



January 30, 2017

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

**Comments of Consumers Union
Contact Lens Rule
Notice of Proposed Rulemaking
16 CFR Part 315, Project No. R511995**

Consumers Union, the policy and mobilization arm of Consumer Reports, appreciates the opportunity to comment on the Commission's proposed revisions to the Contact Lens Rule, as set forth in the above-referenced matter. We strongly supported the Fairness to Contact Lens Consumers Act of 2003. We believe that Act, and the Contact Lens Rule implementing it, have significantly benefitted consumers by enabling them to comparison shop for their contact lenses, for lower cost and greater convenience for a necessity that can be a significant family budget expense.

Previously, consumers often had difficulty obtaining a copy of their prescription from their eye doctor, which effectively meant they had no choice but to obtain their lenses from their eye doctor, or from their eye doctor's designated supplier. Under the Act and the Rule, consumers have the right to obtain a written copy of their prescription, at no additional cost, and the right for a retailer to be able to verify the prescription within 8 business hours. The Act and the Rule prevent eye doctors from tying the medical service to the product sale, thus enabling effective competition and meaningful consumer choice.

We appreciate the Commission's careful consideration, reflected in the Notice, of the comments we and others submitted in the September 2015 Periodic Review. After reviewing those comments and the Notice, we continue to believe that the Act and the Rule are fundamentally sound and beneficial to competition and consumers. As explained further below, we believe the Commission's proposed revisions are an appropriately measured approach, based on the comments and evidence submitted, that would further improve the functioning of the Rule and promote reduction of unnecessary burdens for eye doctors, retailers, and consumers. We urge you to adopt the proposed revisions.

In response to your request for further comment on certain issues, we recommend a few additional refinements and clarifications for your consideration. We also give our thoughts on several recommendations by others that the Commission has chosen not to incorporate into further changes to the Rule, but encourages retailers and eye doctors to consider adopting voluntarily.

Many of the comments submitted in the Periodic Review, and much of the discussion in the Notice, relates to the process set forth for a retailer to verify the accuracy of a prescription. In assessing these comments, we are mindful that the verification process is intended to be a back-up, failsafe means for a retailer to ascertain the accuracy of a prescription that has been described to the retailer by the consumer, in the absence of having an actual copy of the prescription. Therefore, achieving an efficient verification process that minimizes and fairly allocates the burdens involved is made easier if the number of prescriptions requiring verification is reduced.

Acknowledgement form for receipt of prescription

We believe the Commission's principal proposed change, to require eye doctors to have each patient sign a written form acknowledging receipt of a copy of the prescription, should significantly reduce the number of prescriptions that require verification. It is a constructive step that should make a significant difference in helping ensure that patients are receiving the prescription, and that they understand that having the prescription enables them to choose where to purchase their contact lenses. We believe the language specified for the form simply and clearly documents the receipt and communicates to patients their ability to choose where to purchase, without steering patients away from their own eye doctor as one potential choice.

In our view, the Commission has sufficient reliable evidence that a significant number of eye doctors appear to be failing to provide the prescription in accordance with the Rule, or failing to inform the patient of the choice of seller that having the prescription enables, so as to warrant making this change. The burden of having copies of the one-page form available in the eye doctor's office, having each patient sign a copy of the form when receiving the prescription, and keeping that copy in a file for three years, is minimal and entirely manageable, and will enable more effective enforcement of the rule while also making it easier for eye doctors to show compliance.

The other proposed specifications of what should be on the form, and the requirement that nothing else be added, appropriately eliminate uncertainty and keep the form from being crowded with unnecessary words that could increase the likelihood that some patients might not read the important words that are the reason for requiring the form.

We recommend the Commission consider adding one sentence to the statement, to help encourage the patient to give an actual copy of the prescription to the retailer. The more patients

do this, the less need there will be for retailers to verify prescriptions with eye doctors. The statement might be revised to read as follows (addition in bold):

“My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand I am free to purchase contact lenses from the seller of my choice. **I also understand that my having the copy of my prescription means I can give a copy to the seller I choose.**”

Consistent with the purpose of the Act and the Rule, this added sentence would not impose a new *requirement* that the consumer provide the copy to the retailer in order to exercise the right to choose that retailer. Nor would it relieve the eye doctor of the requirement to verify the prescription or provide a copy to the retailer, or to provide another copy to the patient, upon request; but it would help further reduce the likely incidence of such requests.

As it has in other required consumer disclosures, the Commission may wish to consider requiring that the form be provided in the foreign language of the patient. The Commission could provide the forms on a website in a variety of languages, making it easy for eye doctors to comply.

We agree that there could be advantages to giving eye doctors the option of using an electronic format for the acknowledgement forms. We also see potential risks, however. We are concerned that patients could be less likely to read the form carefully – even though it is short – if “signing” means clicking an electronic box, or adding an electronic signature where the full statement is obscured, rather than using a pen to sign a sheet of paper where the full statement is completely and conspicuously in view – or, with a patient portal, perhaps an even more passive form of assent. There could also be security issues in relying on an electronic storage system, perhaps based in an Internet cloud, that could have vulnerabilities. Paper files, can have their own vulnerabilities, but it may be easier to take effective precautions against those.

We would therefore recommend that the Commission require paper forms. The eye doctor could choose to also make a scanned copy of each form, but we recommend that the paper form be retained as the primary copy for the required recordkeeping.

We see significant potential advantages of providing the *prescription* to the patient in electronic form, whether by email attachment or online patient portal. Either of these could make it easier for the patient to keep track of the prescription and send it to the retailer, either right after the doctor’s visit or later, thereby further reducing the likely need for communications between retailers and eye doctors to verify or obtain copies of prescriptions.

We believe this electronic copy should be a supplement to, and not a substitute for, providing a paper copy of the prescription to the patient at the end of the fitting. It is much easier for the patient to acknowledge receipt of a prescription that is actually in hand, and therefore also easier for the eye doctor to document that the patient has received it. Furthermore,

not all patients have access to, and are comfortable relying on, the Internet for handling and keeping track of important medical documents.

Finally, the Commission should consider requiring eye doctors to attach a copy of the prescription to the acknowledgement form. This could make it easier for eye doctors to respond to requests from retailers, as well as to demonstrate compliance. Even in the absence of the Commission requiring it, eye doctors may wish to consider doing this on their own volition.

Efficiency in Interactions Between Retailers and Eye Doctors

Eye doctors and retailers have both raised issues and made suggestions regarding the prescription verification process, its burdens and potential gaps. We agree with the Commission that the new patient acknowledgement form should help promote significant reduction in the need for verifications. We also generally agree that the issues raised regarding the verification process do not warrant additional changes in the Rule.

We do recommend the Commission consider one change, discussed below, a refinement to the 8-business-hour time period for passive verification, to better accommodate different preferences among eye doctors for processing verification requests. And we think there are steps retailers and eye doctors can and should consider taking on their own, without the need for a change in the Rule to require them, based on recognition of their shared interests in an efficient and reliable process. These are also discussed below. Doctors, retailers, and consumers can all play a role in reducing the need for retailers to call eye doctors to verify or obtain prescriptions.

In evaluating these issues and suggestions, we are mindful that *patient protection* is the purpose behind the Rule's requirements regarding efficient prescription verification, including the eight-business-hour time period and the "passive verification" triggered in the absence of a response within that period. Specifically, the purpose is to ensure that patients can efficiently and effectively exercise their choice of where to obtain contact lenses in a competitive marketplace, to shop for the price and convenience that suits them, while also ensuring that the prescription is filled correctly. To achieve this purpose, the verification system needs to be efficient and cost-effective for all parties to the communications involved – the eye doctor and the retailer, as well as the patient.

Automated calls

A number of eye doctors complained in comments in the Periodic Review about the inconvenience of handling automated telephone calls from large retailers. As we noted in our own comments, and as the Commission has also noted, the use of automated telephone calls from a large retailer to an eye doctor's office would appear to be a generally workable and efficient mechanism for verification communications between these retailers and eye doctors. Eye doctor offices should by now be familiar with the Rule, and able to recognize these automated calls and deal effectively with them. It should generally take the eye doctor's office no more time and effort to respond to an automated call or recording than to a live call from an employee of the retailer, or a recording of such a live call.

We are sensitive to the potential for robocalls to be burdensome. Indeed, we have supported legislation and rulemakings to protect consumers who are all-too-often on the receiving end of unwanted robocalls. Based on the record here, it does not appear that the incidence of these automated verification calls is high enough to constitute a significant burden. We nevertheless agree that the calls and their content should be structured with the convenience of both parties to the calls in mind. In truth, both parties benefit when the process is structured to eliminate burden for either. Ideally, both parties would recognize this. We would hope that a change to the Rule would ultimately not be necessary, that both retailers and eye doctors would structure their side of the process in recognition of their mutual interest in efficiency.

For example, the retailers could carefully tailor the script for prescription verification and copy request calls to give only the information the eye doctors need, and to give that information in the manner that best facilitates efficient processing. To better enable eye doctors to efficiently respond, retailers could provide one or more specific names and phone numbers that an eye doctor's office can call, as well as one or more email addresses. Retailers should recognize that it is in their interest to provide efficient avenues for eye doctors to respond. A long recorded answering message with a frustrating menu of all-purpose options does not serve anyone's interests.

Eye doctors who truly believe the automated calls are tying up their phone line too long could set up a separate line for receiving those calls. Or the person answering the phone, or the automated device that answers during off-hours, could transfer the verification call to a recording device. These are all easy and inexpensive ways to manage these calls efficiently.

One concern raised by eye doctors with regard to automated calls is the potential for erroneous passive verification, when the call is of such poor quality that the eye doctor's office cannot hear which patient is being referred to, or even where the call is coming from, and therefore is unable to respond. Another passive verification concern raised by eye doctors is the potential for a consumer seeking to refill an expired prescription, without having a current prescription, to provide a false phone number for a nonexistent eye doctor, so there is no one to respond within the 8-business-hour period.

(A variation on the second concern, raised by some eye doctors, of a consumer falsely giving the retailer a randomly chosen eye doctor's number, does not present the same difficulty. That eye doctor's office records can be checked, and the office can inform the retailer that the consumer is not a patient of the eye doctor's.)

As the Commission notes, there is no reliable indication in the record of the actual incidence of any of these scenarios, to provide a basis for revising the Rule. But we would hope that, out of shared interest in confirming the correct prescription, the retailer could, before exercising passive verification, make a follow-up in-person call. If it turns out that the number is false, the retailer can decline to fill the prescription, or seek the correct information from the consumer. If it turns out that the automated message did not record clearly, the retailer can provide the necessary information in the live call. And again, with the improvements flowing from the new patient acknowledgement form, and a recognition of shared interests in efficiency,

we would hope and expect that the need for resorting to passive verification would be substantially reduced.

As an alternative to automated calling, the retailer might consider sending emails with a receipt confirmation request. This could be another effective way to reduce the number of non-completed communications that could be misconstrued by the retailer as failures to respond, triggering passive verification.

Time limit for eye doctor response, triggering passive verification

Eye doctors have expressed concern that the 8-business-hour window for responding to a verification request before passive verification is triggered does not permit enough time to respond without creating undue burden. Retailers have stated that 8 business hours is sufficient, and have recommended that the same time period be applied to requests for prescription copies.

We believe the 8-business-hour period is generally sufficient and has proven workable. The Commission may wish to consider making one adjustment, however, to accommodate eye doctor offices that prefer to take care of administrative tasks such as prescription verification at the end of the day, or after regular office hours. Under the current Rule, an eye doctor's office that is open 8 hours or more in a day, and that receives a verification request at the beginning of that day, or during a weekend or holiday before that day, has no option but to process that request during regular office hours in order to meet the 8-business-hour period.

We would recommend the Commission consider whether adjusting the time period to accommodate the option to process such a request at the end of that working day, or during that evening, could help promote efficiency and minimize burden for eye doctors without significantly increasing burden on retailers or impairing consumer convenience. One way to adjust the time period would be to have a 24-hour period, excluding any 24-hour period during weekends and holidays when the office is typically closed. In most cases, that would work out to be the same as the 8-working-hour period. Even in the absence of a change in the Rule, we would recommend that retailers consider making this adjustment in their operations.

(We would not recommend further adjustments in the time period to accommodate eye doctor offices with unusual non-business days; we believe those offices can reasonably be expected to monitor closely enough to reply that the office is closed, and to state when it re-opens, so the retailer can adjust the period accordingly. We would expect this scenario to be rare, and when it occurs, manageable for both affected eye doctors and retailers.)

Regarding retailer requests for copies of prescriptions, we support the Commission's decision not to impose a required time limit that conforms to the window for verification requests. As the Commission notes, failure of the eye doctor to meet the window for a verification request simply triggers passive verification; failure to meet a new required time limit to provide a copy of the prescription would constitute a violation of the Rule. We do recommend, however, that the eye doctors treat the verification window as a good reference point, of their own volition. It may be just as easy for them to provide the copy as to provide the verification, or to provide them together. And providing the copy may reduce the need for

further verification requests from the retailer in the future, as the retailer can keep the copy on file.

(And again, the overall need for retailers to contact eye doctors should be reduced by improvements flowing from the patient acknowledgement form.)

Other steps to promote efficiency

Among other steps we would encourage retailers and eye doctors to take to reduce compliance-related burdens are the following:

- Eye doctors should consider informing patients at the initial visit that they will be getting a copy of the prescription after the fitting, will be able to use it to purchase contact lenses from the retailer of their choice, and should give a copy of the prescription to that retailer. We had earlier suggested that the Commission consider requiring this; we agree that requiring it is now unnecessary, given the new patient acknowledgement form. But we still believe it could further reinforce to patients the importance and use of the prescription copy, reducing the likely instances when it will be necessary for retailers to contact eye doctors.
- Eye doctors should consider posting signs in their offices informing patients that they will be getting a copy of the prescription after the fitting. The eye doctors have proposed requiring this as an alternative to the patient acknowledgment form. We agree with the Commission that the acknowledgement form will be far more effective in promoting and demonstrating compliance, and in furthering the goal of reducing the number of calls from retailers to eye doctors. But we believe the signs could be an important further reinforcement.
- Retailers should consider stressing to consumers prominently – in advertising, in online order web pages, and in calls for orders by phone – the advantage to consumers of sending a copy of the prescription they received from their eye doctor. Like the other recommended steps, this should help further reduce the need to call eye doctors for prescription verifications or copies.

Other Matters

Deterring Retailers From Selling Without a Prescription

As we noted in our comments in the Periodic Review, patient safety is a top priority of Consumers Union. As stated then, we do not believe the concerns regarding selling contact lenses without a prescription warrant any further change to the Rule. But we urge the Commission, along with the Food and Drug Administration and other appropriate authorities, to be vigilant in investigating and enforcing against violations so as to provide effective deterrence.

Clarifications as to Required Verification of Prescriptions

We continue to recommend two additional clarifications to §315.5 regarding prescriber verification, to help avoid possible confusion.

First, in subsection (c)(3), we recommend explicitly clarifying what we believe to be the understood intent, that the communication described, the failure of which to happen within 8 business hours permits the retailer to treat the prescription as verified, must satisfy either subsection (c)(1) or (c)(2). That is, the eye doctor must either confirm that the prescription is accurate, or must provide the accurate prescription. This clarification could be accomplished by inserting, after “seller” the first time it appears, the phrase “in accordance with paragraph (c)(1) or (c)(2) of this section”.

Second, in paragraph (d), we recommend explicitly clarifying what we believe to be the understood intent, that all of the information the eye doctor is required to provide the retailer, including the basis for saying the prescription submitted by the retailer is inaccurate or invalid, and the correct prescription information, must be provided within the same 8-business-hour timeframe in order to avoid triggering “passive verification” in paragraph (c)(3).

Private label substitution

The Commission’s proposed change to conform the Rule to the Act, and to clarify that a retailer can substitute private label lenses for identical lenses manufactured by the same company, as well as vice versa, is a sensible change, and one we support. It increases the choices available to consumers, including potentially more affordable options, without in any way undermining patient safety.

Ensuring Effective Monitoring and Enforcement

As we noted previously, with the Rule now in effect for more than 10 years, there is no justification for eye doctors to be unfamiliar with it. In addition to providing education and guidance, the Commission should actively monitor complaints, and follow up with warning letters and enforcement as appropriate to ensure that the Rule is working effectively. We are hopeful that the new patient acknowledgement form will be a further reminder, to all concerned, of the importance of compliance, and will reduce the need for enforcement actions.

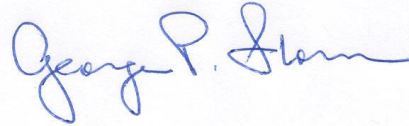
Addressing Manufacturer Restrictions on Retail Discounting

As we noted in our comments in the Periodic Review, we have been concerned that the effectiveness of the Rule has been undermined by restrictions imposed by contact lens manufacturers on retail discounting. As we noted then, we believe these retail discounting restrictions are not only flagrantly anti-consumer, but also potentially a violation of the antitrust laws.¹ It is our understanding that contact lens manufacturers have modified their retail pricing

¹ See our testimony before the Senate Subcommittee on Antitrust, Competition Policy, and Consumer Rights, <http://www.judiciary.senate.gov/meetings/pricing-polices-and-competition-in-the-contact-lens-industry-is-what-you-see-what-you-get>

practices since we submitted those comments. We urge the Commission to remain vigilant in investigating any indications of such anticompetitive practices, and to take appropriate enforcement action as warranted by the facts uncovered, so that competition and consumer choice are protected in accordance with the purposes of the Rule.

Respectfully submitted,

A handwritten signature in blue ink that reads "George P. Slover". The signature is fluid and cursive, with the first name being the most prominent.

George P. Slover
Senior Policy Counsel
Consumers Union