

March 4, 2004

To the Committee overseeing the Fairness in Contact lens act,

My name is Dr. Eric Lamp and I practice optometry in Wichita Kansas. I appreciate the opportunity to contribute to the contact lens rulemaking process that you are currently overseeing. I will submit several opinions regarding the rule as it is written and will respond to questions raised in the rule itself.

Business hour

I would like to begin by addressing the definition of Business hour which is found in II Section 315-2 Definitions. This definition is sufficiently clear as written, and the examples are ample for the general case. I would not suggest changes to the definition or understanding of 8 hours that the FTC is putting forth, but it does not deal with time zone issue or, as is raised in the general question section of IX, "exception to normal business hours." Many doctors have separate locations or work for multiple employers making it difficult to comply with the rule as written. There seems to be an unreasonable rush which will invoke many "deemed verified" occurrences. The impact of this in costs will be seen in ways which I will articulate in my comments on verification events.

Direct communication

The definition of Direct communication is sufficiently clear but, as is raised in the questions section IX, should require receipt of communication in fax or e-mail form and should not include the leaving of a message unless that event too has some sort of evidence of receipt. Only under these circumstances can it be said by the definition that “completed communication with the recipient” has indeed occurred. It is of no value to know that communication has occurred with an answering machine, computer, or fax machine. These entities are instruments of communication with the recipient but do not constitute actual completed communication. Therefore, receipt or feedback is necessary to meet the definition of Direct communication, as given in the rule.

Section 315.5 Prescription Verification

Section (c) relates a strange understanding of the term verified. “Three circumstances under which a seller can consider a prescription verified and proceed to sell contact lenses to a consumer” are evaluated. The third event in section (c) outlines a failure of the prescriber to communicate with the seller within 8 business hours after receiving (emphasis mine) a proper verification request.

In the first two subsections 1) and 2) verification actually occurs and therefore need not be “considered” or “deemed” verified. Meanwhile, in subsection 3) “deemed” verified or “considered verified are synonymous with unverified or not

verified as no verification was established but instead was assumed, as the “prescriber failed to respond”. The costs and impact of patients receiving prescription devices with potential for harm without verification from the prescriber will be counted in health, quality of life, work lost, and medical expense. It is also a dangerous precedent to put forth in an environment of online and out of the state pharmacies.

An alternative would be to consider a prescription unverified since direct communication could not be established with the prescriber in the required time period. The patient then should be notified that no verification exists and permission should be obtained from the patient to allow refusal of the unverified prescription. Meanwhile, the seller must continue efforts to establish direct communication and verification. This scenario, though honest, would conflict with current FDA Law as does current “passive” verification as will be discussed below.

Above I emphasized the word “receiving”. The reason for this is the notion that the actual receiving of the request will be difficult to determine on the part of the seller. Starting the time of 8 hours on a local holiday or vacation would be inappropriate as it is unknown if the prescriber received the proper request. Perhaps a fax machine received it somewhere but the prescriber has yet to receive it. The rule clearly states that the Prescriber receive the request, therefore some sort of positive response from the actual prescriber would be needed to “start the clock” and comply with the rule as it is written.

Advertising

The release of prescription materials under the current writing of 315.5 (c) would violate the spirit of the advertising content section of the rule. It states that companies are not able to suggest that contacts can be obtained without a prescription whereas in 315.5 (c)(3) no prescriber response results in no verification of the prescription. Thereby, effectively contacts are sold without a prescription or at best a spurious or assumed prescription. A good example would be someone ordering contacts with phone book in hand and creating their own parameters which if not responded to would effectively be obtained without a valid prescription.

FDA Law

Section VII Regulatory Flexibility Act subsection E states that the FTC believes there are no other federal statutes, rules, or policies that would conflict and goes on to cite the FDA 21 U.S.C. 352 (f), 21 CFR 801.109 (a)(2). In fact, due to the “deemed verification” clause countless contacts would be sold without prescription. Consider this scenario with oxycontin! After calling the pharmacy if a physician doesn’t verify the “prescription” then it is deemed verified after eight hours? This is inconceivable for narcotics. Why is it okay for other prescriptions? Clearly, without active participation by a doctor a prescription not

a prescription at all, but an order. Thereby, this rule clearly violates the above reference FDA statute.

Costs of Implementation

Pursuant to the paperwork/reduction act (Section VI), the commission estimates prescribers will spend one minute providing each prescription to a patient or authorized third party. This resulted in 600,000 hours with a cost of 25.2 million. What is overlooked in the commission's estimates is the fact that although each prescriber will spend one minute writing the required prescription but that rarely settles things. Typically, when patients request lenses from a seller a prescription verification request then arrives at the prescriber's office which requires staff to spend one minute finding the corresponding chart and another one minute for the prescriber to fill out the request. Some patients could request verification as many as eight times in one year. This would result in nine minutes of provider time and eight minutes of staff time per year moving the estimated cost to \$226,800,000 in prescriber time and perhaps one fourth of that in staff time, nearing 300 million in costs if every contact lens wearer utilized an outside seller. This is unlikely but certainly shows the possible ceiling of the cost burden. Perhaps patients could actually utilize the prescription the Doctor writes and decrease the burden substantially. Scanners and fax machines are readily available.

I appreciate the opportunity to be heard on these subjects and I look forward to the FTC carefully considering each topic and rendering a decision that is both consumer friendly, business equitable and yet protects patients in keeping with FDA prescription law.

Sincerely,

Eric W. Lamp, O.D.