



American Optometric Association

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April 5, 2004

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

Re: Comment of the American Optometric Association Regards "Contact Lens Rule, Project No. R411002"

Dear Sir/Madam,

The American Optometric Association is pleased to provide comments on the proposed rule implementing the Fairness to Contact Lens Consumers Act. AOA is the national organization representing some 33,000 doctors of optometry. We believe the proposed rule provides the framework for appropriately addressing very real issues relating to both competition and health concerns in the contact lens market. We offer the following comments to further those goals.

#### Business Hours/Eight Hour Response Time

We believe the proposed rule has set forth a reasonable definition of business hours as hours between 9AM and 5PM, Monday – Friday (excluding Federal holidays). This recognizes the fact that while some offices are open on some Saturdays, most are not open every Saturday, and many are not open any Saturday. Further, those offices that might be open on a given Saturday may only be open for several hours. We believe that inherent in this definition is the intent that the time frame for verification shall be based on the time zone of the doctor, not the seller. To avoid unnecessary confusion we suggest that be explicitly stated in the final rule.

We have concerns over the eight business hour response time for verification requests. While it may be that a good number of verification requests can and will be handled by practices within an eight business hour time frame, there are legitimate circumstances which could cause a practice to miss this arbitrary deadline. This is true for large group practices who in addition to multiple verification requests also face a full schedule of appointments, unscheduled emergency visits and numerous telephone inquiries; small practices where adequate manpower may be an issue on specific days due to illness or other factors; and multi-group practices where records may be maintained in another location. We continue to receive alarming reports that doctors are being sent a large number of requests to verify prescriptions for consumers who are not their patients or whose prescriptions have expired long ago. Additional time is appropriate in order to afford doctors sufficient opportunity to thoroughly review their records and respond. Extending the time for responding to a minimum of twelve business hours would take into account all these circumstances without unduly delaying the verification process. In most situations such a

modest extension would have virtually no impact on the verification and shipping process, it would simply push the deadline for responding later into the same day.

There are several other issues related to the verification process we believe the commission should address. We have received numerous reports from doctors indicating they are unable to communicate at times with sellers by any means (telephone, fax, website, email) within the eight business hours. For the system to work as intended, sellers must be required to have sufficient fax capability to respond to the volume of requests they send out, sufficient phone lines manned by an adequate number of operators who are able to handle questions or responses relating to prescription verification, and an e-mail address dedicated to prescription verification to accommodate prescribers who wish to respond via the Internet. Interestingly, when doctors facing this situation seek to contact the company through the ordering numbers the seller provides to consumers, they have no problem getting through (although those operators are not equipped to handle the verification information). It is a waste of the doctor's time to make repeated efforts to contact the seller. It is also an unwarranted and unnecessary increase in the cost of complying with the act and may detract from providing care to other patients. Moreover, it can undermine a basic purpose of the law because if a prescriber is unable to communicate to the seller that the prescription has expired, the seller can complete the sale. We have also heard from doctors that many requests from sellers do not contain complete information required by the act. We believe the final rule should clarify that in these instances, where doctors have to request the additional information, the verification clock does not start until all information required by the law is received.

The final rule should also provide a reasonable accommodation for doctor absences from the office for continuing education, vacation and illness. In these instances, the practice should inform the seller of the prescriber's return date at which time the eight business hours would commence. We believe special rules should be adopted for satellite offices. In many rural parts of the country, practices may include a satellite office that is open only part time, perhaps just one day a week. These offices provide access to care that might not otherwise exist in smaller communities. Patient records are generally only available at these locations. To address these special circumstances we suggest the final rule allow means for doctors to notify sellers of the day (or days) when verification requests can be responded to, or as an alternative, extend the verification response time for these offices to account for these special circumstances. In any event, in those situations where a doctor's office notifies the seller that the office is closed and the records cannot be verified, the rule should make clear that the time for response begins when the office reopens.

#### Direct Communication

Sellers continue to use automated recordings to request verification, often at night, with incomplete or no patient information, and no real means for doctors to clarify the request. We believe these recorded messages do not allow for "direct communication" as described in the law and the proposed rule. These recordings should be specifically precluded by the final rule. As

an example, the seller's automated message that connects to a prescriber's after hours voice recording or answering service, will not be recognized, and the seller will not be in a position to determine that "direct communication" was achieved, only that a call was made. As a practical matter, voice messages of any sort are susceptible to human error in transcribing and the Commission should consider precluding this entire area of communication. At a minimum, the final rule should provide doctors the ability to opt out of phone contact similar to reported provisions of the Vistakon-1-800 Contacts settlement.

### Specialty Lenses

The statute states that prescribers may not require purchase of contact lenses from the prescriber as a condition of providing or verifying the prescription. In the vast majority of cases this will pose no issues for doctors because manufacturers provide complimentary trial lenses to doctors for fitting purposes. But, there is a set of specialty lenses where the doctor receives no trial lenses and thus the lens is fit specific to an individual patient. Examples include lenses to treat kerataconus, high and irregular astigmatic lenses, gas permeable lenses, and lenses used for orthokeratology. In these cases the doctor must order and purchase the lenses, which can then only be used by that patient. In other words, a "fit" really cannot occur until the patient is wearing a specific pair of lenses for his or her specific condition purchased by the prescriber. It would seem reasonable, and not inconsistent with the intent of the law, that in these cases prescribers be able to charge the patients for these lenses as part of the fitting process, and when the fitting process is complete, provide the patient with a copy of his/her prescription.

### Prescription Definition

In order to fully comply with the intent of the statute that prescriptions not be altered or lenses supplied to patients beyond the prescription expiration date we believe the final rule should make clear that prescriptions can contain the following: language underscoring that there should be no substitutions; the number of lenses and refills appropriate for the prescription; no refills when a year's supply has already been provided unless approved by prescriber; a means for the doctor to limit requests for an additional supply of lenses that would exceed the quantity needed consistent with the expiration date and wearing schedule, and any information required or permitted by state law. We would note that the act contemplates quantity limits are appropriate since the act requires that a request for prescription verification must contain the quantity of lenses ordered.

### Number of Refills

As currently written, the proposed rule does not address the very real issue of patients obtaining multiple supplies of lenses from several sources. For instance, a patient could fax a prescription to several sellers and also take it to a large retailer, thus obtaining lenses far in excess of the number prescribed for the expiration date. To assure that the intent of the legislation with regard to expiration dates and invalid prescriptions is maintained, we believe the final rule should require the seller to notify the prescribing doctor when an order for lenses is filled, and the

quantity of lenses provided. This will assure better patient compliance with wearing schedules and appropriate regular care, and reduce unnecessary complications as a result of wearing lenses long after a prescription has expired.

#### Verification Request Form

Sellers have thus far been inconsistent in their development of verification request forms, with some leaving off required information or doctor choices, such as the prescription has expired. We believe a consistent national verification form with all the information required by the law would be very useful and we urge the Commission to publish a model form with the final rule. All forms should include at least the following options for doctors: the prescription has expired; this is not my patient; excess quantity requested, only supply X lenses; further information required, with a space for the doctor to specify the information needed.

#### Decorative Contact Lenses

We believe the rule should state explicitly that it applies to all contact lenses, including so-called decorative contact lenses. Congress had the opportunity to draw a distinction between corrective lenses and decorative but chose not to. The law simply states “contact lenses” and the rule should accordingly apply to both types of lenses.

#### Issue Date

While the statute and proposed rule seem clear that the issue date is a one time date based on the initial presentation of the prescription to the patient there seems to be some confusion over its interpretation. Some have expressed concern that it can be construed to mean a new date anytime the patient requests another copy. Inasmuch as the one year expiration date is tied to the issue date, that interpretation would be inconsistent with the statute, but we ask that the Commission clarify in the final rule that the issue date is the date the doctor provides the patient with a copy of the prescription at the completion of the contact lens fitting, as defined in the law.

#### Federal and State Employed Prescribers

The proposed rule does not address the issue of federal and state employed prescribers. Consistent with the Eyeglasses rule, we believe the final rule should clarify that it does not apply to these employed prescribers, who in many if not most cases, do not have access to patient files and information.

#### Expiration Date

The proposed rule asks for examples of situations where prescribers might want a shorter expiration date. Such examples might include patients where the corneal integrity has been or might be compromised for a number of reasons, including but not limited to neovascularization, hypoxia, dry eyes, history of frequent conjunctivitis and history of non-compliance with wearing schedules.

We also suggest that with regard to expiration dates less than one year, that the final rule state that providing the medical documentation for these situations be in accordance with applicable state and federal privacy laws.

### Seller Record Keeping Requirements

We agree with the record-keeping telephone log requirements set forth in Section 315.5(f) of the proposed rule and suggest that it should also include the name of the individual in the prescriber's office who the seller spoke to directly.

### Specific Seller Problems

We have noted a number of specific seller deficiencies in complying with provisions of the law since the February 4 implementation date as follows: Faxes with no date and time; multiple requests for the same patient after receiving a doctor response that the prescription had expired or the patient was not known to the practice; refusal to accept "the prescription has expired" as a compliant response; selling lenses after the doctor has responded that the prescription has expired; shipping lenses to patients well before the eight business hours have expired; substituting lenses or otherwise altering the prescription, for instance telling a patient they can wear a lens for a month after the doctor has noted a two week schedule on the prescription because of the specific condition of the patient. Each of these are clear violations of the law and the final rule or the preamble to the final rule should list them explicitly as actions that will be subject to enforcement. We know you have received numerous complaints from doctors on these practices, and because they are such clear violations, and because they create in many cases an undue burden on doctors, we urge you to take enforcement action now, in advance of this final rule. We have also just seen a recent addition to one verification form informing doctors that if they have varied the expiration date based on medical judgment, as permitted by law, they must provide that medical record documentation to the seller (attached). This is not supported by the law, and indeed appears to be a violation of HIPAA privacy rules.

### General Seller Issues

We have become aware of general seller activity that also merits the attention of the Commission. Most troubling are reports that some sellers are billing patients' credit cards immediately upon receiving orders, and then subsequently informing consumers whose prescription may no longer be valid that the lenses are already in the shipping department and the transaction cannot be cancelled. This situation could be easily addressed by amending the rule to provide that a sale cannot be completed, and a consumer credit card cannot be charged, until the seller has received either a copy of the prescription or verification from the doctor. Also of concern is the unauthorized use of doctors' names on search engines in connection with the sale of contact lenses. Essentially, the engine will list doctors from a specific location, with a link that says click here to order lenses, and the link goes to an Internet seller. None of the doctors have been contacted for permission to be listed in this manner. Finally, 1-800 Contacts and Cole Vision have recently entered into an agreement that in and of itself we believe should be further

investigated by the Commission. We are specifically concerned that in cases where verification requests have been legitimately denied by doctors as expired, 1-800 Contacts is unfairly characterizing the doctor as uncooperative and suggesting to the patient that they go to one of “their” doctors.

Thank you for the opportunity to comment on this important rulemaking.

Sincerely,

A handwritten signature in black ink, appearing to read "Victor J. Connors". The signature is written in a cursive, flowing style with a distinct loop at the end.

Victor J. Connors, O.D.  
President