

September 14, 2015

FTC COMMENTS ON CLCA, 15 USC 7601-7610

As you know in 2003, Congress enacted The Fairness to Contact Lens Consumers Act, 15 U.S.C. 7601–7610, and pursuant to the Act, the Commission promulgated the Contact Lens Rule on July 2, 2004.¹ The Rule went into effect on August 2, 2004. As you know the Contact Lens Rule was intended to facilitate the ability of consumers to comparison shop for contact lenses while ensuring that contact lenses are sold only in accordance with a valid prescription. . . . this has not occurred in my personal experiences several times. An Rx is often ignored or the vendor does not wait for verification of the Rx.

My comments are based on the following factual information that I believe to be correct:

1 The Rule requires that eye care prescribers provide a copy of a prescription to the consumer upon completion of a contact lens fitting and verify or provide prescriptions to authorized third parties.

2 The Rule specifies that a prescriber may not require the purchase of contact lenses as a condition of providing the prescription or verification, may not require payment in addition to, or as a part of, the fee for an eye examination, fitting, and evaluation as a condition of providing the prescription or verification, and may not require the patient to sign a waiver or release as a condition of releasing or verifying the prescription.

3 The prescriber is also prohibited from requiring immediate payment before the release of a prescription, unless the prescriber requires immediate payment when an exam reveals that the consumer does not need ophthalmic goods.

4 The Rule also places certain restrictions on sellers. It mandates that sellers sell contact lenses only in accordance with a prescription that is either presented to the seller or verified by direct communication with the prescriber.

5 The Rule sets out the information that must be included in a seller's verification request, and directs that a prescription is only verified under the Rule if: (1) A prescriber confirms the prescription is accurate, (2) a prescriber informs the seller that the prescription is inaccurate and

provides an accurate prescription, or (3) if the prescriber fails to communicate with the seller within eight business hours after receiving a compliant verification request.

6 The Rule states that if the prescriber informs the seller within eight hours of receiving the verification request that the prescription is inaccurate, expired, or invalid, the seller shall not fill the prescription.

7 Sellers may not alter a prescription, but for private label contact lenses, may substitute identical contact lenses that the same company manufactures and sells under a different name.

8 Sellers and others involved in the manufacture, assembly, processing and distribution of contact lenses are prohibited from representing that contact lenses may be obtained without a prescription.

9 The Contact Lens Rule sets a minimum expiration date of one year after the issue date of a prescription with an exception based on a patient's ocular health.

10 The Rule also implements the Act by providing that “state and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are pre-empted.”

Issue for Comment

Per your request I, a practicing Optometrist for 24 years, am providing written comments on the following questions. My comments are in **RED**.

1. Is there a continuing need for the Rule? Why or why not? **IF INDIVIDUAL STATE OPTOMETRY AND MEDICAL BOARDS DO NOT ADDRESS THIS ISSUE THEN THE RULE IS NEEDED BUT IF SO THE RULE IS REDUNDANT AND TAKES AWAY INDIVIDUAL STATES RIGHTS.**

2. What benefits has the Rule provided to consumers? What evidence supports the asserted benefits? **IT PROVIDES CONSUMERS A CHOICE, A FREEDOM GRANTED AS A US CITIZEN.**

3. What modifications, if any, should be made to the Rule to increase its benefits to consumers? **IN MANY CASES THE RULE IS SOMEWHAT OF A JOKE. VENDORS OFTEN SEND FAXES TO MY CLINIC IN THE MIDDLE OF THE NIGHT, EXPECTING AN IMMEDIATE RESPONSE. IF ONE IS NOT PROVIDED THEN THE RX IS FILLED..... RIGHT OR WRONG. I HAVE CLINIC EVIDENCE OF HARM CAUSED TO THE AMERICAN PUBLIC BECAUSE OF THIS.....SOME BEING LOSS OF VISION.**

a. What evidence supports the proposed modifications? **SEE ABOVE**

b. How would these modifications affect the costs the Rule imposes on businesses, including small businesses? **THIS IS COSTLY TO MY BUSINESS. THE PATIENT SHOULD HAVE A WRITTEN COPY OF THEIR RX TO PROVIDE TO THE VENDOR OF THEIR CHOICE.**

c. How would these modifications affect the benefits to consumers? **PREVENT PERMANENT VISION LOSS.**

4. What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers? **THE RULE IS A MIXED BAG IN MY OPINION. CONSUMERS FEEL THAT LENSES ARE NOT A MEDICAL DEVICE AND ANY "GENERIC" BRAND CAN BE SUBSTITUTED OBVIOUSLY THIS IS NOT THE CASE AND I HAVE EVIDENCE OF PERMANENT VISION LOSS BECAUSE OF THIS.**

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

6. What modifications, if any, should be made to the Rule to reduce any costs imposed on consumers? **THE RX SHOULD BE FILLED AS WRITTEN AND THE PROVIDER SHOULD BE GIVEN AMPLE TIME TO RESPOND TO AN RX REQUEST FROM A VENDOR TO PROTECT THE RIGHT TO CHOOSE AND A PATIENTS EYE HEALTH. NO CONTACT LENSE SHOULD BE SUBSTITUTED AND NO RX SHOULD BE CHANGED BY A VENDOR WHO DOES NOT KNOW A PATIENTS EYE AND MEDICAL CONDITIONS TO PREVENT VISION LOSS IN A PATIENT OR THE AFFECTS ON SOCIETY (E.G. COST FOR DISABILITY, COST FOR ACCIDENTS BECAUSE THE PATIENT COULD NOT SEE CORRECTLY, ETC).**

a. What evidence supports the proposed modifications? b. How would these modifications affect the benefits provided by the Rule? **CLINICAL DATA AND OFFICE EXPERIENCES**

7. What benefits, if any, has the Rule provided to businesses, including small businesses? What evidence supports the asserted benefits? **PROVIDES CHOICE**

8. What modifications, if any, should be made to the Rule to increase its benefits to businesses, including small businesses?

INCLUDE A PROVISION IN THE LANGUAGE TO ELIMINATE LIABILITY TO THE RX PROVIDER IF AN RX IS CHANGED IN ANY WAY BY THE VENDOR OR CONSUMER. THIS WOULD REDUCE MALPRACE COSTS.

THE MAJORITY OF PATIENTS IN OUR CLINIC WHO WANT THEIR RX HAVE BEEN INFORMED BY US BEFORE HAND OF SUCH AND THAT THEY NEED EYECARE BUT CHOSE TO CONTACT ANOTHER VENDOR TO BYPASS THE NEED FOR EYECARE. OFTEN THE RX IS FILLED AND IT WAS EXPIRED. VENDORS VIOLATE THE EXPIRATION DATE AND ARE NOT HELD RESPONSIBLE FOR THIS.

a. What evidence supports the proposed modifications? **PERSONAL**

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?

9. What significant costs, if any, including costs of compliance, has the Rule imposed on businesses, including small businesses? **OUR CLINIC IS BURDEONED BY VENDORS REQUESTING AN RX AT ALL TIMES OF THE DAY, RUDE ENDORS, THREATENING VENDORS AND EXTRA TIME IT TAKES TO PROVIDE AN RX THAT THE PATIENTS ALREADY HAS.** What evidence supports the asserted costs? **CLINICAL AND OFFICE DATA.**

10. What modifications, if any, should be made to the Rule to reduce the costs imposed on businesses, including small businesses? **TURN THE ISSUES OVER TO INDIVUAL STATES BOARDS AND MAKE THE CONSUMER A PARTNER BY TAKING RESPONSIBILITY TO PROVIDE THE WRITTEN RX TO THEIR VENDOR OF CHOICE.**

a. What evidence supports the proposed modifications? **PERSONAL EXPERIENCES**

b. How would these modifications affect the benefits provided by the Rule? **DECREASE COST TO RX WRITERS**

11. What evidence is available concerning the degree of industry compliance with the Rule? **SEE NUMBER 6.**

12. What modifications, if any, should be made to the Rule to account for changes in relevant technology or economic conditions? **AS NEW TECHNOLOGY INCREASES THE NEED TO COMPLY IS EVEN MORE IMPORTANT. SOME PRODUCTS DO NOT MATCH SOME EYES!** What evidence supports the proposed modifications? **CLINICAL DATA**

13. Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how? **INTERFERENCE WITH INDIVIDUAL STATES RIGHTS.....STATE MEDICAL AND OPTOMETRY BOARDS.**

a. What evidence supports the asserted conflicts? **PERSONAL EXPERIENCES**

b. With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not? **PROTECT STATES RIGHTS**