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Sent: Friday, April 02, 2004 12:36 PM
To: CONTACTLENSRULE
Cc: Jeff Mays
Subject: Contact Lens Rule Project No. R411002

Re: Contact Lens Rule Project No. R411002

The Ohio Optometric Association (OOA) appreciates the opportunity to provide comment on the Federal Trade Commission's proposed rule to implement the Fairness to Contact Lens Consumers Act. The OOA also wishes to express its appreciation to the Commission for its provision of some significant clarifications regarding the passive verification of contact lens prescriptions. Based upon the contents of the currently proposed rulemaking request for public comment as well as ongoing problems with contact lens prescription verification by various companies, we would request that the Commission consider the following recommendations in its implementation of the Rule:

1. Forbid the use of automated telephone calls to verify contact lens prescriptions.

The use of automated or computer-generated telephone calls to verify contact lens prescriptions does not constitute "direct communication." It is a process that doesn't work. It is a well-accepted fact substantiated by research that systems of automated communications frequently malfunction. Automated systems require responses from doctor's offices which often aren't feasible after normal business hours, on weekends, or at night. These systems also require responses from doctors' offices which aren't always practical because the systems demand immediate responses which are often interruptive to practice operations and demand a disruptive delay in care to patients with previously-scheduled appointments. The instructions contained in such messages are frequently unintelligible or garbled. Additionally, some doctors' answering machines or answering services do not provide for the recording of incoming messages and are limited to the generation of outgoing messages such as messages detailing the doctors' hours of practice operation as well as emergency information. Many office answering machines across the country are not powered by uninterruptible power supplies and may lose important prescription information stored in their electrically-programmable memory modules (EPROMS) in the event of a power interruption from a storm or an electrical power blackout. In light of these problems, the use of automated telephone calls for the verification of contact lens prescriptions should be specifically precluded by proposed Rule.

2. Incorporate provisions in the Contact Lens Rule that address the problem of uncontrolled prescription refills and provide for the mandatory notification of the prescribing doctor of all refills that are sold to patients.

The Rule in its present form mandates that prescribing doctors verify their patient's contact lens prescriptions and number of prescription refills; however, it does not require that the seller(s) keep the prescribing doctor apprised of the number of refills sold pursuant to each contact lens prescription. This should be a requirement that is incorporated in the Rule. Since the Rule currently requires the prescribing doctor to verify a patient's contact lens prescription within eight business hours, optometrists would be—should a refill notification requirement be added—forced to assume the additional role of pharmacist (practically speaking) in their practices. While this requirement would result in more

paperwork for prescribing doctors, it would also help to reduce and in many cases eliminate the current problems of: (1) unlawful patient “gray market” or “black market” provision (often from multiple sources), sale and distribution of contact lenses; (2) inadequate patient compliance with prescribed schedules of necessary contact lens follow-up care; (3) potential public health, safety, vision or ocular health problems associated with unsupervised contact lens wear or wear of outdated contact lens prescriptions. The current Rule, without refill-related provisions, will result in a system where the refill process is unmonitored, patients neglect to adhere to prescribed follow-up care and prescription expiration dates are ignored.

Additionally, it is important that the Commission’s proposed Contact Lens Rule clearly state that a contact lens prescription is expired when the prescribed refills are sold. Prescribing doctors should be able to note that a contact lens prescription is expired at the time refills are sold regardless of the expiration date. This would be consistent with common medical and optometric practice standards of care as applied to all prescriptions. Prescribing doctors should not be unjustly accused of failing to release when the refills have been sold. This has occurred and will continue to occur without adequate controls as provided by the above-mentioned Rule provisions.

3. Provide for medically-necessary extension of the verification period in patients requiring refitting of their contact lenses with trial lenses. There should be a specific provision in the proposed Rule permitting a reasonable extension while a patient is being refit with trial lenses. This situation often entails the refitting of a patient who has worn contact lenses previously but isn’t aware of the specifics of his or her prescription(s). The OOA concurs with the view of numerous authorities who view this as a valid medical reason for not proceeding with verification of the contact lens prescription in order to ensure the eye health of the patient before a final prescription is determined and written. The period of this extension should terminate and the fitting should be judged by the doctor to be completed when lenses are ordered for a patient and the patient is released for long-term (three months or longer) follow up and the ocular health and physiology of the eye(s) is/are judged to be within normal limits by the doctor.

4. Allow doctors to substitute the actual contact lens prescription in their response to verification requests. Contact lens sellers should be required to use a standardized verification form which would include all required information including expiration dates, the number of refills prescribed, the contact lens parameters and the number of refills to be sold. The seller should always be required to indicate the number of contact lens prescription refills on this form as well. Such a standardized form could be developed by all parties interested in the Rule. This would simplify the process and result in fewer processing errors for all parties.

5. Eight Business Hour extensions for incorrect prescriptions or questions by the prescribing doctor to ensure direct communication. The proposed Rule must address what constitutes direct communication and clarify the eight-business hour requirement when a prescription needs to be corrected or the doctor has a question. Once a doctor notifies a seller that the verification request involves a question or a need to correct a prescription, the eight-business hour requirement should be extended or treated as a new verification request. Currently, no requirement exists for sellers to communicate to the doctor if the prescribed corrections were made or received. The seller should be required to fax a corrected request to

ensure a complete medical record for the patient/doctor plus provide a reasonable opportunity to allow the prescription to be corrected prior to shipping to the patient.

6. Mandatory notification of all passive eight-business hour sales must be provided by the seller to the prescribing doctor.

The Rule should require that the seller notify the prescribing doctor, by mail, of all sales (including the number of contact lens prescription refills) provided to the patient without doctor verification. This provision would allow the prescribing doctor to notify the seller of an incorrect or outdated fax number or e-mail address. Such a requirement is necessary for the doctor to be able to maintain a complete medical record and to accurately monitor the contact lens wearing schedules for patients. It also provides a necessary safeguard for patients in the event that the prescription supplied was incorrect.

7. Provide for reasonable extensions to the eight-business hour contact lens prescription verification requirement in special cases.

Doctors who practice in rural locations often maintain satellite office locations to ensure patient access to care in smaller communities. The proposed Rule should require doctors in such locations to notify contact lens sellers that they are only available to verify contact lens prescriptions at the satellite location on specific days. Since the patient records are generally only available in those rural locations, this would constitute a reasonable case where an extension of the eight business hours verification period should be provided to the doctor in order to allow for proper verification of the contact lens prescription.

Doctors of optometry are required to complete continuing education in order to obtain re-licensure annually. While a doctor's absence for continuing education (and, therefore, their inability to verify a contact lens prescription during the time they are in attendance of such courses) would be infrequent, the Commission should acknowledge this situation in the proposed Rule through the specification of a reasonable period of accommodation. The doctor should be permitted to notify the seller of their return date at which time the eight-business hour verification period would commence. Similar accommodations should be provided in cases of illness, vacation or periods of unplanned practice interruptions in service/communication (fire, weather, etc.).

The proposed Rule should also clarify that the eight-business hour requirement is based upon the prescribing doctor's time zone rather than the contact lens seller's.

8. Allow for different verification methods and require that sellers maintain open, readily accessible and cost-free avenues for direct verification.

The doctor's office should be allowed the option of specifying to the seller the means of communication by which they will provide verification of the contact lens prescription, given the demands of the Rule which require that the prescribing doctor provide a written prescription plus subsequent verification of the prescription. If a busy office receives a telephone call requesting immediate approval, it can be difficult for doctors to provide an immediate answer by the time the patient records are located and the doctor becomes available. Live operator calls are sometimes the easiest and most efficient way to verify a prescription if the office and the doctor have sufficient time. In some cases, the sellers' operators have been extremely demanding when a doctor is busy treating patients and doesn't have time for an immediate response. The Rule should permit the prescribing doctor's office the opportunity to request that the verification be faxed or transmitted online when time permits. Further, measurements concerning connection on the first call versus busy signals should also be incorporated

in the Rule. A reasonable business model is that 90% of the first-time calls should not reach a busy signal. Anything less results in unnecessary administrative cost and waste.

Many Ohio doctors are complaining that various sellers' return facsimile or voice telephone lines are frequently busy. This creates a burdensome administrative problem for doctors and their staff members who are finding it difficult to efficiently provide verification of the contact lens prescription. This problem may also endanger patient vision or ocular health if it interferes with the necessary process of prescription verification and results in patients receiving their contact lenses inappropriately by default. In order to assure that doctors, their staffs and patients are not inconvenienced or harmed by this communication problem, sellers should be required to maintain an adequate number of operational telephone and facsimile lines in order to assure easy and efficient communication of this information. The OOA supports this basic business requirement in the interest of providing timely, convenient and safe accessibility of contact lenses to patients. If possible, the Commission should incorporate provisions in the Rule that stipulate that adequate communication access is being maintained for prescribers seeking to provide prescription verification. Sellers should be required to disburse the costs associated with this access and they should be required to periodically provide evidence to the Commission that adequate communications access exists through periodic telephone/internet service provider audit confirmation.

Several Ohio doctors are also reporting that sellers requesting contact lens prescription verification do not provide a toll-free telephone response line. It is the contention of these doctors that sellers want the business associated with selling contact lenses to patients but do not want to pay for the communication costs associated with conducting that business. The OOA strongly recommends that the Commission include language in the Rule that requires all sellers to maintain readily accessible, toll-free telephone, facsimile and electronic mail avenues for direct communication prescription verification.

9. Minimize frivolous verification requests.

A significant number of prescription verification requests are made by sellers for expired prescriptions. Consumers should be required to certify or at least be asked if they have obtained an eye examination within the last year to avoid wasting the time of both the prescribing doctor and the seller in the verification process.

10. Address confusion that exists in contact lens terminology related to "prescribing" of contact lenses versus "fitting" or "recommendation" of contact lenses.

The OOA has documented evidence that at least one contact lens seller is aggressively recommending certain brands of contact lenses to patients and that patients are without the supervision of a doctor attempting to obtain these contact lenses with the assistance of the seller (through the seller's facsimile of a spurious prescription verification request to the prescriber). In this case, a patient was informed by the seller that the seller "recommended" a certain brand of contact lenses—a brand that the patient had never worn. In other cases, sellers are attempting to misconstrue the "fitting" of contact lenses as constituting their "prescribing." of a contact lens.

The Commission should specifically stipulate in the Rule's language that the "Fitting" of a contact lens constitutes only a small component of prescribing a contact lens for a patient and it should only be performed by appropriately trained health care practitioners in the strictest accordance with the instructions and supervision of the prescribing doctor.

“Prescribing” of a contact lens includes the proper determination of refractive correction, fitting of the lens, and proper assessment of the performance of the lens and the health of the eye after contact lens dispensing and a medically appropriate trial wearing period (as defined in the last sentence of recommendation #3). In accordance with long-established federal law, it is the strong opinion of the OOA that the Commission should specifically clarify that “fitting” of a contact lens shall be forbidden to be autonomously undertaken by a seller and is a process that shall be initiated and directed only by a licensed optometrist or ophthalmologist. Only doctors licensed to “prescribe” a contact lens prescription are, by law, permitted to release a contact lens prescription to a patient or a seller.

11. Address fraudulent advertising claims by sellers regarding savings on contact lenses as well as seller’s misleading patients about the validity of the contact lens prescription expiration date or whether or not the prescribing doctor released the contact lens prescription. The proposed Rule should include penalties for false or misleading advertising regarding the Rule and its provisions. These provisions should include fraudulent claims of “50-70 percent” savings for contact lenses which aren’t typical or accurate.

Sellers who encourage patients to file false complaints against their prescribing doctor(s) should be found in violation of this Rule. Numerous doctors have reported frivolous claims were generated by 1-800-CONTACTS to State Boards of Optometry, alleging failure to release contact lenses. In such cases, the doctors were able to provide proof of verification or provide a copy of an actual prescription provided to the patient. In other cases, the prescribing doctor never received a request. These patients relied on the word of the company and never checked with the doctor. The tactics of unlawfully misleading or deceiving patients with the objective of disrupting the doctor/patient relationship are deplorable and should not be tolerated by the Commission. Likewise, indiscriminately selling contact lenses prescriptions (a practice that 1-800-CONTACTS has specifically admitted to in its company filings with the Securities and Exchange Commission as one example) or encouraging consumers to obtain their contact lenses based upon expired prescriptions raises health care costs because of resulting ocular health complications. Such unlawful corporate behavior results in consumers obtaining contact lenses with inaccurate prescriptions. Such behavior increases the risks of contact lens-related ocular morbidity.

12. Address the public health hazard of unsupervised plano contact lens wear.

Optometrists remain concerned about the complications resulting from patients’ unsupervised acquisition, wear and exchange between patients of plano contact lenses in order to change eye color. Numerous documented cases exist in the medical literature detailing ocular health complications and vision loss sustained by patients, often teenage children, from the inappropriate wear of these medical devices. In many cases, these lenses have been obtained online with no fitting and no instructions regarding appropriate contact lens handling, hygiene, care or wear. Other well-documented reports involve such contact lenses being sold in flea markets, beauty salons, gas stations or clothing shops. In many cases, the contact lenses were being sold with no professional supervision at prices of up to 300-400% over typical pricing. This is a serious and real public health problem that should be addressed in the proposed Rule.

13. Credit card processing prior to verification.

Doctors have reported complaints from patients that some sellers had already initiated credit card processing of charges for contact lenses prior to the patient’s provision of an eye examination and valid contact lens prescription. In some of these cases, the patient was instructed by the seller to have an eye examination within thirty days. Other patients found

lower prices at other sellers and attempted to purchase their contact lenses elsewhere. In light of these cases, the OOA believes that the Rule should prohibit the initiation of credit card processing prior to the completion of the verification process.

Thank you for the opportunity to provide comments regarding the Commission's proposed Contact Lens Rule. It is our sincere hope that the above suggestions will be incorporated into the Rule as we jointly seek to make cost-effective and safe contact lens prescriptions and wear available to consumers of these medical devices. Please contact Richard Cornett, executive director of the Ohio Optometric Association (phone: 614-781-0708) if you have any questions regarding these issues.

Sincerely,

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