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March 31, 2004

Client-Matter: 57914-001

BY E-MAIL CONTACTLENSRULE@FTC.GOV

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



Re: Contact Lens Rule, Project. No. R411002

Dear Sir or Madam:

On behalf of the New York State Optometric Association, we wish to express our views on the proposed regulations that you have published for comment relating to the implementation of the Fairness to Contact Lens Consumers Act (FCLCA).

First, let us emphasize our support of the intent of the FCLCA to provide patients with their contact lens prescriptions and to require prescribers to respond to requests by or on behalf of patients to verify those prescriptions. As optometrists practicing in New York, we have for many years been required to release contact lens and eyeglass prescriptions to our patients upon their request. We appreciate the balanced and reasonable approach that has been taken to address the complex and challenging issues relating to both competition and health concerns raised by the FCLCA and pledge the best efforts of the members of the Association to satisfy its requirements.

We know a number of commentators are seeking clarification of various other provisions of the statute and proposed regulations. While we will be awaiting clarification of these other issues along with our professional colleagues across the country, we thought it would be useful to focus on two issues; one of which addresses a concern we share with our colleagues nationwide and the other of which is an issue of particular interest to New York practitioners.

First, under Section 5 of the FCLCA, prescriptions are subject to a one-year expiration requirement, unless state law sets a longer expiration date, or unless an earlier date is necessitated by a medical condition. Contact lens sellers are expressly prohibited from filling a prescription that is past its expiration date.

Federal Trade Commission
March 31, 2004
Page 2

In order to ensure that these expiration dates are honored, we recommend that Section 315.5 of the FTC rules be expanded to include the requirement of the expiration date of the prescription in the information a contact lens seller must provide a prescriber when seeking verification of a contact lens prescription. The number of refills prescribed and requested should also be noted in the verification request. The rules should also make clear that a contact lens prescription is deemed expired when it is past its expiration date *or* when the prescribed number of refills have been filled, whichever occurs first. The rules should further allow for a reduced number of refills in the case that the number of refills remaining would outlast the expiration date of the prescription. These steps will help ensure that contact lens patients are undertaking a proper wearing regime, a health concern for all contact lens wearers.

To this end, contact lens sellers should be required to notify prescribers of the number of refills sold pursuant to each prescription. This is the only way a prescriber will be able to track the number of refills filled, especially when patients may seek to fill their contact lens prescriptions from multiple sources. Requiring confirmation of prescription refills could also ensure, in the case of a corrected prescription verification request or a prescription filled by passive verification, that the prescriber is aware of the prescription filled for his or her patients and has the opportunity to correct any continuing errors occurring after the verification period.

Our second concern relates to the third party designation codified in the FCLCA. Section 2 of the FCLCA and Section 315.3 of the proposed rules set out the requirement for the provision or verification of a contact lens prescription “as directed by any person designated to act on behalf of the patient,” including a contact lens seller. What is not clear from the language of the statute or the proposed rules, however, is how a prescriber may ascertain whether the person or entity requesting a prescription or verification of a prescription has indeed been so designated to act on behalf of the patient. Responding to a patient request is straightforward. We are not certain, however, how optometrists are supposed to determine whether a patient has authorized some other person to make a request for release or verification.

As noted, practitioners in New York have long been required by state regulation to furnish contact lens patients with a copy of their prescription upon their request. As with the FCLCA, releasing a prescription to the patient requires no verification of the patient’s wishes. In light of heightened concerns over releasing personally identifiable information to third parties other than the patient, the New York State Education Department advised optometrists to confirm that the patient has actually made that designation before releasing otherwise confidential information. In substance, the Department urged optometrists in New York to confirm, in writing if possible, that the patient authorized the release of the information to the third party in a letter dated September 11, 2002, which is attached hereto.

Federal Trade Commission

March 31, 2004

Page 3

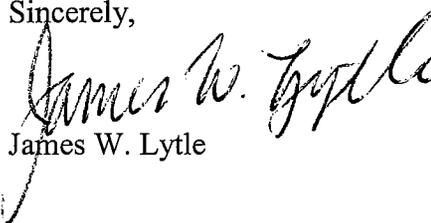
Our concerns regarding this issue are twofold. First, we seek clarity in the proposed rules as to how the FCLCA's third party designation is to be determined. Given the silence in the proposed regulations on this matter, one might presume that the Commission has determined that a contact lens seller has been designated by the patient to seek confirmation of a prescription by the mere fact that the seller is making that request. While the request by the seller for confirmation of the prescription may, in most instances, reflect the patient's wishes, we can imagine scenarios by which contact lens sellers, acting in bad faith, may wish to confirm information they have obtained about a patient's contact lens prescription through some other means, and potentially without the patient's knowledge or request. We do not, for that reason, believe it would be unreasonable to require the contact lens seller to furnish some reasonably reliable evidence that the seller has, in fact, been designated to act on behalf of the patient. That evidence might include the furnishing of a signed request, a copy of an e-mail order or some other similar confirmation that indicates that the seller is acting upon the patient's request and has been authorized by the patient to do so. We believe that further clarity on this essential aspect of the FCLCA would be beneficial to practitioners and contact lens sellers alike. Our recommendation to require the provision of some evidence of designation would help to address the important privacy concerns raised by such designation and would be consistent with the broader concerns relating to patient privacy and autonomy reflected by the HIPAA statute and its accompanying regulations. Further, it would not hinder the goal of competition among contact lens sellers addressed by the FCLCA and would not unduly burden patients' efforts to obtain nor sellers' efforts to provide contact lenses.

Second, we seek direction as to whether we should advise our members that the prior position taken by the New York State Education Department would be preempted by the FCLCA. Under the HIPAA statute, if a state patient privacy rule is more restrictive than federal requirements, the state rule prevails (i.e., it is not preempted by HIPAA). As noted, the New York State Education Department has stated that it would "be prudent for the optometrist to release contact lens prescriptions to a third party only on the written permission of the patient," especially in light of Part 29.1(8) of the Rules of the Board of Regents which makes the release of personally identifiable information, without the prior written consent of the patient, unprofessional conduct that could subject the licensee to professional discipline. As discussed above, these designation verification requirements are not inconsistent with the goal of the FCLCA, but do address important privacy concerns raised by such designation and are consistent with the broader concerns relating to patient privacy and autonomy reflected by HIPAA. Since these New York State requirements do not appear to conflict with the FCLCA, we would presume that they would not be preempted by the Act. Your guidance as to whether this is indeed the case would be most appreciated.

Thank you for the opportunity to present our concerns on these important issues. Please feel free to contact me with any questions that you may have.

Federal Trade Commission
March 31, 2004
Page 4

Sincerely,

A handwritten signature in black ink, reading "James W. Lytle". The signature is written in a cursive style with a large, sweeping initial "J".

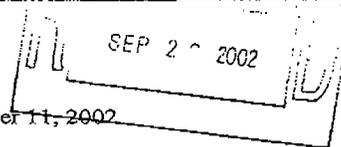
James W. Lytle

Attachment



THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

EXECUTIVE DIRECTOR
Office of Professional Responsibility
Tel. (518) 486-1765
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September 11, 2002

James W. Lytle, Esq.
Kalkines, Arky, Zall & Bernstein, LLP
121 State Street, 3rd Floor
Albany, NY 12207

Dear Mr. Lytle:

I write in response to your letter dated July 2, 2002 regarding the release of contact lens prescriptions.

Part 29.8(3) of the Rules of the Board of Regents specific to optometry, requires the practitioner "to provide a patient, upon request, with the patient's prescription, including the name, address and signature of the prescriber and date of prescription." Although "upon request" is not qualified, it would be appropriate for the practitioner to ask for a written request for the release of contact lens prescriptions in most cases. This is particularly important in light of Part 29.1(8), also part of the Rules of the Board of Regents, which makes the release of personally identifiable information, without the prior consent of the patient, unprofessional conduct. For all of the above reasons, it would therefore be prudent for the optometrist to release contact lens prescriptions to a third party only on the written permission of the patient.

As to the expiration date of a contact lens prescription, neither state law nor regulation places a time limit on the validity of a contact lens prescription. I believe that the ultimate resolution of this issue will require legislative action. However, to explore other possible resolutions, I have asked Dr. Milton Lawney to refer this matter to the State Board for Optometry for advice. Specifically, I would like to determine if a compelling argument can be made that a prescription for lenses loses validity after a period of time.

I thank you for bring these matters to my attention. If you have additional questions or concerns, please let me know.

Sincerely,

Frank Muñoz

cc: Milton Lawney