



January 30, 2016

Federal Trade Commission  
Office of the Secretary  
ATTN: Secretary Donald Clark  
600 Pennsylvania Avenue, NW  
Suite CC-5610 (Annex C)  
Washington, DC 20580

Re: Contact Lens Rule, 16 CFR part 315, Project No. R511995

Dear Secretary Clark:

The American Society of Cataract and Refractive Surgery (ASCRS) appreciates the opportunity to comment on the Federal Trade Commission's (FTC) proposed amendments to the Contact Lens Rule.

ASCRS is a medical specialty society representing more than 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures performed annually in the U.S. In addition, a large percentage of ASCRS members practice general ophthalmology and regularly prescribe contact lenses. Many ASCRS members also dispense contact lenses from their offices and optical shops.

**ASCRS is writing in opposition to the proposal, "Patient Receipt of Contact Lens Prescription," which would require prescribers to obtain a patient's signed acknowledgment that the patient received a copy of his or her prescription and that a prescriber must maintain the signed acknowledgment for three years. This proposal is an unnecessary burden that will have significant cost implications on prescribers, as well as patients, and the unintended impact of reducing time spent on patient care. Furthermore, no evidence has been presented to assert that prescribers fail to comply with the law and provide portable prescriptions.**

***Significant Administrative Burden***

ASCRS is very concerned that this proposal would affect a significant patient population, and would undoubtedly add substantial regulatory burdens for a practice. Continuous training sessions would be needed to ensure that prescribers are in compliance with the rule. In addition, many will have to develop and update electronic patient portals to store the documentation. The time and cost of maintaining additional documentation would be a

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significant cost burden and could potentially be passed on to the patient. We encourage the FTC not to underestimate the potential impact of these changes.

ASCRS is also very concerned that the additional documentation will take away from time ophthalmologists spend caring for their patients. The current health care and regulatory system requires a substantial amount of documentation from ophthalmologists that ultimately limits time spent on patient care. Adding an additional piece of documentation will only be a further burden that ultimately takes away from the time an ophthalmologist spends with patients.

***Lack of Evidence of Non-Compliance with Requirement to Provide Prescriptions***

Moreover, the proposed collection of information is unnecessary and provides no practical utility to promote the practice of medicine or better patient care. Already, ophthalmologists must provide copies of contact lens prescriptions to contact lens wearing patients at the end of the contact lens fitting process to be in compliance with the Fairness to Contact Lens Consumers Act (FCLCA) and the Contact Lens Rule. ASCRS fully supports the patient's right to receive a copy of his or her contact lens prescription, though we are concerned that this proposal would be an unnecessary administrative burden that has no impact on improving patient care. According to the proposal, the patient will be asked—not required—to sign a paper or electronic form acknowledging receipt of the prescription. If the patient refuses to sign, the prescriber must note the refusal on the form. All forms must be maintained for at least three years. We encourage the FTC to consider regulations that address an identified need to protect patient safety. This proposal does not address an identified need currently lacking in the practice of medicine.

Furthermore, no evidence has been presented to assert that prescribers fail to comply with the law, choosing not to provide portable prescriptions. In fact, ASCRS is not aware of any widespread noncompliance activity that would justify such a drastic amendment. It seems that this proposal would be favorable to online retailers of contact lenses. We encourage the FTC to present valid data reflecting a need in regulatory change before making an amendment that impacts a very large patient population and that will have significant cost implications.

***Remaining Concerns with Eight-Hour Validation Window***

We are also disappointed that the FTC chose not to propose any changes to the eight-hour window prescribers have to validate prescriptions. Under the current rule, ASCRS contends that eight hours is not a sufficient amount of time to allow for the validation of prescription. Many of our members practice in solo or small practices that often do not have the resources to respond to verification requests within the eight-hour timeframe. This rule allows a seller to fill a prescription that is inaccurate, expired, or falsified simply because the prescriber has been unable to respond within eight hours. As a result, patients suffer serious eye injuries by wearing ill-fitted contacts.

ASCRS would like to remind the FTC that contact lenses are medical devices regulated by the Food and Drug Administration. Contact lens wearers require regular visits to an eyecare professional, as well as proper maintenance. A patient who wears poorly fitting contact lenses could suffer very serious eye injuries, and the magnitude of the injury would depend in part on how long the patient wears improperly prescribed contacts

and whether the patient wears the contacts on an extended or overnight schedule. Thus, allowing retailers to sell full prescriptions that have never been verified by a prescriber raises a very real risk that patients will suffer serious injury. **We urge the FTC to reconsider its decision not to lengthen the timeframe for prescription validation.**

***Conclusion***

ASCRS strongly urges the FTC to consider the significant cost implications and regulatory burden the proposal to require patient acknowledgement of receipt of a prescription will have on small- to medium-size practices, and the unintended effect of limiting time for patient care. We urge the FTC to withdraw this proposal. In addition, we urge the FTC to revisit the requirement that prescribers must validate prescriptions within eight hours. We encourage the FTC to ensure that regulations promote the best interest of patients for better health outcomes.

Thank you for the opportunity to submit these comments on the proposed changes to the Contact Lens Rule. We would be happy to meet with the FTC staff to answer any questions that it may have about contact lens prescribing practices or to discuss our concerns with the changes to the Rule. Please contact Allison Madson, manager of regulatory affairs, at 703-591-2220 if you have any questions or would like to arrange a meeting.

Sincerely,

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Kerry D. Solomon, MD  
President, ASCRS