in our office or potential patients calling our office.

Doctors should be able to fax a written copy of the prescription: Per the FCLCA, the prescriber can choose to fax, voice mail, or e-mail responses regardless of how they were contacted. The actual written prescription should be allowed to be faxed rather than use the requesting seller's form. The reason is two fold; if the seller accepts the written prescription from the patient, then the prescriber should not have to waste time duplicating the information on the seller's form. Secondly, it will be impossible to develop a single form that could incorporate all state law contact lens prescription definitions.

Liability Issues: Under Section 315.8 Prohibition of Certain Waivers, 'the Act provides that this provision does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.' Under this Act, a prescription is defined to be correctly verified if we do not respond to the request within eight hours. My concern is the case that my office does not respond to a request, due to being out of the office, for an expired or invalid contact lens prescription and the patient suffers vision loss secondary to a contact lens complication. Under this scenario, what is the liability exposure? This gets back to the problem that the requested prescription is assumed to be valid and unexpired.