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January 30, 2017

Donald S. Clark
Secretary
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue N.W.
Suite CC-5610 (Annex B)
Washington, D.C. 20580

Re: Contact Lens Rule

The American Academy of Ophthalmology is pleased to offer the Commission our comments on the proposed changes to the Contact Lens Rule. The American Academy of Ophthalmology is the largest national member's association of ophthalmologists—medical and osteopathic doctors who provide comprehensive eye care including medical, surgical, and optical care. The Academy seeks to protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public.

The Academy was encouraged by the Commission's 2015 decision to review the Contact Lens Rule, as we believed minor changes to the existing rule could greatly enhance patient safety. We proposed lengthening the verification window from 8-business hours to two business days to enhance prescriber's ability to confirm patient prescriptions. We also called for the Commission to identify and outline new actions to enhance penalties on those selling contact lenses without a prescription. Given the modest changes proposed by the Academy, we are dismayed by the results of the Commission's review. The Commission has offered no changes to the Rule to enhance patient safety, instead pursuing changes that would simply alter administrative procedures that would levy financial costs and place increased regulatory burdens on eye care providers.

The Academy does not support the Commission's proposal for prescribers to issue and have signed a prescription acknowledgement form. The Academy supports the right of each patient to receive a copy of their prescription, ensuring their ability to comparison shop for contact lenses in an open marketplace. Our members have diligently complied with this component of the Rule since 2004 and we are unaware of compliance issues among the ophthalmic community. Ophthalmic practices utilize various processes for ensuring patient access to their prescription, including providing copies through email, facsimile, and direct office pick-up. Thus, it is our view that modifications that place additional compliance measures in place during each patient visit, such as an acknowledgement form, are unwarranted. The Commission's prioritization of contact lens sales over contact lens safety is extremely misguided.

While the Academy is unaware of rampant failure to provide copies of prescriptions, we remain concerned with the growing number of consumers that can purchase contact lenses without a prescription at all. Online sales of contact lenses without a prescription is a

growing practice, with consumers able to find a seller far too easily. The Commission's failure to address this growing problem in the marketplace is of great concern to the Academy and its members. A contact lens is a medical device and misuse can lead to serious vision complications, including corneal ulcers. It is critical that the Commission understand the detrimental health and financial impact that can occur due to the misuse of contact lenses.

The Federal Trade Commission stated that the concerns of prescribers were not supported by concrete empirical data and thus the suggested changes to passive verification and the strict verification window were not warranted. It is concerning to the Academy that instead the Commission put forward changes to the Rule that were proposed solely by the seller community. Specifically, the acknowledgement form was a direct suggestion from Lens.com in their comment which stated; "Lens.com proposes that the Commission require prescribers to provide a document to each patient that outlines their rights as a contact lens wearer and correspondingly require each patient to sign this document to acknowledge receipt of their prescription." This proposal was not supported by any empirical evidence that proved rampant problems with prescription release and so we are mystified as to why the Commission found this to be a warranted change to the Rule.

The Academy is also concerned about the acceptance of data put forward by these stakeholders during the review process. The Commission details "data" that was collected through surveys commissioned by these sellers and uses it to support both its overall conclusions and changes to the Rule. These surveys have no scientific merit and should not have been considered supporting evidence to their claims. If the Commission is aware of broad compliance failure by ophthalmologists, we welcome the Commission to provide us with it. In absence of such evidence, we call on the Commission to rescind the proposed changes to the rule.

FTC Questions:

What benefits would a proposed change confer and on whom? The Commission in particular seeks information on any benefits a change would confer on consumers of contact lenses.

Academy Response: It is unclear how the proposed change to the Contact Lens Rule would benefit consumers, as there is no credible evidence that points to rampant failure by prescribers to provide copies of existing prescriptions. Mandating a new patient form from eye care prescribers would increase costs for consumers in need of eye care, as the administrative costs of implementing new processes increase the cost of patient visits.

What costs or burdens would a proposed change impose and on whom? The Commission in particular seeks information on any burdens a change would impose on small businesses.

Academy Response: The costs and burdens would fall solely on prescribers of contact lens because they would be required to generate and store the proposed acknowledgement forms. For prescriber practices that do not utilize electronic medical records, or other electronic data storage, the cost burden would be substantial. This is due to the proposed change requiring storage of the acknowledgement form for a period of 3 years. For practices that do have electronic medical records or electronic data storage, the cost and burden would still be substantial. Prescribers would need to work with their EHR system to incorporate the acknowledgement form, which could be costly and require extensive administrative support.

What regulatory alternatives to the proposed changes are available that would reduce the burdens of the proposed changes while providing the same benefits?

Academy Response: The Academy is unaware of credible evidence that supports the need for the proposed acknowledgement form and does not believe changes to the Rule regarding the issuance of prescriptions is necessary.

Acknowledgment of prescription release:

Would the proposed amendment to require prescribers, after the completion of a contact lens fitting, to request the contact lens patient acknowledge receipt of the contact lens prescription by signing an acknowledgment form increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

Academy Response: Ophthalmologists have a strong record of compliance with the Contact Lens Rule, including the release of prescriptions to our patients. In addition to getting copies through initial or routine visits, practices issue copies at the request of patients via several avenues. For practices that utilize electronic medical record systems, patients can request a copy of their prescription and by issued one electronically. Many practices also utilize patient portals to fill prescription requests. The acknowledgement form would have an insignificant impact on compliance and would only increase administrative burden and financial costs for small businesses.

Would the proposed amendment to require prescribers to maintain copies of the signed acknowledgments for a period of not less than three years increase, decrease, or have no effect on the Commission's ability to measure and enforce the Rule's automatic prescription release provision? Why?

Academy Response: The Academy believes the benefits of the proposed amendment would be minimal, as it would apply to tens of thousands of prescribers who are already in compliance with the Rule. The Commission should focus on broader reforms of the verification system and not on adding compliance requirements that only increase burdens and costs on prescribers of contact lenses.

Would the proposed amendment to require the acknowledgment form to inform patients that they may purchase contact lenses from the seller of their choice increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

Academy Response: Ophthalmology has a broad history of compliance with the Contact Lens Rule, including educating our patients on their rights to their prescription and opportunities to get affordable contact lenses. The Academy supports a competitive contact lens marketplace that enables patients and consumers the opportunity to comparison shop but does not support efforts by the seller community and the Commission to prioritize the sale of contact lenses over consumer safety.

Should the Commission consider other language to be included in the signed acknowledgment form? If so, what?

Academy Response: The Academy does not support the proposed acknowledgement form.

In this NPRM, the Commission has preliminarily determined that requiring prescribers to provide additional copies of contact lens prescriptions to a patient upon request is required by the Act. How does this determination affect, if at all, the portability of contact lens prescriptions?

Academy Response: Ophthalmologists provide patients with copies of their prescription at their request and do so in a manner that allows for portability. We are aware of different methods by which our physicians get additional copies to their patients, including through electronic means.

Does this determination affect the accuracy of contact lens prescriptions presented to sellers? If so, how?

Academy Response: A copy of a patient prescription for contact lenses should not impact the accuracy presented to sellers. The Academy reminds the Commission that our members frequently see patients that are dealing with complications stemming from wearing contact lenses with expired prescriptions and/or without a prescription. These issues remain unaddressed by the Commission.

The Academy appreciates the Federal Trade Commission's efforts to engage with stakeholders on updates to the Contact Lens Rule. We believe that the proposed changes represent a failure to address critical flaws in the verification system and levy unwarranted penalties on eye care providers. We call on the Commission to rethink proposed changes to the Rule and reaffirm their commitment to protecting consumers by prioritizing contact lens safety over contact lens sales. Should you have questions about any of our comments or seek additional input, please feel free to contact myself or Scott Haber, Government Affairs Representative, at shaber@aaodc.org or via phone at 202-737-6662.

Sincerely,

Michael X. Repka, MD, MBA
Medical Director for Governmental Affairs
American Academy of Ophthalmology