



HEALTH CARE ALLIANCE FOR PATIENT SAFETY

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Health Care Alliance for Patient Safety: FTC Proposed Contact Lens Rule Recognizes Health and Safety, but Opportunities Remain to Address Prescription Verification Loophole and Illegal Sale of Contact Lenses

(WASHINGTON) – The Healthcare Alliance for Patient Safety (Alliance) released the following statement in response to last week’s Federal Trade Commission (FTC) proposed supplemental rulemaking on the 2016 proposed Contact Lens Rule.

Congress charged the FTC with enforcing contact lens prescription verification requirements with the passage of the 2004 Fairness to Contact Lens Consumers Act (FCLCA). However, a lack of enforcement of some patient safety protections and the allowance of robocalls as a permissible form of communication for prescription verification has contributed to a growth in illegal sales, including through the filling of expired or non-existent prescriptions and the filling of prescriptions with devices other than what was prescribed by the doctor which put patients eye health and safety at risk.

The FTC’s proposed rule acknowledges some of the key problems associated with prescription verification via robocalls but does not close the verification loophole. Instead, the proposed rule only requires that automated verification telephone messages are “delivered in a slow and deliberate manner and at a reasonably understandable volume,” and “that prescribers be able to repeat the message.”

The FTC shared its concern about the misuse of the prescription verification process to substitute a different brand or manufacturer of lenses. The Alliance agrees with the FTC that contact lens brands are not interchangeable and that substitution is a growing problem in the market, but the Alliance believes that greater enforcement is necessary to ensure that patients receive the exact lenses prescribed by their doctor.

Dr. Deanna Alexander, Chairwoman of the Health Care Alliance for Patient Safety, said, *“The FTC’s proposed rule does recognize important issues with the contact lens market, but it does not fully address patient safety concerns around robocall verification of contact lens prescriptions or the ongoing enforcement of illegal substitution for what the patient’s doctor has prescribed. Re-playable, slow and deliberate messages are not the same thing as accurate and secured verification. We believe there is more work to be done to close the verification loophole and protect patients throughout the verification process.”*

More than 45 million Americans rely on contact lenses – U.S. Food and Drug Administration Class II and Class III regulated medical devices – for safe and effective vision correction. Contact lenses are more complex than they appear, having differing shapes, strengths, and water contents. [There are no generics](#). Improper lens usage, which

can result from the substitution of lenses not as prescribed by the patient's doctor, can lead to serious health complications, including infections and other sight-threatening conditions, such as corneal edema, ulcers, and neovascularization.

The Health Care Alliance for Patient Safety has made it a priority to close loopholes within the existing verification process and prevent the substitution of lenses to reduce the risk of preventable vision loss. We will continue to work with the FTC, the Food and Drug Administration, the Centers for Disease Control and Prevention, and Congress to be a strong voice and advocate for patient health and safety.

The Alliance was founded in 2018 to advocate for patient safety and to protect and defend the doctor-patient relationship—the essential foundation of personalized health care decision making. For more information, please visit www.PatientSafetyToday.com.