

October 26, 2015

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Office of the Secretary
600 Pennsylvania Avenue NW.
Suite CC-5610 (Annex B)
Washington, DC 20580

Re: Eyeglass Rule, 16 CFR part 456, Project No. R511996

The American Optometric Association (AOA) represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation's family eye doctors and a leading authority on eye health, vision care and patient safety issues. Doctors of Optometry are the independent primary health care professionals for the eye. Doctors of optometry examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye.

As part of their patient care and treatment of visual disorders, doctors of optometry prescribe eyeglasses for their patients and take professional pride in furnishing eyeglasses to patients in need of vision correction. This craftsmanship is appreciated by patients, who view independent eye care providers (primarily doctors of optometry) as experts with the highest credentials who provide the most advanced care and the highest quality materials.¹ Ophthalmologists also provide eyeglasses to patients as part of their services to patients, who may pay out of pocket or have some health or vision insurance that covers the bulk of the cost of eyeglasses. Medicare covers eyeglasses for beneficiaries immediately following cataract surgery; in 2013, doctors of optometry provided this necessary eyewear to more than 70,000 patients while ophthalmologists provided this eyewear to more than 155,000 patients. These doctors work to ensure post-surgery patients receive the most appropriate eyewear needed to meet their vision needs. While doctors of optometry delight in solving eye and vision issues for patients, including those who need prescription eyeglasses, we also respect the right of patients to obtain prescription eyewear through other sources.

The market for eyeglasses has changed considerably since the Federal Trade Commission (FTC) first issued the Eyeglass Rule in 1978 (16 CFR 456) to allow consumers to better comparison shop for prescription eyeglasses. In the last decade, the market expanded with the rise of Internet sellers of eyeglasses. The Internet also allowed consumers to obtain more information about prices and styles and features. As a result, the Internet, like the Eyeglass Rule, has facilitated

¹ Petito, Olivares, Schnider and Alford, "Study of Market Segmentation in Vision Care: How Consumers Make Choices in Vision Care Purchases," *Journal of the American Optometric Association*, Vol. 83, No. 6 (June 2012).

more comparison shopping for eyeglasses. The AOA believes the ability of new sellers to establish new channels demonstrates the vitality of the market. However, the AOA remains concerned that anticompetitive practices could undermine key components of the market for eyeglasses. An AOA study published in 2011 found 44.8% of eyeglasses purchased online had incorrect prescriptions or safety issues.² Patients may choose lower quality eyewear but competition should not facilitate the sale of illegal or relatively dangerous devices to the unsuspecting public.

The AOA seeks to lower barriers to access eyeglasses for patients who need vision correction. For example, the AOA advocates for patients to get comprehensive eye examinations to most efficiently determine the need and options for vision correction. Vision screening alone does not result in a prescription for eyeglasses. Eye tests administered to oneself or online do not include all components of a comprehensive eye examination and may miss important health risks for a patient. States typically determine the components of a prescription for eyeglasses, as well as the necessary credentials for prescribers. The AOA supported eye exams and eyeglasses for children as essential benefits for health plans under the Affordable Care Act. Coverage for exams and glasses, along with the option to use a flexible spending account to pay for glasses, reduces the burden of the cost of prescription eyewear. The FTC can improve competition in the market for eyeglasses, to the benefit of consumers, by ensuring that consumers continue to have the option to get high quality products and services from doctors of optometry. The FTC should take action against sellers who use unfair or deceptive tactics, such as providing substandard materials or products that do not meet federal standards.

The AOA appreciates the opportunity to comment on the Ophthalmic Practice Rules (Eyeglass Rule). Responses to the Federal Trade Commission's questions in the Advance Notice of Proposed Rulemaking (80 Fed. Reg. 53274 (Sept. 3, 2015)) are included below.

Is there a continuing need for the Rule? Why or why not?

The FTC has previously considered whether to retain the Rule. In 1989, the FTC decided to retain the Rule to address perceived non-compliance with the rule and a continued lack of patients' awareness about their ability to obtain their prescription and purchase eyeglasses from a range of retailers. In 2004, the Commission again confirmed its decision to retain the rule due to concerns with non-compliance. The AOA does not believe compliance with the prescription release rule remains an issue. In addition, patients are well informed of their ability to obtain their eyeglass prescription from doctors of optometry and other physicians. Patients also have a greater expectation to receive their health information from their doctors due to rights provided under the Health Insurance Portability and Accountability Act (HIPAA). It is our understanding that doctors of optometry widely comply with the Rule. Given that the requirements outlined in the Rule are now standard practice, it is questionable as to whether the Rule serves a continued benefit to patients. However, as written, the rule is not necessarily harmful. The AOA would be concerned about any proposal to change the Eyeglass Rule that would undermine competition, including competition for patient safety in the marketplace.

² <http://www.aoa.org/newsroom/let-the-buyer-beware-a-closer-look-at-ordering-eyeglasses-online>

What modifications, if any, should be made to the Rule to increase its benefits to consumers? (a) What evidence supports the proposed modifications? (b) How would these modifications affect the costs the Rule imposes on businesses, including small businesses? (c) How would these modifications affect the benefits to consumers?

If the FTC decides to retain the Eyeglass Rule, then the AOA recommends keeping the Rule mostly intact to best serve competition. One section of the rule that AOA recommends updating is the section of definitions. The current regulation defines a prescription as derived from an eye examination, and defines an eye examination primarily as the determination of the refractive condition. While the need for eye and vision care, including treatment (such as prescription eyeglasses) for vision correction is determined during a comprehensive eye exam, the patient's actual prescription is usually obtained by a determination of the refractive state, which is an additional service above and beyond the eye examination. The definition of an eye examination in the Rule is actually more similar to the definition of a refraction. Furthermore, the definition of "ophthalmic services" in the Rule is more closely aligned to "fitting" eyeglasses. Thus, in 16 CFR 456.1, the AOA believes the Rule should be modified to increase its accuracy, for the benefits of patients, by correcting the terminology. The definition in 456.1(b) is the definition of a "refraction" not a definition of an "eye examination." An eye exam is an evaluation of the complete visual system and includes many components that are not used to determine the refractive condition. The FTC may want to review the Current Procedural Terminology (CPT) definitions of "general ophthalmological services" (which includes eye examinations, not fitting eyeglasses) and "special ophthalmological services" (which includes determination of refractive state). The AOA does not suggest using the CPT definitions verbatim but does urge the FTC to consider revising the definitions in the regulations so that they do not directly conflict with the CPT. The CPT definitions are used as a uniform language of health care transactions, not necessarily as a glossary of terms for the public. As discussed in more detail in other sections of this letter, the AOA recommends the FTC otherwise defer to state law to determine the content of a prescription.

What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?

The AOA is concerned that there is significant misunderstanding with regard to what the Rule actually requires and how the Rule defines an eyeglass prescription. For example, during the 2004 review of the Rule, the FTC decided not to set expiration dates for eyeglass prescriptions. The AOA agrees with the analysis of the Commission a decade ago:

The Commission declines to initiate a proceeding seeking to amend the Rules to set expiration dates for eyeglass prescriptions. As explained above, the purpose of the Rules is to prohibit acts and practices that deter consumers from comparison shopping for eyeglasses. There is no evidence in the record that eye care practitioners are using expiration dates as a means of impeding the ability of consumers to purchase eyeglasses from other sellers or otherwise causing consumer injury. In the absence of such evidence, the Commission has decided not to consider setting expiration dates for eyeglass prescriptions.

The AOA continues to believe eye care practitioners do not use expiration dates to impede the ability of their patients to purchase glasses from other retailers. Doctors of optometry and ophthalmologists follow a code of ethics and resolve to keep their patients' eye, vision, and general health paramount at all times.

In the public comments received during the current review of the Rule, however, the AOA is concerned that some patients have been misled to believe the Rule set a specific expiration date on eyeglass prescriptions. Efforts to encourage patients to submit public comments on the Rule review, based on misinformation, disrespect the rulemaking process. It appears consumers are using a template comment letter to downplay the importance of regular eye exams based on an erroneous assumption that prescriptions remain stable indefinitely. To the contrary, patients often go to an eye doctor precisely because they have noticed a change in vision. A recent survey of consumers found among those who had an eye exam in the last year, 94% indicated that their prescription had changed since their last visit.³ The AOA questions the practice of selling eyeglasses based on older prescriptions. Some states do establish expiration dates for eyeglasses prescriptions, however. The AOA recommends that the FTC defer to state law and the medical judgment of optometrists and ophthalmologists to determine if and when a prescription expires.

Additionally, there seems to be some confusion regarding what information the Rule actually requires to be included in an eyeglasses prescription. According to the Rule, a prescription is defined as, “the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.” During an eye examination, it is not standard practice for a physician to obtain pupillary distance (PD) measurement. Obtaining a patient’s PD measurement is most frequently conducted by opticians or individuals trained in the fitting of eyeglasses. While the Rule does not specifically contain a requirement for physicians to include PD on an eyeglass prescription, some falsely assert that physicians are withholding complete prescription information by not including PD on eyeglass prescriptions. This mischaracterizes the requirements of the Rule and the work of physician prescribers and health care professionals who facilitate the purchase of prescription eyeglasses.

What significant costs, if any, has the Rule imposed on consumers? What evidence supports the asserted costs?

Over the past several years new eyeglass retailers have emerged giving patients more options in selecting an eyeglass retailer. While the AOA believes this increased competition is a benefit to patients, it is imperative that patients are receiving eyeglasses that appropriately address their eye health needs, regardless of where the eyeglasses are purchased. Purchasing eyeglasses that are not appropriately fit for a patient or have an inaccurate prescription has both a financial cost and a cost to the patient’s overall eye health and wellbeing. An AOA study published in the Journal of the American Optometric Association in 2011 with the Optical Laboratories Association and

³ APCO Insight August 2015 telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc.

The Vision Council pointed to certain deficiencies with glasses purchased online.⁴ The study found that out of 200 glasses ordered online, only 154 pairs were received; 44.8 percent had incorrect prescriptions or safety issues; 29 percent had at least one lens fail to meet required the prescription; 19 percent of adult lenses failed impact resistance testing; and 25 percent of children's lenses failed impact resistance testing. These findings are concerning as patients may be receiving glasses that are not of true value to them. Additionally, the AOA is concerned that many online companies use foreign countries, such as China, to produce unsafe products that are not appropriate for the patient's needs. The AOA is also concerned that some retailers may be using foreign manufacturers with questionable labor standards.

The AOA believes taking shortcuts imposes a significant cost on consumers. To enhance a robust marketplace, it is critical that the patient's eye health and safety are a central focus of competition.

What modifications, if any, should be made to the Rule to reduce the costs imposed on businesses, including small businesses? (a) What evidence supports the proposed modifications? (b) How would these modifications affect the benefits provided by the Rule?

Doctors of optometry and their staff members often provide care to patients who have experienced problems or discomfort from glasses purchased from other retailers. This often includes ensuring that the prescription in the glasses is appropriate, readjusting frames for appropriate fit and sometimes remaking glasses entirely. Patients and small businesses of doctors of optometry often absorb these added costs that resulted from careless work by other retailers. The AOA is also concerned that many patients are being misled to believe the product that they are buying online is exactly what is needed, when the reality may be that the poor accuracy and fit of the glasses might not actually address the patient's vision correction needs.

Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how? (a) What evidence supports the asserted conflicts? (b) With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not?

The AOA urges the Commission to defer to state law to define the components of a prescription, including (or not) an expiration date or measure of pupillary distance (as discussed elsewhere in this comment letter).

Should the definition of "prescription" be modified to include pupillary distance? Why or why not? (a) What evidence supports such a modification? (b) How would this modification affect the costs the Rule imposes on businesses, including small businesses? (c) How would this modification affect the benefits to consumers?

The AOA believes it is unnecessary to modify the definition of "prescription" to include pupillary distance. The regulations currently indicate that a prescription is "the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses."

⁴ Citek et al, "Safety and compliance of prescription spectacles ordered by the public via the Internet," *Journal of the American Optometric Association*, Volume 82, No. 9 (September 2011).

While several states specify that PD must be included in an eyeglass prescription, most do not. The person fitting the eyeglasses for the patient is in the best position to determine whatever measurements are needed for optimal results, and takes pride in this service. We are under the impression that some online retailers depend on their ability to use computer algorithms and other approaches to fit eyeglasses for a patient. The AOA believes that the Commission should continue to defer to the states and the market on this issue.

Should the Rule be extended to require that prescribers provide a duplicate copy of a prescription to a patient who does not currently have access to the original? Why or why not? (a) What evidence supports such a modification? (b) How would this modification affect the costs the Rule imposes on businesses, including small businesses? (c) How would this modification affect the benefits to consumers?

The AOA believes mandating duplicate copies of prescriptions be provided to patients is unwise. Federal regulation does not require doctors provide multiple copies of pharmaceutical prescriptions to patients, and some physicians require patients to pay for additional copies of their pharmaceutical prescriptions. In an effort to provide the best and courteous care to their patients, it is already common practice for doctors of optometry to provide duplicate copies of eyeglass prescriptions when requested. However, the AOA objects to mandating such a requirement. Doctors of optometry and ophthalmologists must be allowed to use their clinical judgment to determine whether it's appropriate to provide additional copies of prescriptions long after the refraction was performed. For example, a doctor of optometry might have performed a comprehensive eye examination of the patient more recently and be aware that the previous prescription is no longer appropriate. A doctor of optometry might be aware of other health changes for the patient that could necessitate a different prescription. In some cases, the doctor of optometry might not have any information about the patient's current eye and vision needs. Thus, while we believe most doctors of optometry provide additional copies of an eyeglass prescription upon request of the patient, we do not believe that the doctor's professional judgment should be overruled by FTC regulation.

Should the Rule be extended to require that a prescriber provide a copy to or verify a prescription with third parties authorized by the patient? Why or why not? (a) What evidence supports such a modification? (b) How would this modification affect the costs the Rule imposes on businesses, including small businesses? (c) How would this modification affect the benefits to consumers?

The AOA strongly opposes using the Contact Lens Rule and the verification process outlined in the Fairness to Contact Lens Consumers Act (FCLCA) as a model for the eyeglass market. Similar to the Eyeglass Rule, the Contact Lens Rule is currently undergoing a ten year review. The AOA believes the Contact Lens Rule review will yield valuable information regarding the problems and weaknesses in the contact lens sale verification process. Until the verification system used for contact lenses is improved it would be ill advised to use that process as a model. Additionally, the Contact Lens Rule is rooted in legislation passed by Congress. There is no parallel with regard to eyeglasses. The Commission might not have legal authority to establish a comparable third party verification system for eyeglasses prescriptions without legislative authority such as that provided to the FTC under the FCLCA.

The AOA stands ready to assist the FTC in working towards the best and safest eyeglass market for patients. We appreciate the opportunity to comment on this review of the Eyeglass Rule. If you have questions or need additional information, please contact Rodney Peele, Associate General Counsel for Public Policy, at rpeele@aoa.org

Sincerely,



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