July 29, 2019

Federal Trade Commission
Office of the Secretary
Constitution Center
400 7th Street SW, 5th Floor, Suite CC-5610 (Annex F)
Washington, DC 20024

Comments of Consumer Reports
Contact Lens Rule Review
Supplemental Notice of Proposed Rulemaking
16 CFR Part 315, Project No. R511995

Consumer Reports[1] has supported, over many years, efforts to ensure that consumers can exercise effective choice in where they can purchase their contact lenses. Choice allows consumers to benefit from competition among sellers in providing better prices and more convenience. And contact lenses are different from other prescribed health care products, in that the prescribing doctor is permitted to also sell the product. At the same time, we have supported keeping health and safety of consumers who wear contact lenses a top priority.

Accordingly, we have supported the Fairness to Contact Lens Consumers Act of 2004, the Commission's Contact Lens Rule implementing the 2004 Act, and the efforts to ensure that the Rule is properly interpreted and effectively enforced. We have also been actively engaged in the Commission's review of the Rule to ensure it is functioning effectively. We filed comments in the September 2015 Periodic Review,[2] in the December 2016 Notice of Proposed Rulemaking,[3] and following the March 2018 workshop.[4] We appreciate the Commission's careful consideration of our views and recommendations, as reflected in this Supplementary Notice.

As we have stated, we believe the Contact Lens Rule is significantly benefiting consumers, by enabling them to comparison shop for contact lenses, for lower cost and greater convenience for a health necessity that can be a significant family budget expense. Our goal has been to ensure that the Rule is functioning effectively, so as to fulfill its purpose reliably and efficiently, while

[1] Our previous comments were filed under the name Consumers Union, our organization's founding name, and the name used until recently for our policy advocacy work. Since October 2018, we have used the name Consumer Reports for all our work, including policy advocacy.
[2] https://advocacy.consumerreports.org/wp-content/uploads/2015/10/ContactLensRuleFTCComments.pdf.
[3] https://advocacy.consumerreports.org/wp-content/uploads/2017/02/FTC-Contact-Lens-Rule-CU-comments-1-30-17-FINAL.pdf
[4] https://advocacy.consumerreports.org/wp-content/uploads/2018/04/FTC-Contact-Lens-Rule-CU-comments-4-6-18-FINAL.pdf.

minimizing unnecessary burden, delay, or confusion for eye doctors, contact lens sellers, and consumers, and while ensuring that consumer health and safety are not compromised.

As set forth in the Supplemental Notice, the Commission now proposes to amend the Contact Lens Rule:

1. to permit the contact lens prescriber – with the consent of the patient – to give the patient a copy of the prescription in electronic form, instead of paper form;

2. to require the prescriber to obtain confirmation from the patient that the patient has received the copy of the prescription, but to allow the prescriber to determine how the confirmation is worded, presented, and recorded;

3. to exempt prescribers with no financial interest in the sale of contact lenses from the requirement to obtain and keep records of patient confirmation of prescription receipt;

4. to require that, when the patient, or someone acting on the patient's behalf, requests an additional copy of the prescription, the prescriber must provide it within 40 business hours of the request;

5. to clarify that the contact lens seller may verify the prescription through using an automated call to the prescribing eye doctor, and to establish standards to ensure that the automated call clearly provides the necessary information;

6. to require the seller to provide a clear and prominent method for the patient or prescribing eye doctor to present the seller with a copy of the patient's prescription;

7. to clarify that the prohibition against a seller altering a prescription includes prohibiting the seller from providing the subscriber, in a verification request, with the name of any lens manufacturer or brand other than the one specified on the patient's prescription, unless it is the name that the patient actually provided to the seller.

Our comments on these proposed amendments are set forth below.

1. **<u>Providing the prescription in electronic form</u>.**

As explained in our earlier comments, providing a paper copy does not create any burden, and is a very effective way of ensuring that the patient has actually received the prescription at the end of the contact lens fitting, while still in the eye doctor's office. And for purposes of the confirmation of receipt requirement, it is easier for a patient to *confirm* actually having received the prescription if it is physically in hand. To do the same with a digital copy, the patient would need to access the email or portal while in the office, and confirm that the prescription has been received. Furthermore, not all patients have access to, and are comfortable relying on, the Internet for handling and keeping track of important medical documents.

At the same time, we recognize that for some patients, an electronic copy could be easier to handle and keep track of, which could reduce the need to ask the eye doctor for an additional copy later. The best solution is to provide it both ways. There would be no burden in doing so, and

there would be considerable potential benefit. The electronic copy should therefore be a supplement to, and not a substitute for, providing a paper copy at the end of the fitting. The electronic copy should, as the Supplemental Notice proposes, be transmitted in a way that the patient can have easy access to it again later, and can easily forward it to a seller. (If the Commission ultimately decides to allow the electronic copy to be a substitute, the prescriber should be required, as discussed below, to confirm with the patient in writing, or electronically in a manner substantially as reliable as written confirmation, at the end of the fitting, that the prescription *has been received* by, and is accessible to, the patient.)

2. **Flexibility in new required patient confirmation of receiving the prescription.**

In previous comments, we supported the specific wording and format proposed by the Commission, with modifications. We continue to do so. It is not at all burdensome, and keeping the confirmation separate from any other document is the most effective way to ensure that the patient is aware of making the confirmation. In contrast, a statement added to the doctor's copy of the prescription, or added to the doctor's copy of the examination receipt, may not even be noticed by the patient; and unspecified "evidence" that the prescription was provided electronically does not require that the patient even be aware of whether or not the prescription was provided.

We therefore recommend that the Commission stick with its earlier proposal to require standardized wording, on a separate document that contains nothing else but the date and the patient's name, and the doctor's letterhead and address. In light of comments received and described in the Supplemental Notice, we would recommend revising the statement the Commission proposed in its December 2016 Notice, to read as follows:

> "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I should give a copy of my prescription to the contact lens seller I choose."

This statement, presented in this format, efficiently and reliably documents prescriber compliance with the core requirement of the Rule, and simply and clearly communicates to patients their ability to choose where to purchase, without steering patients away from their own eye doctor as one potential choice, and without insinuating in any way that the eye doctor is doing anything inappropriate. There are clear advantages to standardized wording, and no apparent advantage in allowing variation.

The revised wording we recommend has the additional benefit of furthering the purpose of another change the Commission is proposing, discussed below, to encourage the seller to seek the prescription itself rather than to contact the prescribing eye doctor to verify the prescription.

The paper form of confirmation is very clear and effective. The patient will see it and physically sign it; and with nothing else added, it will be virtually impossible for a patient to avoid reading the two short sentences. In contrast, depending on how a "confirmation" is presented on a computer screen, the significance of the signature could very well be less clear to the patient, perhaps even obscured in a nondescript "I have read and agree" box of the sort becoming all-too common in digital consumer contracts. If the goal of allowing a digital alternative is simply more convenient storage for the prescribing eye doctor, the signed paper confirmation can easily be scanned later into digital form.

There may be a way to devise a digital version of the confirmation statement that would be similarly clear to the patient, and similarly reliable for purposes of confirming compliance. That should be the standard for any digital version to take the place of the paper confirmation that the Commission proposed in its December 2016 Notice.

3. **Exemption for providers with no financial interest in sale of contact lenses.**

The proposed exemption for prescribing eye doctors who have no direct or indirect financial interest in the sale of contact lenses makes sense. Although getting and keeping a record of the patient confirmation will not pose any significant burden, by definition these prescribers would seem not to pose any risk of conflict of interest in releasing the prescription; indeed, they would have an inherent interest in releasing it. And for that reason, they would not be expected to be an important subject of any compliance investigation or enforcement action.

4. **Providing an additional copy of the prescription within 48 hours of request.**

We support this proposed strengthening of the requirement that a prescriber provide an additional copy of the prescription upon request, by requiring that it be provided within a specific time after the request. It should be made clear that this is in addition to, and not in lieu of, the requirement that the patient be given the initial copy at the time of the fitting.

But the period of time the Commission is proposing, 40 business hours after the request, is far longer than it should be. For most eye doctors, that translates into a full week, or potentially longer. One important purpose of providing the additional copy is to avoid the seller needing to call the eye doctor to verify the prescription; this avoids the attendant difficulties, burdens, and risks described in the Supplemental Notice.

We would therefore recommend a prompter period, closer to the period for responding to a request for verification – which is, essentially, one business day. Requiring this prompter response would not seem to create any significant burden on eye doctors, since the same amount of work is required to retrieve the prescription and send a copy as to retrieve it and tell the seller what the prescription is. And it would avoid undercutting the desired incentives to opt for using the prescription itself instead of a verification.

We would hope that the other proposed changes proposed in the Supplemental Notice, and those recommended in our comments, would increase the likelihood that the patient would have the original copy of the prescription on hand and not need to request another one. But the burden of sending a prescription is not greater for a prescribing eye doctor than locating the prescription to confirm or correct it in a communication with the seller.

5. **Standards for automated seller calls to verify the prescription.**

We agree that when the seller uses an automated call to verify a prescription, the call should be clear – the message delivered in a "slow and deliberate manner" and at a "reasonably understandable volume," as those terms are defined in the Supplemental Notice. We also agree with the other requirements proposed in the new section 315.5(d) – with the exception of the requirement in (d)(1) that the seller "record the entire call." Assuming that this means that a complete recording of every call made to every prescribing eye doctor must be retained, that seems unnecessarily burdensome. While perhaps superficially analogous to the requirement that an eye doctor keep a record of each patient's confirmation of prescription receipt, the numbers are

likely to be on a far greater order of magnitude. Further, we are not aware of indications of noncompliance similar to those for prescription release.

More reasonable would be requiring a seller who uses automated calls for verifying prescriptions to retain a sample recording of the standard script used, leaving blank the spaces for patient name and prescription details.

6. **Clarifying requirement that the seller accept presentation of a prescription, by requiring the seller to provide a clear and prominent method for presenting it.**

We agree that clarifying this requirement in this manner would help reduce the incidence of seller verification calls to eye doctors, thereby reducing the attendant difficulties, burdens, and risks. Nothing is more reliable than for the seller to have an actual, dated copy of the prescription.

The Supplemental Notice proposes to make a number of changes to encourage and facilitate the availability of the prescription, by better ensuring that a copy is provided at the end of the contact lens fitting, and by requiring the prescribing eye doctor to provide an additional copy promptly upon request.

Here, the Commission proposes to require the seller to "accept" a copy of the prescription from the patient or prescribing eye doctor in lieu of verification, and to "provide a clear and prominent method for the patient and prescriber to present" it. We support this proposal. And we would go further, and require the seller to request that the patient provide the prescription, and to actively encourage it. We would also recommend, as stated earlier, that the wording on the patient confirmation of receipt specifically say that the patient "should give a copy of my prescription" to the seller. These are reasonable, and likely very effective, steps to reduce the incidence of seller verification calls.

The proposed change to 315.5(g) lists alternative ways that a seller could offer for the patient or prescriber to provide the copy of the prescription, listing electronic mail, text message, file upload, or facsimile – "without limitation." We believe it would be reasonable to require a seller to offer all four of those alternatives, without limitation. None of them would present any burden to the seller, and there may be important reasons that a particular patient or eye doctor prefers one option over others. We therefore recommend changing "may include" to "shall include."

7. **Clarifying prohibition against a seller altering a prescription.**

We support the patient safety purposes of clarifying the prohibition against a seller altering a prescription. As explained, the lack of clarity on this point makes it possible for an unscrupulous seller to name its own favored lens in the verification request to the prescribing eye doctor, in hopes that the eye doctor will not reply in time to avoid triggering "passive verification" and thus authorizing the seller to sell the wrong lens. Closing off this pathway is necessary as a matter of consumer safety.

We recommend some further clarifying revisions to the proposed language. Specifically:

- The prohibition excuses the seller if the seller is simply relaying to the prescriber the name of the manufacturer or brand of lens that was provided to the seller by the patient. It should be made unmistakably clear that this means the seller must have had no reason to

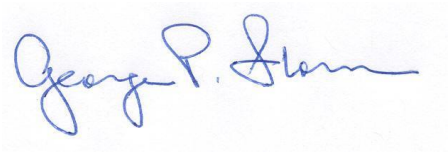
believe that the name provided was incorrect – for example, that the seller did not somehow induce the patient to provide an incorrect name, or "mishear" the patient.

We would therefore recommend adding the words ", and the seller had no reason to believe that the name so entered or orally given was not so specified" at the end of the sentence in the new 3155.5(f) beginning "In the context of".

- For clarification, we would recommend revising the sentence in the new 315.5(f) beginning "Notwithstanding" to read "preceding two sentences" instead of "preceding sentences".

We appreciate the Commission's conscientiousness in considering, and re-considering, proposed changes and clarifications to the Contact Lens Rule. We look forward to a final rule that makes the proposed improvements, incorporating our further recommendations, reaffirming the Contact Lens Rule, and improving its functioning.

Respectfully submitted,



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