

October 26, 2015

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Re: Contact Lens Rule

The American Academy of Ophthalmology is pleased to offer the Commission our comments on the Contact Lens Rule. The American Academy of Ophthalmology is the largest national members association of ophthalmologists—medical and osteopathic doctors who provide comprehensive eye care including medical, surgical, and optical care. The Academy appreciates the Commission’s efforts to maintain the Contact Lens Rule pursuant to the 2004 Fairness to Contact Lens Consumers Act. While we believe that the Rule has been beneficial to consumers, we believe modifications to the Rule that promote patient safety are long overdue. The strict verification window for providers continues to promote the passive verification of prescriptions and puts patients at risk. In reviewing the Contact Lens Rule, the Academy hopes that the Commission will prioritize patient safety when considering any future modifications.

**Is there a continuing need for the Rule? Why or why not?**

The Academy supports the continuing need for the Contact Lens Rule, as we believe it empowers consumers to comparison shop for contact lenses and believe the Rule provides some modicum of patient safety assurances. With that said the Academy has concerns regarding the verification and sales tactics of third party contact lens vendors and believes modifications in the rule would further strengthen the benefits to patients. Those are outlined throughout the comment.

**What benefits has the Rule provided to consumers? What evidence supports the asserted benefits?**

Consumers have benefitted from the Rule by giving them the ability to comparison shop and find prescription lenses that fit their budget. The marketplace for contact lenses has expanded significantly, promoting competition and driving down prices. While that certainly has benefitted the consumer’s pocketbook, it has driven some retailers into tactics that endanger patient safety by using questionable sales tactics to skirt the requirements of the Contact Lens Rule. This includes the sale of contact lenses without a valid prescription, a practice that the Academy hears far too frequently about.

**What modifications, if any, should be made to the Rule to increase its benefits to consumers?**

The Academy continues to have significant concerns with regards to the passive verification of prescriptions and the rigid eight-business-hour window for prescribers to verify prescriptions with sellers. We believe that modifying the Rule and extending that window to two business days is an improvement. Physician verification is a critical safety check and without it, patients face the possibility of significant medical problems. Wearing improper lenses can further complicate

existing vision issues, including leading to infection in the eye. The sale of lenses without a prescription is a practice that continues despite the Rule, and the Academy believes that the Commission should take swift action to improve enforcement of the Rule.

**What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?**

The Academy is concerned that consumers continue to misunderstand the Rule and the necessity for a prescription for the use of contact lenses. With an ever-expanding marketplace, the Academy continues to hear of instances where contact lenses are being sold without a prescription leading to significant eye injuries. The Commission should act to mitigate these risks to the consumer, by placing additional safeguards to protect consumers from retailers willing to provide consumers contact lenses without a prescription. If this practice continues, ophthalmologists will continue to see patients who are dealing with significant vision issues stemming from wearing lenses without the proper prescription. For additional evidence of the current dangers of this practice look to the actions of CDC, which organized National Contact Lens Health Week in part to educate consumers about the faulty practices of retailers and the importance of receiving a prescription from a trusted eye-care provider.

**What significant costs, if any, has the Rule imposed on consumers? What evidence supports the asserted costs?**

Consumers have not faced additional costs stemming from the Rule, as the marketplace has continued to grow and prices have fallen. Some consumers have faced indirect costs from the Rule, as the current safeguards to protect patients are not strong enough. These are patients who suffer significant eye injury due to the ability to easily obtain contact lenses without a prescription face significant costs.

**What significant costs, if any, including costs of compliance, has the Rule imposed on businesses, including small businesses?**

For ophthalmic practices, the eight-business-hour verification requirement continues to be disruptive. The Academy believes that this requirement is far too short and ultimately imposes significant burdens on providers and in many instances eliminates a necessary patient safety check. If sellers provide consumers with contact lenses without specific provider verification, ultimately providers will have to deal with the medical fall-out from patients wearing incorrect prescription lenses. In addition, ophthalmologists are frequently unable to reach retailers with regards to follow up verification or to outline problems with a prescription. The inability to reach retailers, in many instances, leads to the passive verification issues previously touched on in this comment.

**What evidence is available concerning the degree of industry compliance with the Rule?**

The Academy has data from ophthalmic practices that outline instances of verification issues and prescriptions attributed to providers with no record of seeing the patient. In 2004, one such provider informed the Academy of a 58.7% verification error rate. That number has since decreased but the most recent data continues to show an error rate above 25%. Another ophthalmic practice reported a 60% error rate in a sample of 137 verification requests received between January of 2013 through September of 2015. In this sample, a significant proportion of the errors were due to incorrect prescriptions or expired prescriptions. With an error rate that high, it is quite obvious that compliance by retailers continues to be an issue. While ultimately not the sole reason for such errors, it is difficult to not place some blame on industry. Any modifications to the

Rule that would loosen existing verification requirements for contact lenses would be vigorously opposed by the Academy and viewed as an assault on eye health in this country.

**What modifications, if any, should be made to the Rule to account for changes in relevant technology or economic conditions? What evidence supports the proposed modifications?**

The emergence of online retailers only makes it more imperative that the Commission look to modify the rule to ensure patient safety. This includes steps to ensure proper verification by prescribers, alleviating the current burden on providers that stems from the strict eight-business-hour verification window, and continuing to educate consumers on the necessity of obtaining a prescription for contact lenses with periodic evaluations of contact lens fit.

The Academy appreciates the Federal Trade Commission's efforts to ensure that the Contact Lens Rule is reviewed and important stakeholder input gathered. With the Academy's membership representing a significant portion of eye care providers nationwide, we look forward to working with the Commission to strengthen the Rule to protect patient's vision health. 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](mailto:shaber@aaodc.org) or via phone at 202-737-6662.

Sincerely,



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