



April 6, 2018

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 providing comments on the current Contact Lens Rule and several aspects of the proposed amendments, including:**

- **Opposition to the proposal, "Patient Receipt of Contact Lens Prescription," which would impose an administrative and financial burden on prescribers by requiring them 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. There is no evidence suggesting physicians are not providing the prescription, and the proposed collection of information is unnecessary and does not promote better patient care;**
- **Concerns that the eight-hour validation window is insufficient to allow a prescriber to validate a prescription. We recommend that the FTC lengthen the validation window to five business days, which will give prescribers an adequate amount of time to properly verify a prescription and prevent adverse patient outcomes;**
- **Significant concerns with patient safety, as the current eight-hour validation window allows inaccurate, falsified, and expired contact lens prescriptions to be filled.**

Our full comments on these issues are provided in detail in the following:

**Receipt of Contact Lens Prescription**

ASCRS strongly opposes the proposal, "Patient Receipt of Contact Lens Prescription," which would amend the Contact Lens Rule and 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, as there is no evidence that physicians are not providing the prescription, and it is an unnecessary burden. Currently, ophthalmologists are required by law to provide copies of contact lens prescriptions to contact lens-wearing patients at the end of the contact lens fitting process to comply 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, however, the **Patient Receipt of Contact Lens Prescription** proposal is 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 withdraw this proposal and, in the future, consider amendments to the Contact Lens Rule that address an identified need that ensures patient safety.**

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

ASCRS contends that the **Patient Receipt of Contact Lens Prescription proposal, and the collecting of this information, is unnecessary and provides no practical utility to promote the practice of medicine or better patient care.** No significant evidence has been presented to assert that prescribers fail to comply with the Contact Lens Rule by choosing not to provide portable prescriptions. In fact, ASCRS is not aware of any widespread non-compliance activity that would justify such a drastic amendment. **We encourage the FTC to present valid data reflecting the need for a change before making an amendment to the Contact Lens Rule that impacts a large patient population and that will have significant cost implications for practices.**

**Significant Administrative Burden**

**Additionally, ASCRS is concerned that the Patient Receipt of Contact Lens Prescription proposal places an undue regulatory burden on physician practices.** The current healthcare and regulatory system requires a substantial amount of documentation from ophthalmologists and practice administrators. We would like the FTC to recognize that many ophthalmic practices do more than just prescribe contact lenses. In fact, the majority of ASCRS members spend their time performing cataract and refractive

surgery. Currently, ophthalmic administrators experience significant burdens with the required federal quality reporting programs, prior authorization requests, medical billing, and daily tasks of running a medical practice. To add an additional piece of documentation that would need to be stored for at least three years will only be a further regulatory burden.

Additionally, ongoing training sessions would be needed to ensure that prescribers comply with the rule. Many practices will have to develop and update electronic patient portals to store the documentation. The time associated with maintaining additional documentation would be a significant administrative burden. Congress, the Administration, and the Centers for Medicare and Medicaid Services (CMS) all recognize the need to alleviate the administrative burden federal programs place on physician practices and are launching initiatives and working with stakeholders to reduce these burdens. **We strongly urge the FTC to recognize the need for regulatory relief and withdraw this amendment to the Contact Lens Rule.**

#### **Financial Burden**

**ASCRS is concerned that the costs associated with developing and updating the electronic patient portals to store the documentation would impose a financial burden and could potentially be passed on to the patient.** Many of our members practice in solo or small practices that often do not have the financial resources to easily develop or spend supplementary time adding additional documentation to patient portals.

A study conducted by Avalon Health Economics found that the financial impact associated with this FTC rule would cost a solo practitioner \$18,795 in the first year of implementation.<sup>1</sup> This is a significant additional cost for a solo practice to incur. If finalized, many practices may have to consider eliminating current part-time positions. **We encourage the FTC not to finalize the proposal due to the potential financial impact on physician practices.**

#### **Eight-Hour Validation Window**

**We are also disappointed that the FTC chose not to propose any changes to the current eight-hour window prescribers have to validate prescriptions for contact lenses.** Under the Contact Lens Rule, ASCRS contends that eight hours is not enough time to allow for the validation of a prescription. As we mentioned, many of our members practice in solo or small practices and do not have the resources to respond to verification requests within the eight-hour timeframe. The eight-hour window favors online retailers of contact lenses as it allows a seller to fill a prescription, even though it may be inaccurate, expired, or falsified, simply because the prescriber has been unable to respond within eight hours. As a

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<sup>1</sup>Avalon Health Economics (2017). Economic Evaluation of FTC Ruling on Contact Lens Prescriptions.

result, patients may suffer serious eye injuries by wearing ill-fitted contacts. Patients who wear contact lenses experience higher risks of developing ocular problems, such as giant papillary conjunctivitis, corneal abrasion, corneal infiltrates, and neovascularization.<sup>2</sup> These risks increase when patients wear poorly fitted contact lenses.

**Therefore, we recommend that the FTC lengthen the eight-hour validation window to five business days to give prescribers the ability to verify the prescription.** This would provide solo and small practices, who often have limited resources and staff, adequate time to respond to a third-party request. Additionally, with the expected increase of online contact sales, as discussed at the FTC Workshop, “The Contact Lens Rule and the Evolving Contact Lens Marketplace,” requests for prescription validations would also increase. It is unreasonable to expect small ophthalmic practices to have the resources to validate all requests they receive within eight hours, especially when third-party requests are projected to grow due to online sales. Furthermore, many of our members have reported that third-party requests are communicated by robocalls, that are extremely difficult to understand. The current rule has no details on how these requests are communicated, which allows a vendor to take advantage of the limited review time, further exacerbating the problem with the eight-hour validation window. Therefore, maintaining an eight-hour validation window is inadequate due to the limited resources ophthalmologists have when operating in solo and small practices and with the projected increase of online contact sales.

**More importantly, the current eight-hour validation window may also impact patients negatively if the prescriber does not have sufficient time to respond to a request.** For example, a patient whose prescription was not verified by the prescriber, and who wore poorly fitting contact lenses over the course of a year, may develop keratitis, an inflammation of the cornea that impairs vision and may lead to blindness. Allowing retailers to fill prescriptions that have never been verified by a prescriber raises a very real risk that patients will suffer serious injury. Providing an extended timeframe of five business days for prescription validation would greatly mitigate patient risks associated with poorly fitted contact lenses. **We urge the FTC to extend the timeframe for prescription validation in the Contact Lens Rule to five business days, which will give prescribers adequate time to properly verify a prescription that may prevent adverse patient outcomes.**

### **Ensuring Contact Lens Wearers’ Safety**

**The U.S. Food and Drug Administration (FDA) classifies contact lenses as Class II and Class III medical devices, and as such, patients should have regular examinations by their eyecare professional to ensure safety and efficacy. We urge the FTC to recognize the importance of contact lenses’ medical**

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<sup>2</sup> CDC.gov. (2018). Show Me the Science | Contact Lenses | CDC. [online] Available at: <https://www.cdc.gov/contactlenses/show-me-the-science.html> [Accessed 27 Feb. 2018].

**device classification and not to underestimate their potential risk to patients, as described during the FTC workshop panel discussion, “Contact Lens Health and Safety Issues,” specifically highlighting comments from the FDA and the Centers for Disease Control and Prevention.** While daily-wear contact lenses are Class II devices, posing a moderate risk to patients, extended-wear contact lenses are Class III, posing a high-risk of injury to patients. Unlike Class II devices, Class III devices adhere to stricter guidelines, requiring pre-market approval and scientific review before subject to marketing. In fact, extended-wear contact lenses are in the same device classification and pose the same high risk to patients as cardiac medical devices used to support life, such as pacemakers and heart valves. **We strongly urge the FTC to take into account the FDA’s classification of contact lenses and the risk associated with their use, as well as ensure regulatory standards that protect patients.**

In addition, ASCRS encourages the FTC to review the “Refractive Errors & Refractive Surgery Preferred Practice Pattern” that was developed by the American Academy of Ophthalmology, with input from ASCRS and the ophthalmic community, on best practices for contact lenses. In this document, the ophthalmic community agrees that contact lens wearers require regular visits to an eyecare professional, as well as proper maintenance.

“The initial contact lens fitting process should include follow-up examinations to assess visual acuity, comfort, contact lens fit, and the effect of the contact lens on the health of the ocular surface. First-time daily-wear or extended-wear contact lens users should be checked soon after the contact lenses are initially dispensed. Experienced contact lens wearers should generally be examined every 1 to 2 years to monitor for adverse effects of contact lens wear and for an update on healthy practices in contact lens wear and care. Patients should be questioned about problems such as irritation, redness, itching, discharge, decreased vision, or eyeglass blur upon contact lens removal. The patient’s wear schedule and contact lens care regimen should be reviewed, and any deviations from recommended practice addressed.”<sup>3</sup>

Without these medical standards in place, patients are exposed to higher risks that may have an adverse impact on their ocular health.

**It seems, through the FTC’s actions when implementing the Contact Lens Rule, that it is encouraging the expansion of online markets for contact sales at the expense of patients by rejecting the ophthalmic community’s medical standards for ocular health and the use of contact lenses.** We would like to clarify that purchasing contact lenses through a reputable online vendor does not necessarily pose the risk of ocular complications, but rather the FTC’s regulations governing the sale of contact lenses that allow patients to purchase medical devices, such as extended-wear contact lenses, without a valid prescription. To allow a patient to fill a prescription for a Class II and or Class III medical device that has not been verified by their physicians poses significant risks to their ocular health. That is why it is

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<sup>3</sup> American Academy of Ophthalmology (2017). Refractive Errors & Refractive Surgery Preferred Practice Pattern.

vital that the FTC lengthen the validation window to five business days to guarantee prescribers have adequate time to verify the prescription to protect the health of their patient. **We encourage the FTC to protect the health of contact lens consumers by recognizing the medical standards practiced by prescribers of contact lenses and to ensure that the Contact Lens Rule never allows an opportunity for an inaccurate, falsified, or expired contact lens prescriptions to be filled.**

### ***Conclusion***

ASCRS reiterates that we fully support the patient's right to receive a copy of his or her contact lens prescription, however, we urge the FTC to consider the regulatory burden and significant cost implications the proposal to require patient acknowledgement of receipt of a prescription will have on solo and small practices and the unintended effect of limiting time for patient care. We request that the FTC withdraw this proposal. In addition, we urge the FTC to revisit the requirement that prescribers must validate prescriptions within eight hours and extend it to five business days to ensure prescribers have adequate time to validate the patient prescription. Further, we encourage the FTC to ensure that regulations regarding contact lenses 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,

Bonnie An Henderson, MD  
President, ASCRS