



United States of America  
FEDERAL TRADE COMMISSION  
Washington, D.C. 20580

Office of Commissioner  
Terrell McSweeney

To: Donald Clark, Secretary  
From: Joshua Tzucker and Sheya Jabouin  
Date: August 10, 2017  
Re: Proposed Changes to the Contact Lens Rule: Comments to be placed on the public record

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On August 10, 2017, representatives of the American Optometric Association (“AOA”) and the American Academy of Ophthalmology (“AAO”) met with Commissioner Terrell McSweeney and FTC Staff<sup>1</sup> regarding a Notice of Proposed Rulemaking (“NPRM”) regarding the Contact Lens Rule (“CLR”). Appearing on behalf of the AOA were Dr. David Cockrell (Past President); Kara Webb (Associate Director for Coding and Regulatory Policy); Dr. Fred E. Goldberg (Optometrist, Mclean Eyecare Center). Appearing on behalf of the AAO was Scott Haber (Government Affairs Representative).

The NPRM at issue was published in the Federal Register on December 7, 2016, in Volume 81 of the Federal Register at page 88,526. The NPRM announced the FTC’s proposal to amend the CLR to require that prescribers obtain a signed acknowledgment after releasing a contact lens prescription to a patient, and maintain each such acknowledgment for a period of not less than three years; and sought comment on that proposal and several other issues. This memorandum is to be placed on the public record pursuant to 16 C.F.R. § 1.26(b)(5) and the NPRM, under which summaries or transcripts of oral communications respecting the merits of the proposed rulemaking from any outside party to any Commissioner or Commissioner’s advisor are to be placed on the public record.

During the August 10, 2017 meeting, the AOA and AAO representatives raised concerns about the potential burden of the proposed requirement that prescribers obtain a signed acknowledgement after giving patients their prescriptions at the end of a contact lens fitting. The AOA representatives questioned the basis for the proposed rule change in light of the strength of eye care provider compliance with the rule, as evidenced by the warning letters sent to fewer than 100 out of 50,000 contact lens providers in the U.S since the adoption of the rule in 2004.

To emphasize the burden of the proposed rule, the AOA stated that different state jurisdictions have different processes regarding how a contact lens prescription is derived. For instance, the state of Virginia has regulations in place that could cause complexities with the proposed rule. The AOA and AAO expressed concern about the burden the rule change would have on smaller businesses, most of whom rely on a hard-copy record keeping system. In

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<sup>1</sup> Also in attendance from the FTC were Commissioner McSweeney’s Attorney Advisors Joshua Tzucker and Jenny Schwab, Honors Paralegal Sheya Jabouin, and Morgan Kennedy from the FTC’s Office of General Counsel.

addition, they stated that incorporating anything new into any Electronic Health Records (“EHR”) system would result in a financial burden and a disruption of how each prescriber operates his or her practice. The additional resources devoted to implementing the proposal could cost \$20,000 annually for a larger practice and up to \$40,000 for a smaller practice. In addition to the financial burden, the AOA representatives stated that the requirement to obtain a signed acknowledgement might undermine trust between the patient and the doctor.

The AOA representatives stated that any new regulation requires staff training, periodic check-ins, and conversations with staff. As such, they assert the FTC has likely underestimated the actual monetary burden posed by the proposed rule change. As an alternative to obtaining a signed acknowledgment, the AOA representatives proposed that prescribers post signs setting forth the CLR’s requirements and the need for doctors to comply with the CLR under federal law. They believe that signage would be less burdensome for AOA members and other prescribers.