



Contact Lens Association of Ophthalmologists, Inc.®
An International Educational Association

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October 26, 2015

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Secretary of the Commission

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TREASURER
Thomas L. Steinemann, MD ('16)

Washington, D.C.

FOUNDATION REPRESENTATIVES
S. Lance Forstot, MD ('17)

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

INTERNATIONAL RELATIONS
Bruce H. Koffler, MD ('17)

Dear Mr. Clark,

PAST PRESIDENT
S. Lance Forstot, MD ('17)

Contact Lens Association of Ophthalmologists (CLAO) appreciates the opportunity to comment on "The Contact Lens Rule" 16 CFR part 315.

JOURNAL EDITOR
Penny A. Asbell, MD, MBA ('16)

"Passive verification" under §315.5(c)(3) puts the health of consumers at risk and is inconsistent with regulatory practices for confirmation of the validity and accuracy of prescriptions for drugs and for other Class II and Class III medical devices.

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Under the current rule, lack of response within 8 hours allows the seller to proceed with the sale, as below:

PARLIAMENTARIAN
Peter R. Kastl, MD, PhD, PRP

(c) *Verification events.* A prescription is verified under paragraph (a)(2) of this section only if one of the following occurs:

(3) The prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section. During these eight (8) business hours, the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request.

CLAO contends that the passive aspect creates a mechanism for renewal of expired prescriptions which is in the seller's interest, may be in a consumer's immediate interest, but is not in the interest of the consumer's long term ocular health and the public health.

Centers for Disease Control (CDC) Morbidity and Mortality Weekly Report MMWR 2015 **64(32);865-870** found that outbreaks of serious eye infections among contact lens wearers continue and that these are associated with failure to wear, clean, disinfect and store their lenses as directed. The CDC points out that the largest single risk factor for microbial keratitis is contact lens wear, and that nearly one million U.S.

The Mission of CLAO is to advance quality medical eyecare for the public by providing comprehensive ophthalmologists and other eyecare professionals with education and training in contact lenses and related eyecare science.

healthcare visits for keratitis (inflammation of the cornea) or contact lens complications occur annually, at a cost of \$175 million. The CDC advises that prevention efforts could include vigorous health promotion activities that encourage contact lens wearers to improve their hygiene behaviors, such as keeping all water away from contact lenses, discarding used disinfecting solution from the case and cleaning with fresh solution each day, and replacing their contact lens case every 3 months.

It is "standard of care" for contact lens prescribers to review wear and care practices at the time of contact lens exam, in addition to assessing ocular health and the fit and optical power of the contact lens. At the time of contact lens examination patients are counseled and educated as to best practices for ocular health.

CLAO also contends that eight hours is not sufficient time to allow for validation of prescription. Validation requests arrive with incomplete or erroneous patient information complicating the process by which clinical records are retrieved, reviewed first by office staff for validity as far as expiration date. If expired, the clinician must be contacted to determine if clinical data based on examination records allows for "renewal." We are not aware of any other clinical validation in medical, optometric, or optical practice that requires 1 day or 8 hour response.

Passive verification eliminates a critical opportunity to improve the public health of contact lens consumers by addressing risky wear and care practices. Furthermore, passive verification is inconsistent with regulatory practices related to the sale of other FDA Class II and III drugs and devices. We believe that the "passive" aspect of verification should be eliminated and that the window for "active" verification should be extended to at least 2 business days.

CLAO appreciates the opportunity to comment and is happy to provide further input to the FTC as required.

Sincerely,


Deborah S. Jacobs, MD, President
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