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FEDERAL AFFAIRS DEPARTMENT

VIA FACSIMILE AND ELECTRONIC MAIL

April 2, 2004

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 Number R411002

Dear Chairman Muris and fellow Commissioners,

The American Academy of Ophthalmology is pleased to offer the Commission our comments on the proposed Contact Lens Rule. Below we address each section of concern to the Academy.

Section 315.2 Definitions

For purposes of responding to contact lens prescription verification requests within “8 business hours” as required by statute, the proposed rule defines “8 business hours” as meaning 9am to 5pm, Monday through Friday, with federal holidays excepted. The Academy appreciates the Commission’s efforts to define this time period in a reasonable manner in light of the limitations imposed by the statute. However, we would like to take this opportunity to explain why the above formulation does not fully address the realities of ophthalmologic practice and care on a daily basis.

Cost burden

Approximately 40% of Academy members are solo practitioners with extremely small staffs. Responding to a high volume of contact lens prescription verification requests—10 a day is not uncommon—will require staff to divert attention from existing patients, patients calling in seeking appointments or follow up visits, etc. thus increasing operating costs for the ophthalmologist’ practice. Assuming a short average of 5 minutes per chart pulled for prescription verification purposes, staff could easily spend an hour per day pulling and reviewing charts, and this excludes additional physician review and response time, which would be required in many cases.

Academy request: The cost of the regulatory burden should be addressed by the Commission in the final rule.

Need for additional exceptions to the "8 business hour" provision

Because of the unique nature of ophthalmologic practice and the various demands upon the time of physicians, the Academy feels that the FTC must, to the extent possible, create an additional series of exceptions to the proposed "8 business hour" prescription verification response time promulgated in the draft rule. The following Academy comments are designed to illustrate the need for several specific exceptions that should have a minimal impact on overall prescription verification response times.

a) Surgery scheduling and physician availability

Most solo practitioner ophthalmologists perform non-emergency patient surgery at least one day per week and are thus not even in their offices to review contact lens prescription verification requests. Should an ophthalmologist be required to perform emergency surgery on a patient, the additional time away from the office would further delay responses to prescription verification requests. The Academy strongly feels that the Commission should include an exception for days the solo practitioner is in surgery in the final rule when calculating "8 business hours." Non-medical staff could reply to prescription verification requests with a note that the physician is performing surgery on the day in question but will respond to the request the next business day after all scheduled surgeries are concluded and that no lenses should be dispensed until the necessary medical review of the records is completed.

Academy request: That the FTC include an exception to the "8 business hour" prescription verification response time for days the solo practitioner is in surgery.

b) Continuing medical education requirement absences

Virtually all states require that for physicians to maintain their licensure, they must complete a certain number of hours of continuing medical education (CME) on an annual basis. Academy members frequently attend our annual meeting to take specific courses for this exact reason. Ophthalmologists who attend our annual meeting are out of their offices for several days, and are thus unable to review contact lens prescription verification requests during that time. Additionally, the American Board of Ophthalmology (ABO) requires that ophthalmologists take a recertification examination every 10 years to maintain clinical and professional competency. Time off to complete required courses and examinations for this certification are also necessary for the ophthalmologists. The Academy strongly feels that the Commission should include an exception for days the practitioner is out of the office to meet CME requirements per existing state law in the final rule when calculating "8 business hours."

Academy request: That the FTC include an exception to the “8 business hour” prescription verification response time for days the solo practitioner is attending state-required continuing medical education classes or those necessary to maintain national board certification.

c) Actual provider office hours

The Commission should be aware of the fact that an increasing percentage of providers have offices hours Monday through Thursday, Tuesday through Friday, or with certain days of the week where the office is closed. Accordingly, a blanket “Monday through Friday, 9am-5pm” provision in the final rule would not reflect the actual office hours offered by an increasing number of practices.

Academy request: That the FTC structure the final rule language in a way that takes into account the actual office hours offered by providers.

The Academy would recommend the following language:

“For purposes of section 315.5(c)(3), ‘eight (8) business hours’ shall begin at the time that the seller provides the prescription verification request to the prescriber and conclude after eight (8) business hours have elapsed, except that the period for verification requests received during non-business hours shall begin at 9 a.m. on the next business weekday that the office is open and that is not a Federal holiday.”

d) Provider absences due to other factors

The proposed rule provides an exception only for federal holidays. The Academy feels that the rule must recognize exceptions for other state or religious holidays not observed by the federal government. Provider unavailability due to illness should also be an exception incorporated into the final rule, as should an exception for vacations. Finally, public service requirements such as jury duty would also take the ophthalmologist out of the office for one or more days in specific circumstances and should likewise be an exception included in the final rule.

Academy request: That the FTC include an exception to the “8 business hour” prescription verification response time for state or religious holidays, solo practitioner illness and/or vacation days, and for local, state, or federally mandated jury duty.

Section 315.3 Availability of Contact Lens Prescriptions to Patients

The Academy feels that the FTC should clarify this section so that patients and providers understand that this provision does not exclude transactions whereby providers may offer a “package deal” on an exam and the initial set of diagnostic lenses used to establish proper fit, medical suitability of the patient for contact lens wear, etc. as part of a single transaction. Since the consumer has a choice of provider and there is significant

competition among practitioners providing contact lens services, the practitioner should be able to offer their services in a bundled package as long as they do not charge an extra fee for providing the prescription.

Due to the number of questions raised by practitioners regarding the impact of HIPAA, the Academy feels that the FTC should explicitly state the policy in the final rule to ensure that sellers, patients, and providers are clear on the relationship of the rule to the patient privacy protection requirements of HIPAA:

“For purposes of compliance with the patient privacy protection provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), sellers are classified as a "Health Care Provider" (see 45 C.F.R. Section 160.103) when selling or dispensing contact lenses pursuant to a prescription. Accordingly, under HIPAA providers are supplying information to another health care provider for purposes of "treatment" and no specific authorization or consent from the patient is required.”

The Academy also believes that the Commission should carefully examine HIPAA's small business exemptions to determine whether they are applicable to the proposed rule or in conflict with it.

Section 315.4 Limits on Requiring Immediate Payment

The Academy feels that the following phrase is problematic:

“The Act treats presentation of proof of insurance coverage as a type of payment.”

The Academy request that the FTC modify the proposed rule language to read as follows:

“The Act treats presentation of proof of current, valid insurance coverage accepted by the provider as a type of payment.”

Such a clarification is necessary to ensure that patients do not attempt to defraud providers for payment of goods and services rendered through the use of expired or otherwise invalid or nonexistent insurance coverage, as well as to ensure that any insurance coverage offered as payment is from a plan in which the provider actually participates.

Section 315.5 Prescriber Verification

(c) Verification Events

This section of the proposed rule states, in part:

“This provision clarifies, however, that prescribers must use a method of direct communication (i.e., telephone, facsimile, or e-mail) in conveying their response

to the seller's verification request. The method of direct communication used by the prescriber to respond need not be the same method of direct communication that the seller used to send a verification request. For example, an eye care practitioner may respond by telephone to a seller's fax seeking verification."

The Academy has received numerous complaints from members about 1-800-CONTACTS phone verification process, which generally requires the provider to call a number then respond to menu prompts. A common complaint Academy members make about this "service" is that the menu generally consists of "Press 1 if you verify this prescription, Press 2 if you are not willing to verify this prescription," or words to that effect. An even more frequent complaint involves disconnects, hang-ups, or inexplicable tones coming from 800 CONTACTS call-back numbers. Academy members believe that such a "service" does not comply with the Act in that there is no opportunity to verifiably provide corrected information.

To preclude the abuses outlined above, the Academy feels most strongly that the FTC should add the following language to the above section:

"Due to the potential medical complexities associated with the use of prescription medical devices such as contact lenses, sellers may not employ automated, menu-driven telephone response mechanisms to obtain prescription verification information, but must make available in real-time company representatives capable of taking prescription verification information over the phone from providers. Should the provider not be available due to the exceptions cited in this rule, the seller's communication with the provider shall not be considered successful and the seller may not fill the prescription until such successful communication with the provider has been achieved."

(d) Invalid Prescription

In this particular section, the proposed rule states, in part:

"The Act precludes a seller from filling a contact lens prescription that the prescriber has reported is inaccurate, expired, or otherwise invalid, except that a seller may fill an inaccurate prescription that the prescriber has corrected."

For the sake of clarity and patient safety, the Academy requests that the FTC use the following revised language in this section:

"The Act precludes a seller from filling a contact lens prescription that the prescriber has reported is inaccurate, expired, incomplete, or otherwise invalid, except that a seller may fill an inaccurate prescription that the prescriber has corrected for a patient actually under the care of the prescriber in question."

The Academy feels that this provision is essential to help protect providers from any liability associated with the misuse of their name and prescribing authority to fill prescriptions for individuals who are not under their care.

Additionally, the Academy has received numerous complaints from providers—many of which have already been forwarded to the FTC—about contact lens resellers filling expired prescriptions for patients even after receiving confirmation from the doctor's office that the prescription is no longer valid. *Physicians who have contacted the Academy report that the number of expired prescriptions submitted by contact lens resellers is well in excess of 50%, and that contact lens resellers frequently resubmit these expired prescriptions to Academy members even after Academy members have verified the expiration of the prescription.* We have heard from so many Academy members about this problem that we feel the FTC should conduct its own survey of eye care providers to determine the extent and magnitude of potential expired prescriptions being filled in violation of the Act.

The Commission should also understand that a passive verification regime for a prescription medical device is unprecedented in the history of medicine, and is certainly the first time that a prescription medical device will be allowed for sale to the public under a passive verification scheme *that is not allowed* with prescription pharmaceuticals. The Academy feels that the Commission should address the implications of this change in policy in its comments on the final rule when published.

The Academy appreciates the Commission's willingness to consider our views as the FTC moves forward in this rulemaking process. Should you have any questions about these comments, please contact the Academy's FTC liaison, Patrick Eddington, at 202-737-6662.

Sincerely,



William Rich III, MD
Secretary of Federal Affairs