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FEDERAL TRADE COMMISSION

16 CFR Part 315

RIN 3084-AB36

Contact Lens Rule

AGENCY: Federal Trade Commission (“FTC” or “Commission”).

ACTION: Supplemental notice of proposed rulemaking; request for public comment.

SUMMARY: As part of its regulatory review of the Contact Lens Rule (“Rule”), the Commission is proposing modifications to its prior proposal to amend the Rule to require that prescribers obtain a signed acknowledgment after releasing a contact lens prescription and maintain each such acknowledgment for a period of not less than three years. The Commission is further proposing to amend the Rule to: permit prescribers to comply with automatic prescription release via electronic delivery in certain circumstances; specify a time-period for prescribers to respond to requests for prescriptions; clarify and institute additional requirements for automated telephone verification messages; more precisely delineate what constitutes unlawful alteration of a prescription; and require that sellers accept patient prescription presentation. The Commission seeks comment on these proposals. The Commission is not adopting any final amendments to the Rule at this time and continues to consider comments and information submitted in response to its Request for Comment of September 2015, its Notice of Proposed Rulemaking of December 2016, and its Notice Announcing Public Workshop and Request for Comment of December 2017.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS**

AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Contact Lens Rule Review, 16 CFR Part 315, Project No. R511995” on your comment, and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address:

Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Alysa Bernstein, Attorney, (202) 326-2903, Paul Spelman, Attorney, (202) 326-2487, or Andrew Wone, Attorney, (202) 326-2934, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

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I. Background

A. Overview of the Contact Lens Rule

In 2003, Congress enacted the Fairness to Contact Lens Consumers Act,¹ and pursuant to the Act, the Commission promulgated the Contact Lens Rule on July 2, 2004.² The Rule went into effect on August 2, 2004.

The Contact Lens Rule promotes competition in retail sales of contact lenses by facilitating consumers' ability to comparison shop for contact lenses. When a prescriber completes a contact lens fitting, the Rule requires that the prescriber automatically provide the patient with a portable copy of the patient's prescription, whether or not the patient requests it. The Rule also requires that the prescriber verify or provide such prescriptions to authorized third parties. At the same time, the Rule requires that sellers only sell contact lenses in accordance with valid prescriptions written by licensed

¹ 15 U.S.C. 7601-7610 (Pub. L. 108-164).

² Contact Lens Rule, 16 CFR part 315 (2015).

prescribers that were either (a) presented to the seller by the patient or a designated agent of the patient or (b) verified by direct communication with the prescriber.³

The Rule further 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 in its stead; or (3) the prescriber fails to communicate with the seller within eight business hours after receiving a compliant verification request.⁴ The Rule states that if the prescriber informs the seller within eight business hours of receiving the verification request that the prescription is inaccurate, expired, or invalid, the seller shall not fill the prescription. The Rule requires that the prescriber specify the basis for the inaccuracy or invalidity of the prescription, and if the prescription is inaccurate, the prescriber must correct it.⁵ 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.⁶

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.⁷ The Rule also incorporates the Act's preemption of state and local laws and regulations that

³ 16 CFR 315.5(a).

⁴ 16 CFR 315.5(b)-(c).

⁵ 16 CFR 315.5(d).

⁶ 16 CFR 315.5(e).

⁷ 16 CFR 315.6.

establish a prescription expiration date of less than one year or that restrict prescription release or require active verification.⁸

B. History of the Rule

The FTC has more than three decades of regulatory and research experience regarding the optical goods industry; this history continues to inform the basis and purpose of the Contact Lens Rule and this rule review. In addition to the Rule, the Commission enforces the Ophthalmic Practice Rules (known as the “Eyeglass Rule”), initially promulgated in 1978.⁹ Prior to the Eyeglass Rule, many prescribers either refused to release prescriptions to their patients or charged an additional fee to do so.¹⁰ Prescribers also used waivers and liability disclaimers to discourage comparison shopping, mislead consumers, and frighten them into purchasing ophthalmic goods from

⁸ 16 CFR 315.11(a). The Rule states further that “[a]ny other state or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency.” 16 CFR 315.11(b).

⁹ Final Trade Regulation Rule, Advertising of Ophthalmic Goods and Services, 43 FR 23992 (June 2, 1978) [hereinafter Eyeglass I]. The Rule was revised in 1992, with the revisions codified at 16 CFR part 456. Ophthalmic Practice Rules, 57 FR 18822 (May 1, 1992).

¹⁰ 43 FR at 23998. The Commission found, for example, that in nearly every survey of practicing optometrists considered in the rulemaking record, more than 50% of optometrists imposed a restriction on the availability of eyeglass prescriptions to patients. *See also* FTC, “Staff Report on Advertising of Ophthalmic Goods and Services and Proposed Trade Regulation Rule” 240-48 (1977) [hereinafter 1977 Staff Report] (detailing myriad accounts of prescribers refusing to release eyeglass prescriptions to their patients), https://www.ftc.gov/system/files/documents/reports/staff-report-advertising-ophthalmic-goods-services-proposed-trade-regulation-rule-16-cfr-part-456/r611003_-_staff_report_on_advertising_of_ophthalmic_goods_and_services_and_proposed_trade_regulation.pdf.

the prescriber.¹¹ The Commission determined that these actions reduced consumers' ability to obtain the lowest prices and hindered competition in the optical marketplace.¹² To address these problems, the Eyeglass Rule required prescribers—generally, optometrists and ophthalmologists—to provide each of their patients, immediately after completion of an eye examination, a free copy of the patient's eyeglass prescription.¹³

The Eyeglass Rule, however, did not encompass contact lens prescriptions. While a majority of states enacted their own statutes requiring some form of contact lens prescription release,¹⁴ many prescribers continued to withhold prescriptions for contact lenses.¹⁵ This, and other prescriber practices (such as requiring liability waivers, refusing

¹¹ *Am. Optometric Ass'n v. FTC*, 626 F.2d 896, 916 (D.C. Cir. 1980) (noting considerable “evidence of abuse” by prescribers); *see also* 1977 Staff Report, *supra* note 10, at 277 (concluding that there could be “little doubt” that the primary intent of waivers was to discourage or dissuade consumers from taking their prescriptions elsewhere to be filled).

¹² FTC, “The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study” 45-46 (2005), <https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf> [hereinafter 2005 Contact Lens Report].

¹³ 16 CFR 456.2 (separation of examination and dispensing). The FTC also has studied the effects of state-imposed restrictions in the optical goods industry. *See* FTC, “The Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry” (1980), <https://www.ftc.gov/sites/default/files/documents/reports/effects-restrictions-advertising-and-commercial-practice-professions-case-optometry/198009optometry.pdf>.

¹⁴ By 2003, more than two-thirds of states had laws requiring some form of contact lens prescription release. H.R. Rep. No. 108-318, at 8 (2003).

¹⁵ *See id.* at 4 (noting that “[t]he practice of optometrists withholding the prescription [for contact lenses] has limited the consumer’s ability to shop for the best price and has impacted competition.”); “Fairness to Contact Lens Consumers Act: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce,” 108th Cong. 1 (2003) [hereinafter FCLCA Subcomm. Hearing] (statement of Ami Gadhia, Consumers Union) (noting that multiple

to verify prescriptions when consumers tried to buy lenses from third-party sellers, and encouraging manufacturers not to distribute contact lenses to third-party sellers), made it challenging for consumers to obtain lenses from anyone other than their prescribers.¹⁶ According to Congress, these obstacles were rooted in an “inherent conflict of interest” in that “[u]nlike medical doctors who are prohibited from selling the drugs they prescribe, eye doctors and optometrists . . . are able to fill the contact lens prescriptions they write.”¹⁷ Third-party sellers are thus forced to compete for the sale of lenses with the

surveys of consumers in Texas had found considerable numbers were unable to their contact lens prescription from their prescribers).

¹⁶ H.R. Rep. No. 108-318 at 4; FCLCA Subcomm. Hearing, *supra* note 15 (statements of Howard Beales, Jonathan Coon, Ami Gadhia, Robert Hubbard, Maria Martinez, Rep. W. J. Tauzin (La.); Peggy Venable). *See also In re Disposable Contact Lens Antitrust Litig.*, No. 94-MDL 1030-J-20A (M.D. Fla.) in which the Attorneys General of 31 states alleged that eye-care professionals engaged in an organized effort to prevent or hinder consumers from obtaining their contact lens prescriptions. The complaints alleged two conspiracies: (1) That the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers, and (2) that manufacturers, practitioners, and trade associations, including the American Optometric Association, conspired to eliminate sales of contact lenses by pharmacies, mail order, and other alternative sellers. *Id.* According to the Attorneys General, the conspiracy severely restricted the supply of contact lenses available to alternative sellers, which hampered the growth of such sellers, decreased the supply of lenses to consumers, and increased the price of lenses. *Id.* The parties reached settlements, the last of which the court approved in November 2001. As part of the settlements, manufacturers agreed to sell contact lenses to alternative distribution channels. During consideration of the FCLCA, one Congressman noted about the case, “The suit was settled, but it shows the extent of distrust for how contact lenses are currently dispensed by eye doctors and optometrists.” FCLCA Subcomm. Hearing, *supra* note 15 (statements of Rep. W.J. Tauzin (La.)).

¹⁷ H.R. Rep. No. 108-318, at 5. *See also* Letter from Senators Richard Blumenthal and Orrin G. Hatch of the United States Senate Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (Aug. 11, 2017) (recognizing the “inherent conflict of

individual who is writing the prescription.¹⁸ To address this inherent conflict of interest and achieve freedom of choice and the benefits of competition for contact lens consumers, Congress passed the Fairness to Contact Lens Consumers Act in 2003,¹⁹ and, in 2004, the Commission issued the Contact Lens Rule,²⁰ implementing the Act.

As specified in the Act, the Rule imposes requirements on both sellers and prescribers of contact lenses. Because the use of contact lenses involves significant health issues²¹ and Congress recognized that consumers may be harmed by contact lenses purchased with an expired, inaccurate, or otherwise invalid prescription,²² the Act requires that contact lenses be sold only to patients with valid prescriptions, which they receive after contact lens fittings by a prescriber. The Act and the Rule only allow sales of contact lenses when a patient presents a seller with a copy of the prescription or the

interest” and noting that the FCLCA was made necessary by “the unique nature of the the contact lens marketplace”),
https://www.ftc.gov/system/files/filings/initiatives/677/public_comment_from_senators_blumenthal_and_hatch_re_contact_lens_rulemaking.pdf [hereinafter Blumenthal Letter].

¹⁸ H.R. Rep. No. 108-318, at 5; FCLCA Subcomm. Hearing (statements of Rep. W.J. Tauzin (LA)) (noting there is a “classic conflict of interest that robs the consumers of the ability to shop competitively for the best price,” and stating that the FCLCA takes the “necessary steps to remedy this stranglehold on contact lens competition.”).

¹⁹ 15 U.S.C. 7601-7610 (Pub. L. 108-164).

²⁰ Contact Lens Rule, 69 FR 40482 (July 2, 2004) (codified at 16 CFR part 315). Pursuant to its congressional mandate, the FTC also issued a study of competition in the contact lens industry in 2005. *See* 2005 Contact Lens Report, *supra* note 12.

²¹ *See, e.g.*, FTC, “Possible Barriers to E-Commerce: Contact Lenses, A Report from the Staff of the Federal Trade Commission” 8-9 (2004), <http://www.ftc.gov/os/2004/03/040329c1reportfinal.pdf>.

²² Contact Lens Rule, 69 FR 40482.

seller has verified the patient's prescription with the prescriber.²³ Sellers also are prohibited from altering a contact lens prescription.²⁴

The Act and the Rule further impose obligations on prescribers. First and foremost, prescribers are required to release a copy of the prescription to the patient promptly upon completion of the contact lens fitting, “[w]hether or not requested by the patient.”²⁵ Prescribers also are prohibited from requiring: (1) The purchase of contact lenses as a condition of either prescription release or verification, (2) a separate payment for prescription release or verification, and (3) that the patient sign a waiver as a condition of prescription release or verification.²⁶

Additionally, prescribers are required to provide or verify a contact lens prescription when “directed by any person designated to act on behalf of the patient.”²⁷ Such verification occurs when the seller provides the prescriber with a consumer's prescription information and: (1) The prescriber confirms that the prescription is accurate, by phone, facsimile, or electronic mail; (2) the prescriber informs the seller that the prescription is inaccurate and provides the correct prescription; or (3) the prescriber does not communicate with the seller within eight business hours of the seller's request

²³ 16 CFR 315.5(a).

²⁴ 16 CFR 315.5(e).

²⁵ 15 U.S.C. 7601(a)(1); 16 CFR 315.3(a)(1).

²⁶ 15 U.S.C. 7601(b)(1)-(3); 16 CFR 315.3(b)(1)-(3).

²⁷ 15 U.S.C. 7601(a)(2) (must, as directed by authorized party, “provide or verify” the prescription); 16 CFR 315.3(a)(2).

for verification (“passive verification”).²⁸ The eight-business-hour passive verification lessens the demands on prescribers in the event a seller forwards a query about an accurate and complete prescription from a properly identified patient. It also prevents prescribers from blocking verification—and impeding consumer access to contact lenses that may be lower-priced, or sold by sellers who offer other benefits or convenience—simply by refusing to respond to verification requests.

One outcome of passive verification, however, if a prescriber does not respond to a verification request containing inaccurate information or for an invalid prescription within eight business hours is that the prescription is deemed verified; thus, passive verification allows for the possibility that patients can be sold lenses for which they do not have a valid prescription. Congress, when considering the FCLCA, was aware that a passive-verification regime could, in some instances, allow sellers to sell and ship contact lenses based on an invalid or inaccurate prescription, and that this could potentially lead to health risks.²⁹ Congress opted for a passive-verification regime despite this concern in order “to ensure that consumers are not caught in the competitive tug-of-war between doctors and third party sellers for the sale of contact lenses.”³⁰ It was also envisioned that prescribers would remain diligent in ensuring that patients did not receive lenses for which they had not been prescribed, since it is in both prescribers’ self-interest and the

²⁸ 15 U.S.C. 7603(d)(1)-(3); 16 CFR 315.5.

²⁹ *See, e.g.*, FCLCA Subcomm. Hearing, *supra* note 15 (statements of Howard Beales, Federal Trade Commission); *Id.* (statements of J. Pat Cummings, American Optometric Association) (“And the problem with passive verification is that people will get contact lenses without a prescription.”).

³⁰ H.R. Rep. No. 108-318, at 5.

health and safety interests of their patients to prevent this from occurring.³¹ In this manner, the passive-verification system was perceived, to a certain extent, to be self-enforcing, as prescribers would have both a financial interest and an ethical duty to police invalid, incorrect, or expired prescriptions.³²

C. Initial Request for Comments in 2015

As part of its periodic review of its rules and guides, on September 3, 2015, the Commission solicited comments on the Contact Lens Rule, seeking input on: the economic impact of, and continuing need for, the Rule; the benefits of the Rule to consumers purchasing contact lenses; the burdens the Rule places on entities subject to its requirements; the impact the Rule has had on the flow of information to consumers; the degree of industry compliance with the Rule; the need for any modifications to increase its benefits or reduce its burdens or to account for changes in relevant technology; and any overlap or conflict with the Rule and other federal, state, or local laws or regulations.³³ The comment period closed on October 26, 2015. The Commission

³¹ Contact Lens Rule, 69 FR at 40498.

³² FCLCA Subcomm. Hearing, *supra* note 15 (statements of Howard Beales, Federal Trade Commission) (stating that passive verification is in many respects self-enforcing). *See also* FCLCA Subcomm. Hearing, *supra* note 15 (statements of Jonathan Coon, 1-800 CONTACTS) (explaining to the Committee that from their experience with an existing passive verification-system in California, doctors have a motivation to block invalid-prescription sales. “So they tell us if there is any problem with the prescription, if it’s expired, it’s invalid, whatever the problem is with the prescription. If they can tell us, you can believe they tell us absolutely every time.”).

³³ Contact Lens Rule, 80 FR 53272 (Sept. 3, 2015).

received approximately 660³⁴ comments from individuals and entities representing a wide range of viewpoints, including prescribing eye-care practitioners (ophthalmologists and optometrists), opticians and other eye-wear industry members, sellers of contact lenses (both online and brick-and-mortar), contact lens manufacturers, and consumers.

D. Notice of Proposed Rulemaking in 2016

After a review of comments, surveys, other submitted information, and its own enforcement experience, the Commission determined that the overall weight of the evidence demonstrated a need to improve compliance with the Rule's automatic prescription-release requirement, as well as a need to create a mechanism for monitoring and enforcing the Rule.³⁵ To achieve this, the Commission issued a Notice of Proposed Rulemaking ("NPRM") on December 7, 2016 that proposed to add a signed-acknowledgment requirement.³⁶ The signed-acknowledgment requirement would be triggered once the prescriber presented the prescription to the patient, and the acknowledgment form could be in either paper or electronic format. As proposed, the acknowledgment form would be entitled "Patient Receipt of Contact Lens Prescription," and state, "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice." Prescribers would be required to

³⁴ Comment figures are approximations because identical comments are sometimes submitted more than once.

³⁵ Notice of Proposed Rulemaking, 81 FR 88526 (Dec. 7, 2016) [hereinafter NPRM].

³⁶ *Id.* The NPRM also proposed a technical amendment, to remove the words "private label" from § 315.5(e) to conform the language of the Rule to that of the FCLCA, but that amendment is not at issue in this Supplemental Notice of Proposed Rulemaking.

maintain copies of the acknowledgment forms in paper or electronically for not less than three years.

The NPRM sought comment on this proposal, and also about the following issues: the provision of additional copies of prescriptions, the amount of time for a prescriber to respond to such a request, the use of patient portals to release prescriptions, and potential modifications to address concerns about automated telephone verification calls. The sixty-day comment period for the Commission's NPRM closed on January 30, 2017.

In response to its NPRM, the Commission received over 4,000 additional comments, many from prescribers concerned about the impact of the proposed signed-acknowledgment requirement. After considering these and other comments, the Commission determined that certain issues deserved additional discussion and examination. To obtain additional input and more fully consider commenter concerns, the Commission solicited additional comments³⁷ and held a public workshop on the Contact Lens Rule and the Evolving Contact Lens Marketplace on March 7, 2018. The workshop included six panels, covering issues relating to the overall contact lens marketplace, health and safety, competition, purchasing and verification, the proposed signed acknowledgment and consumer choice, and the future of contact lens prescribing and selling. In response to the Commission's request and workshop, the Commission received approximately 3,400 additional comments from a wide range of commenters, including numerous consumers and prescribers, as well as industry associations, state attorneys general, contact lens manufacturers, and retailers.

³⁷ Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 FR 57889 (Dec. 8, 2017).

II. Supplemental Notice of Proposed Rulemaking

After reviewing the comments, the Commission now proposes to modify its prior proposal—put forth in the NPRM—that would have required prescribers to request a signed statement from their patients acknowledging receipt of the patient’s prescription. The Commission also proposes new amendments to the Rule. This Supplemental Notice of Proposed Rulemaking (“SNPRM”) summarizes the relevant comments received and explains the Commission’s proposal to modify its signed-acknowledgment proposal and amend other sections of the Rule.³⁸

A. Proposal to Modify Prior Signed-Acknowledgment Proposal

The Commission proposes to modify its prior proposal for a signed-acknowledgment requirement by instituting a more flexible Confirmation of Prescription Release provision. Rather than requiring that prescribers request that each contact lens patient acknowledge receipt of the prescription by signing a form stating, “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,”³⁹ prescribers would be required to do one of the following:

(a) Request that the patient acknowledge receipt of the contact lens prescription by signing a separate statement confirming receipt of the contact lens prescription;

(b) Request that the patient sign a prescriber-retained copy of a contact lens prescription that contains a statement confirming receipt of the contact lens prescription;

³⁸ This SNPRM will only discuss comments specifically related to the modifications and amendments proposed at this time. The Commission will address other issues raised by commenters when the Commission issues its Final Rule.

³⁹ NPRM, 81 FR at 88559.

(c) Request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming receipt of the contact lens prescription; or

(d) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.

The precise wording of such confirmations would be left to the prescriber's discretion, but for prescribers opting for (a), (b), or (c), a patient's written or electronic signature would always be required. The prescriber would have to maintain evidence of the Confirmation of Prescription Release for at least three years, and make such evidence available upon request by the Commission. Unlike the Commission's prior acknowledgment proposal, which applied to all prescribers, the Confirmation of Prescription Release would only be required of prescribers who have a financial interest in the sale of contact lenses.

B. New Proposals to Modify the Rule

In addition to the proposed Confirmation of Prescription Release, the Commission further proposes to modify the Rule for prescribers and sellers in several ways. First, by adding to the Rule a definition of the term "provide to the patient a copy," the Commission proposes to allow the prescriber, with the patient's verifiable affirmative consent, to provide the patient with a digital copy of the patient's prescription in lieu of a paper copy. Second, although the Rule has always required that prescribers, upon request, provide any person designated to act on behalf of the patient with a copy of the patient's valid contact lens prescription, the Rule did not prescribe a time limit in which

the copy of the prescription had to be provided; the Commission now proposes forty business hours as a reasonable time period in which the prescription must be provided. The prescriber would also be required to note the name of the requester and the date and time the prescription was provided.

Third, the Commission also now proposes new requirements for sellers using automated telephone verification messages. The proposal would require a seller to (1) record the entire call and preserve the complete recording; (2) begin the call by identifying it as a prescription verification request made in accordance with the Contact Lens Rule; (3) deliver the verification message in a slow and deliberate manner and at a reasonably understandable volume; and (4) make the message repeatable at the prescriber's option. To aid implementation of this proposal, the Commission further proposes to add definitions for the terms "reasonably understandable volume," and "slow and deliberate manner." The purpose of this amendment is to enable prescribers to fulfill their role as protectors of patients' eye health, since prescribers cannot correct and police invalid, inaccurate, and expired prescriptions if they cannot comprehend a seller's verification request. By requiring preservation of the recording, the amendment will also enable the Commission to better monitor seller compliance with the Rule.

Fourth, the Commission proposes to amend the prohibition on seller alteration of prescriptions by specifying that alteration includes a seller providing the prescriber a verification request with the name of a manufacturer or brand other than that specified by the patient's prescriber, unless such name is provided because the patient entered it on the seller's order form, or because the patient orally gave the seller the other name in response to a request for the manufacturer listed on the patient's prescription.

Lastly, in order to limit the burden of verification and ensure patient choice and flexibility, the Commission proposes to amend the Rule by requiring that sellers provide a mechanism that would allow patients to present their prescriptions directly to the seller.

III. Option for Electronic Delivery of Prescriptions as a Means for Automatic Prescription Release

In the NPRM, the Commission concluded that using online-patient portals to complete the automatic prescription release offered potential benefits for sellers, prescribers, and patients.⁴⁰ Prescribers could post, and patients could obtain, prescriptions online. With an electronic copy, patients could provide prescriptions more easily to sellers when purchasing lenses.⁴¹ In turn, this potentially would reduce the volume of requests by sellers for verification or additional copies of the prescription.⁴² To facilitate portability, the Commission noted that portals should allow patients to download, save, and print the prescription as well as send the prescription directly to a seller. However, the Commission did not have sufficient information to determine whether solely posting a contact lens prescription on a patient portal would be sufficient to satisfy the Rule's obligation for prescribers to provide a copy of a prescription to patients after completing a contact lens fitting. Therefore, the Commission sought comment on the use and adoption of online-patient portals as well as the potential ability for such technology to allow prescribers to comply with the automatic prescription-

⁴⁰ NPRM, 81 FR at 88535.

⁴¹ *Id.*

⁴² *Id.*

release requirement.⁴³

A. Use of Patient Portals by Prescribers and Patients

In response, several commenters noted the benefits and supported the use of patient portals.⁴⁴ Through a portal, patients would have greater access to their prescriptions and would have electronic copies to send to sellers.⁴⁵ However, commenters also expressed concerns that: (1) Online portals are not widely used; (2) patients may not be aware of the portal or may have difficulty accessing or printing

⁴³ In the NPRM, the Commission also clarified that the “directly or by facsimile” language of § 315.5(a)(1) includes the use of online portals by patients and prescribers to present contact lens prescriptions to sellers. The Commission sought comments on this clarification. While the Commission received some comments, the Commission does not believe that any further modifications to this provision are necessary.

⁴⁴ Opticians Association of America (Workshop [hereinafter WS] Comment #482); CooperVision, Inc. (WS Comment #3077); Coalition for Contact Lens Consumer Choice (WS Comment #3239); Grove (NPRM Comment #1702); Opternative (NPRM Comment #3785); Comments of the Attorneys General of 20 States (NPRM Comment #3804); American Optometric Association (NPRM Comment #3830) (“For those doctors who have functioning patient portals and for patients who would like to use them, it would be beneficial for the Commission to clarify that providing access to a contact lens prescription through the patient portal would meet the prescriber requirements of automatic prescription release”); National Association of Optometrists and Opticians (NPRM Comment #3851); Costco Wholesale Corporation (NPRM Comment #4281) (“Patient portals are now commonplace among physician practices and could serve to enhance compliance with the Rule, as well as provide better information to sellers”). *See also* American Academy of Ophthalmology (NPRM Comment #3657) (some prescribers currently provide copies of prescriptions electronically, including through patient portals).

⁴⁵ Opternative (NPRM Comment #3785); American Optometric Association (NPRM Comment #3830); 1-800 CONTACTS (NPRM Comment #3898); Consumers Union (NPRM Comment #3969) (“We see significant potential advantages of providing the *prescription* to the patient in electronic form, whether by email attachment or online patient portal.”).

medical documents online; and (3) prescribers and patients prefer paper copies.⁴⁶

Another commenter was concerned that allowing prescribers to satisfy the automatic prescription release by using an online portal would undercut the signed-acknowledgment requirement proposed in the NPRM.⁴⁷

The Act and Rule clearly envision and support the use of electronic means to convey prescriptions. This is evident by the language of Section 7601(a)(2) of the Act, which requires prescribers to “provide or verify the contact lens prescription by electronic or other means” to patients’ agents.⁴⁸ It would be inconsistent for the Act and Rule to permit prescribers to provide prescriptions electronically to patients’ agents, but prohibit prescribers from electronically conveying prescriptions to patients themselves (or require that patients formally designate themselves as their own agent in order to receive an electronic copy of their prescription).

Although online access to records has increased in the medical field generally,⁴⁹

⁴⁶ Opternative (NPRM Comment #3785); American Optometric Association (NPRM Comment #3830); 1-800 CONTACTS (NPRM Comment #3898); Consumers Union (NPRM Comment #3969).

⁴⁷ 1-800 CONTACTS (NPRM Comment #3898).

⁴⁸ 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2).

⁴⁹ One survey from 2017 found that 52% of individuals were offered online access to their medical records by a health provider or insurer, an increase from 42% in 2014. Of those patients who were offered online access, more than half actually viewed their online medical records at least once in the past year. U.S. Dep’t of Health & Human Servs., The Office of the National Coordinator for Health Information Technology, “Individuals’ Use of Online Medical Records & Technology for Health Needs” 1-2 (2018).

the prevalence of portals among eye-care providers is unclear.⁵⁰ However, portal usage could increase as patients become more comfortable in interacting with their medical providers online and portal capabilities improve.⁵¹ Several eye-care providers already offer copies of prescriptions through patient portals or other electronic means, including email.⁵²

B. Analysis and Proposal

Based on its review of the evidence, the Commission believes that the Rule should be amended to allow prescribers to satisfy § 315.3(a)(1)'s automatic-release requirement by providing the patient with a digital copy of the prescription, including by email, text, or patient portal, in lieu of a paper copy.⁵³ Importantly, the choice is not

⁵⁰ According to a survey conducted by 1-800 CONTACTS, thirty percent of patients were offered the option to use a patient portal at their last eye exam and, of those who had the option, 29% actually used it. 1-800 CONTACTS (NPRM Comment #3898). Comparatively, at the March 7, 2018 workshop, a panelist commented that only 8% of his office's patients used the portal. FTC, The Contact Lens Rule and the Evolving Contact Lens Marketplace, Panel V: Prescription Release & Consumer Choice Tr. at 17 (Mar. 7, 2018), https://www.ftc.gov/system/files/documents/public_events/1285493/panel_v_prescription_release_and_consumer_choice.pdf [hereinafter CLR Panel V Tr.].

⁵¹ CLR Panel V Tr., *supra* note 50, at 18-19.

⁵² *See, e.g.*, Eklund (WS Comment #502); Reed (WS Comment #749); Gitchell (WS Comment #759); Andrews (WS Comment #1014); Carvell (WS Comment #1021); Cecil (WS Comment #1892); Kuryan (WS Comment #3472); Hopkins (NPRM Comment #184); Wilson (NPRM Comment #1310); Grove (NPRM Comment #1702); MacDonald (NPRM Comment #2118); Andrus (NPRM Comment #3345); American Academy of Ophthalmology (NPRM Comment #3657) (“For practices that utilize electronic medical record systems, patients can request a copy of their prescription and [be] issued one electronically. Many practices also utilize patient portals to fill prescription requests.”).

⁵³ In the NPRM, the Commission stated that allowing patients to send prescriptions to sellers through the portal would promote prescription portability. NPRM, 81 FR at 88535. Although potentially beneficial, the Commission's proposed change does not require that patients be able to send prescriptions to sellers through the

whether patients want to receive their prescriptions—since the Rule and statute both require that this be automatic—but rather the method of receiving them. To ensure that patients are not required to accept an unwanted method of delivery, the Commission would limit the use of electronic means to instances where the patient has given affirmative consent to receive a digital copy of the prescription.⁵⁴ The consent must be verifiable (so oral consent alone would not suffice), and the patient must be able to access, download, and print the digital copy for future use. Patients who decline to consent, for any reason, must receive a paper copy of their prescription. Likewise, because technology may be developing still or be costly to implement, prescribers who prefer to provide paper copies to their patients need not offer an electronic option. Therefore, the Commission invites comments on its proposed modification to allow prescribers to satisfy the automatic prescription release requirement by providing a digital

portals. The technology that would allow this type of communication is still evolving, and potential complications exist, including software differences, the number of prescribers and sellers involved, and privacy issues. 1-800 CONTACTS (NPRM Comment #3898); CLR Panel V Tr., *supra* note 50, at 19-20.

⁵⁴ The proposed change to allow for a digital copy in lieu of a paper copy does not alter the timing of when a prescriber must provide the prescription to the patient. In both instances, whether digital or paper, prescribers must provide the prescription immediately after completion of the contact lens fitting, or in the case of a renewal prescription, when the prescriber determines that no change in the existing prescription is required. The Commission's proposal would not expressly require that prescribers maintain records of patients' affirmative consent to electronic delivery, but prescribers may choose to do so in order to have proof that affirmative consent was given. Furthermore, the Commission's proposal would not alter or pre-empt existing state and federal statutes pertaining to the electronic delivery of records, such as the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. 7001 ("E-Sign").

copy in lieu of a paper copy when the patient gives verifiable affirmative consent.⁵⁵

IV. Modification of Prior Signed-Acknowledgment Proposal

A. NPRM Automatic Prescription Release Proposal and Comments

In its December 2016 NPRM, the Commission proposed amending § 315.3(a)(1)—Automatic Prescription Release—to add the requirement that upon completion of a contact lens fitting, and after providing a copy of the contact lens prescription to the patient, the prescriber request that the contact lens patient acknowledge receipt of the contact lens prescription by signing an acknowledgment form entitled, “Patient Receipt of Contact Lens Prescription.” This form would state, “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.” In addition, the form would also include the name of the patient, the patient signature, and the date the form was signed. If the patient declined to sign the acknowledgment form, the prescriber would note the patient’s refusal on the form and sign it. No other statements or information, other than the address or letterhead of the prescriber, would be placed on the acknowledgment form.⁵⁶ The Commission based its proposal on multiple findings. First, the Commission noted that commenters cited or submitted five surveys which, taken as a whole, suggested that a significant percentage of consumers were not receiving their prescriptions, and were unaware of

⁵⁵ Proposed changes to § 315.5(c) would require prescribers who provide digital copies of prescriptions to patients to retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable.

⁵⁶ NPRM, 81 FR at 88535.

their right to receive them.⁵⁷ The Commission acknowledged that none of the surveys, in and of itself, could be considered definitive, and acknowledged that there are inherent limitations to survey evidence.⁵⁸ Even so, the Commission concluded that the evidence was sufficient to indicate a significant problem with prescription-release compliance, particularly when the surveys were viewed in conjunction with supporting evidence from other sources and the lack of contradictory evidence.⁵⁹

Supporting evidence cited by the Commission consisted of the following: the high number of seller verifications (many of which would be unnecessary were patients in possession of prescriptions and able to present them at purchase);⁶⁰ evidence that consumers are still unaware of their right to their prescriptions;⁶¹ the ongoing pattern of consumer complaints and anecdotal reports of failure to release prescriptions;⁶² and the industry's long and documented history of opposition to prescription release and failure to provide patients with prescriptions prior to the Rule's enactment, even when so

⁵⁷ NPRM, 81 FR at 88531-32.

⁵⁸ *Id.*

⁵⁹ NPRM, 81 FR at 88531.

⁶⁰ Approximately three-quarters of third-party contact lens sales occur via prescriber verification, meaning that the consumer did not present a complete prescription at the time of the attempted purchase. *Id.*

⁶¹ According to an October 2015 survey by Survey Sampling International, an independent market research company retained by commenter 1-800 CONTACTS, 46% of contact lens wearers were unaware that they had a right to receive a copy of their prescription, even though the Rule has been in effect since 2004. *Id.* at 88532.

⁶² *Id.*

obligated under state law.⁶³ The Commission also noted that current enforcement of the automatic-release provision is challenging, since the absence of any documentation makes it difficult to ascertain whether a prescriber did or did not release a prescription, and to determine how frequently a noncompliant party may have violated the Rule.⁶⁴ The Commission noted that under the current Rule, allegations and denials can become a matter of a patient's word against that of their prescriber.⁶⁵

The Commission further concluded that the potential benefits of increasing the number of patients in possession of their prescriptions were substantial: increased patient flexibility and choice in shopping for lenses; a reduced number of verification requests, which many prescribers find burdensome; a reduced likelihood of errors associated with incomplete or invalid prescriptions, which can jeopardize patient eye health; and a reduction in the number and complications of failed attempts at verification.⁶⁶ Increasing prescription-release compliance also would likely spur competition and innovation among contact lens sellers and manufacturers, and reduce attempts by sellers to verify incorrect, expired, and invalid prescriptions, or to verify with the wrong prescriber.⁶⁷ The Commission determined that the cumulative effect of increased automatic-release compliance would thus be lower costs and improved convenience and flexibility for patients, sellers, and prescribers, as well as increased accuracy of prescriptions presented

⁶³ *Id.*

⁶⁴ *Id.* at 88533.

⁶⁵ *Id.*

⁶⁶ *Id.* at 88532.

⁶⁷ *Id.*

to sellers, thereby reducing potential consumer harm.⁶⁸ Furthermore, a signed acknowledgment would increase the Commission's ability to assess and verify compliance with the Rule.⁶⁹

The Commission estimated the burden of the proposed requirement at one minute per patient per year to obtain a signed receipt and save it to the patient's file, for a total overall burden on prescribers of 683,333 hours (41 million minutes) per year.⁷⁰ Based on average wages for prescribers, the Commission estimated this would result in an annual cost of \$10,475,495,⁷¹ roughly \$176 per prescriber per year.⁷² The Commission did not

⁶⁸ *Id.*

⁶⁹ *Id.* at 88533.

⁷⁰ *Id.* at 88557 (based on a Center for Disease Control and Prevention estimate of 40.9 million contact lens wearers in the U.S.); *see also*, Jennifer R. Cope et al., "Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections—United States, 2014," *Morb. Mortal. Wkly. Rep.* 64(32):865-70, 866 (Aug. 21, 2015).

⁷¹ *Id.* at 88557 (based on 2015 Bureau of Labor Statistics data about the wage of office staff). If updated to 2017 BLS wage data, the annual cost estimate would be \$11,138,328.

⁷² Based on government and industry estimates, there are 40,200 active optometrists and 19,216 active ophthalmologists in the United States. Bureau of Labor Statistics, U.S. Dep't of Labor, Occupational Outlook Handbook, Optometrists (2016-17 Ed.), <https://www.bls.gov/ooh/healthcare/optometrists.htm>; Am. Acad. of Ophthalmology, "Eye Health Statistics" (2015), https://www.aao.org/newsroom/eye-health-statistics#_edn25. Estimates can vary as to the current number of prescribers. At the CLR workshop, Wally Lovejoy, a consultant for the National Association of Optometrists and Opticians, put the figures at 43,000 optometrists and 16,700 ophthalmologists. FTC, The Contact Lens Rule and the Evolving Contact Lens Marketplace, Panel I: Overview of the Contact Lens Marketplace Tr. at 6 (Mar. 7, 2018), https://www.ftc.gov/system/files/documents/public_events/1285493/panel_i_overview_of_the_contact_lens_marketplace.pdf [hereinafter CLR Panel I Tr.]. The per-prescriber estimate does not take into account that a small percentage of optometrists and ophthalmologists do not prescribe contact lenses, and thus would not bear the burden of the requirement.

consider maintaining the form for three years to be a substantial new burden because a majority of state laws already require maintenance of eye exam records, and the Commission felt that maintaining a one-page two-sentence form should not take more than a few seconds of time, and an inconsequential, or *de minimis*, amount of record space.⁷³ The Commission concluded that the overall burden of the new requirement was relatively minimal and outweighed by the substantial benefit of having so many more patients in possession of their prescriptions.⁷⁴

B. Comments on the Proposed Amendment to § 315.3(a)(1)

1. General Comments

In response to its signed-acknowledgment proposal, the Commission received thousands of comments and has reviewed and considered each comment. Many commenters expressed support for the FTC's proposal, and said it would help effectuate the goal of the FCLCA by ensuring consumer choice and allowing contact lens retailers to better compete on price, service, and convenience.⁷⁵ Hundreds of contact lens

⁷³ NPRM, 81 FR at 88557.

⁷⁴ NPRM, 81 FR at 88534, 88557-58. The Commission further noted that while \$10,475,495 was not insubstantial, it amounted to less than one-fourth of one percent of the overall retail market for contact lens sales in the United States.

⁷⁵ *See, e.g.*, CLR Panel V Tr., *supra* note 50, at 27 (statement of Linda Sherry calling it a “win-win” for both consumers and prescribers); FTC, The Contact Lens Rule and the Evolving Contact Lens Marketplace, Panel III: Competition in the Contact Lens Marketplace (Mar. 7, 2018) [hereinafter CLR Panel III Tr.] at 20 (statements of David Sonnenrich that “there’s strong support among the states attorneys general for the proposed amendment”), https://www.ftc.gov/system/files/documents/public_events/1285493/panel_iii_competition_in_the_contact_lens_marketplace.pdf; Utah Retail Merchants Association (NPRM Comment #2312); Americans for Tax Reform (NPRM Comment #2847) (proposed changes would protect the successes of the FCLCA while giving consumers increased flexibility); Coalition for Contact Lens Consumer Choice (NPRM Comment #3718);

consumers, in particular, expressed support for the Rule and the proposed amendment, with many stating that a signed acknowledgment would help ensure that prescribers release their prescriptions, enabling them to shop around and get the best price for their lenses.⁷⁶

Several commenters said the amendment is necessary because the market for contact lenses remains unique in that—unlike most other medical doctors—eye doctors sell the items they prescribe, and thus are rewarded financially for driving patients to their own retail channels.⁷⁷ According to one commenter, “relying on existing market

Americans for Prosperity (NPRM Comment #3770); Office of Arizona Attorney (NPRM Comment #3922). *See also* Blumenthal Letter, *supra* note 17 (expressing strong support for the signed-acknowledgment provision and applauding the FTC for “proposing pro-consumer and pro-market reforms to the Rule that will ensure robust competition ... and help improve eye care providers’ compliance”).

⁷⁶ *See e.g.*, Izquierdo (WS Comment #12); Clark (WS Comment #14); Clough (WS Comment #18); Forero (WS Comment #21); Ancona (WS Comment #27); Zeemering (WS Comment #34); Hauck (WS Comment #42); Brown (WS Comment #46); De Soto (WS Comment #49); Taylor (WS Comment #66); Cornwell (WS Comment #77); Chambers (WS Comment #91); Torres-Gambini (WS Comment #106); Hollier (WS Comment #113); Miranda (WS Comment #119); Green (WS Comment #134); Watson (WS Comment #138); Fisher (WS Comment #150); Gover (WS Comment #154); Pike (WS Comment #195); Klauscher (WS Comment #201); Kucewicz (WS Comment #215); Dawson (WS Comment #226); Pfeifer (WS Comment #246); Tennison (WS Comment #428); Florey (NPRM Comment #3520).

⁷⁷ Information Technology & Innovation Foundation (NPRM Comment #2848); Warby Parker (NPRM Comment #3867). *See also* Arizona State Representative Heather Carter (NPRM Comment #3193) (noting that in 2016, the 10th Circuit Court of Appeals held that the contact lens industry is uniquely anticompetitive in part because prescribers control the brand consumers use while also selling the lenses); Utah State Senator Curtis Bramble (NPRM Comment #576) (“The portability of a prescription is commonplace in almost every area where a prescription is needed, but often times it is hampered by the conflict that exists when a prescribing eye care provider has the opportunity to profit from the very product they’re prescribing”); Rhode Island State Representative Brian Kennedy (NPRM Comment #3724) (citing “natural conflict of interest that exists in the industry”); Blumenthal Letter, *supra* note 17 (recognizing the “inherent conflict of

forces and industry professional norms to advance the intent and purposes of the FCLCA and Contact Lens Rule does not work because prescribers have both an incentive and ability to limit consumer choice.”⁷⁸

Prescribers, however, were generally⁷⁹ critical of the Commission’s proposal, with many calling it an unnecessary burden that would also interfere with the doctor-patient relationship by implying that prescribers violate the law.⁸⁰ Many remarked that prescribers take an oath of professional conduct and abide by an ethical responsibility to

interest” and noting that the FCLCA was made necessary by “the unique nature of the contact lens marketplace”).

⁷⁸ Information Technology & Innovation Foundation (NPRM Comment #2848) (asserting that for those who would argue that more regulation is not the answer, the reason regulation is necessary in this instance is because the industry is already regulated, but in ways that give prescribers considerable power, since consumers cannot buy lenses without a prescription from their doctor).

⁷⁹ A few prescriber commenters supported the proposal, but these instances were rare. *E.g.*, Richter (NPRM Comment #2706) (ophthalmologist supporting the proposal); Simple Contacts (NPRM Comment #3479) (online prescriber and seller supporting proposal); Opternative (NPRM Comment #3785) (online prescriber supporting the proposal). Other prescriber commenters, such as the National Association of Optometrists and Opticians, supported aspects of the proposed acknowledgment, but not the Commission’s actual proposal. (NPRM Comment #3851).

⁸⁰ *See, e.g.*, CLR Panel V Tr., *supra* note 50, at 6 (statement of David Cockrell); Sorkin (WS Comment #602); Greenberg (WS Comment #628); Carlson (WS Comment #739); Johnson (WS Comment #755); Bryan (WS Comment #987); Martin (WS Comment #1168); Hill (WS Comment #1361); Armed Forces Optometric Society (NPRM Comment #2884); American Optometric Association (NPRM Comment #3830); Contact Lens Association of Ophthalmologists (NPRM Comment #4259).

place their patients' interests above their own.⁸¹ Thus, many felt they were being unfairly maligned, and the proposal was tantamount to an attack on their integrity.⁸²

2. Comments Concerning the Need for the Proposed Signed Acknowledgment Due to Non-Compliance

Several commenters asserted that the proposed signed-acknowledgment requirement is necessary because—even 14 years after creation of the Contact Lens Rule—prescribers often fail to release prescriptions automatically after a contact lens fitting.⁸³ A comment from the Attorneys General for 20 States,⁸⁴ for example, said they

⁸¹ *See, e.g.*, Sclafani (WS Comment #631); Wright (WS Comment #743); Wardell (WS Comment #792); California Optometric Association (NPRM Comment #3845).

⁸² *See, e.g.*, Dieckow (WS Comment #595) (“This is a witch hunt. It is quite parallel to the Spanish inquisition asking a village girl to prove she is not a witch”); Hallak (WS Comment #654) (“The proposed change to the contact lens release of information is ludicrous. The FTC should be ashamed for even consider [sic] it”); Owen (WS Comment #826) (“The FTC should recognize that we are not the enemy of consumers, but allies who are equally committed to protecting our patients’ health and well-being”); Morabito (WS Comment #1135) (“This is a slap in the face of good people whose very purpose is to help people”); Holt (WS Comment #1375) (“having a patient sign a piece of paper that they are entitled to receive the contact lens prescription that they have already been given is just about the FTC and 1-800 trying to find a way to punish ODs for still being in existence”); Pirozzolo (WS Comment #1431) (“No other profession is required to have the patient sign an acknowledgment of receiving a prescription”). *See also, e.g.*, Rosenblatt (WS Comment #841); Smoke (WS Comment #1184); Vosseteig (WS Comment #1205); Siegel (WS Comment #1391).

⁸³ *E.g.*, Institute for Liberty (NPRM Comment #2690); Citizen Outreach (NPRM Comment #3247); League of United Latin American Citizens (NPRM Comment #3326); Coalition for Contact Lens Consumer Choice (NPRM Comment #3718); Attorneys General for 20 States (NPRM Comment #3804); R Street Institute (NPRM Comment #3856); Warby Parker (NPRM Comment #3867); Consumers Union (NPRM Comment #3969).

⁸⁴ Alabama, Delaware, Hawaii, Idaho, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Montana, Nebraska, New Hampshire, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Virginia. Attorneys General for 20 States (NPRM Comment #3804).

“are aware, from their enforcement efforts and collective experience, that not all patients receive their prescription in writing as a matter of course.”⁸⁵ Likewise, the CEO of a large contact lens seller, 1-800 CONTACTS, stated that the company performs “secret shops” of eye doctors and consistently finds that about 50% do not release prescriptions.⁸⁶

Dozens of consumers also recounted personal stories in which they, or a family member, were either not provided with their prescriptions, experienced difficulty obtaining their prescriptions, or had to ask prescribers for them instead of receiving them automatically as required by law.⁸⁷ For example, one consumer said, “My experience has been that the majority of the time the contact lens prescription is not given out unless it’s

⁸⁵ *Id.*

⁸⁶ CLR Panel III Tr., *supra* note 75, at 11 (statements of John Graham).

⁸⁷ *See, e.g.*, Keck (WS Comment #22); Mattox (WS Comment #28); Arthur (WS Comment #47); Barrett (WS Comment #259); Tyree (WS Comment #323); Fielding (WS Comment #376); Tennison (WS Comment #428); Lambrecht (WS Comment #448); Copley (WS Comment #515); Moses (WS Comment #875); Subowicz (WS Comment #926); Brotz (WS Comment #939); Bonner (WS Comment #982); Calk (WS Comment #984); Halston (WS Comment #1101); Gonzales (WS Comment #1437); Boue (NPRM Comment #1806); Collins (NPRM #1811); Herbst (NPRM Comment #1823); Tran (NPRM Comment #1829); Lozano-Adams (NPRM Comment #1831); Krainman (NPRM Comment #1847); Walker (NPRM Comment #1848); Zirbel (NPRM Comment #1849); Zeledon (NPRM Comment #1852); Diedrich (NPRM Comment #1856); Berry (NPRM Comment #1860); Montagnino (NPRM Comment #1866); Hochberg (NPRM Comment #1879); Bogner (NPRM Comment #1881); Rasczyk (NPRM Comment #1904); Fraga (NPRM Comment #1907); Vasquez (NPRM Comment #1917); Megraw (NPRM Comment #1933); Kasal (NPRM Comment #1937); Strobel (NPRM Comment #1940); Quinlog (NPRM #1963); Somerville (NPRM Comment #1966); Stanton (NPRM Comment #2001); Austin (NPRM Comment #2022); Cotten (NPRM Comment #2024); Bulmann (NPRM Comment #2045); Miller (NPRM Comment #2062); Robertson (NPRM Comment #2124); Capuano (NPRM Comment #2722); Martinez (NPRM Comment #2894); Woelfel (NPRM Comment #3131); Thomson (NPRM Comment #3421).

specifically requested and even then on some occasions the doctor's office is reluctant to release it,"⁸⁸ and another recounted, "I have fought with many a doctor and demanded a prescription and they still state that they will not do my eye exam unless I agree to purchase my contacts from them."⁸⁹ Another commenter stated, "Each and every time I have gone to the eye doctor, I have had to ask for a copy of my prescription."⁹⁰ Of those who had to ask for their prescriptions, several consumers complained that they felt uncomfortable making such a request or felt pressured into purchasing lenses from their prescriber and may have paid a higher price in consequence.⁹¹

Many commenters also said the acknowledgment is necessary because consumers are often unaware of their right to their prescription.⁹² One commenter admitted, "I did not know this was a law. I have been charged \$25 extra for receiving my contact lens prescriptions before."⁹³ Another anecdotal, but perhaps telling, indicator of the lack of

⁸⁸ Rushton (NPRM Comment #2649).

⁸⁹ Hamilton (NPRM Comment #1835).

⁹⁰ Acton (NPRM Comment #2070).

⁹¹ *E.g.*, Moses (WS Comment #875); Brotz (WS Comment #939); Calk (WS Comment #984); Fridley (WS Comment #988); Gonzales (WS Comment #1437); Vasquez (NPRM Comment #1917); Austin (NPRM Comment #2022); Ng (NPRM Comment #3289); James (NPRM Comment #4029).

⁹² St. Louis (NPRM Comment #3531); 1-800 CONTACTS (NPRM Comment #3898). *See also, e.g.*, League of United Latin American Citizens (NPRM Comment #3326) ("Consumers who do not know their rights are being 'trapped in the exam chair,' unaware that they can buy lenses elsewhere for lower prices."); R Street Institute (NPRM Comment #3856) ("Consumers are insufficiently aware of their right to copies of their prescriptions, creating information asymmetries" between consumers and prescribers).

⁹³ Monroe (NPRM Comment #4277).

consumer awareness, was the surprising number of consumer commenters who asked the Commission to pass a Rule requiring prescribers to release their prescriptions.⁹⁴ One consumer, for instance, wrote, “I strongly urge the FTC to adopt the rule that will require eye doctors to provide patients with a copy of their prescription,”⁹⁵ and another proclaimed, “Would love to be free to purchase my contacts wherever I choose. I can’t stand that my prescription is held hostage by my eyecare provider! Please help!”⁹⁶ In other words, these commenters, and many others, filed comments urging the Commission to grant them a right that they already have, and have had since 2004, but apparently are not aware of.

a. Empirical Evidence of Compliance

In terms of empirical evidence, two commenters submitted new consumer surveys conducted by third-party polling firms, both of which reported that a substantial percentage of consumers do not receive prescriptions after a contact lens fitting as required by law.⁹⁷ One survey, submitted by 1-800 CONTACTS, reported that only 37% of patients automatically received a copy of their prescriptions after a contact lens

⁹⁴ See, e.g., Barrett (WS Comment #259); Pascucci (WS Comment #403); Biel (WS Comment #902); Randall (WS Comment #912); Rasczyk (WS Comment #913); Elliott (WS Comment #930); Slaydon (WS Comment #944); Palmer (WS Comment #956); Miller (WS Comment #1055); McBride (WS Comment #1088); Wilber (WS Comment #1162); Subach (WS Comment #1364); Krainman (NPRM Comment #1847); Boue (NPRM Comment #1806); Sattler (NPRM Comment #1808); Zeledon (NPRM Comment #1852); Vasquez (NPRM Comment #1917); Herron (NPRM Comment #1982); Tardif (NPRM Comment #2011); Burlingame (NPRM Comment #3115).

⁹⁵ Ballou (NPRM Comment #3331).

⁹⁶ Boue (NPRM Comment #1806).

⁹⁷ Consumer Action (NPRM Comment #3721); 1-800 CONTACTS (NPRM Comment #3898).

fitting.⁹⁸ The other survey, submitted by Consumer Action, reported that just 44% of consumers received prescriptions without having to ask for them.⁹⁹ According to the surveys, when consumers who did not receive prescriptions asked for them, prescribers typically complied.¹⁰⁰ But even counting those who asked for their prescriptions and subsequently received them, 24-31% of consumers—roughly 10-12 million patients a year—never received a copy of their prescriptions and were thus unable to comparison shop for lenses.¹⁰¹ This data is generally consistent with previous consumer surveys discussed in the NPRM, such as the October 2015 Survey Sampling International survey, submitted by 1-800 CONTACTS, which found that 35% of consumers automatically

⁹⁸ 1-800 CONTACTS (NPRM Comment #3898, Ex. A). Data is based on an online survey performed by the polling firm Survey Sampling International (“SSI”) on behalf of 1-800 CONTACTS. According to 1-800 CONTACTS, the survey was conducted during December 2016 and sampled 1000 contact lens wearers.

⁹⁹ Consumer Action (NPRM Comment #3721). Data is based on a Caravan ORC International telephone survey of 2018 adults performed in January 2017. *See also* CLR Panel V Tr., *supra* note 50, at 2 (statements of Linda Sherry).

¹⁰⁰ *See* Consumer Action (NPRM Comment #3721) (showing that 21% of total patients had to ask the prescriber for their prescription, and 20% of total patients received it upon request); 1-800 CONTACTS (NPRM Comment #3898, Ex. A) (showing that 36% of total patients had to ask for their prescription, and 31% of total patients received it immediately upon request, while 5% were told to call the office or return at a later time to receive a copy).

¹⁰¹ *See* Consumer Action (NPRM Comment #3721); 1-800 CONTACTS (NPRM Comment #3898, Ex. A). The 10-12 million calculation is based on the estimate that there are currently 41 million contact lens wearers in the United States and that each patient receives one contact lens fitting a year. The Commission uses this estimate here since it used the same figures to assess the burden of the Rule. In actuality, it is probably less, since some contact lens wearers go longer than twelve months between fittings.

received a prescription, 28% received one after asking for it, and 36% did not receive one at all.¹⁰²

The Consumer Action survey also found that 60% of consumers responded “no” when asked, “Are you aware that under federal law, a doctor or exam provider is required to automatically provide their patient with a copy of their prescription after they get their contact lens exam?”¹⁰³ 1-800 CONTACTS cited a previously submitted survey, which found that 46% of contact lens wearers were unaware that they had a right to receive a “hard copy” of their prescription.¹⁰⁴

Various prescriber commenters criticized the polling evidence as “unreliable,”¹⁰⁵ and said the aforementioned surveys are tainted by the interests of their sponsors.¹⁰⁶

¹⁰² NPRM, 81 FR 88531-32. Data was based on a SSI online survey of 500 contact lens wearers in 2015. As noted in the NPRM, the manner in which the questions were phrased in this particular survey raised some Commission concerns, since some of them were leading, lacked an “I don’t know” option, and used a term—“hard copy”—which not all patients may understand. *Id.* at 88531 n.73.

¹⁰³ Consumer Action (NPRM Comment #3721). Data is based on a Caravan ORC International telephone survey of 2018 adults performed in January 2017. Thirty-eight percent said “yes,” and 2% responded “I don’t know” or refused to answer. The Commission has some concerns that the question was leading, but also notes that it is possible that the 60%-unaware result actually underestimates the number of consumers unaware of their rights. This is due to social desirability bias, the tendency of survey respondents to answer questions in a manner that will be viewed favorably by others. As noted in the NPRM, respondents may be reluctant to admit that they are unaware of their rights under the law. NPRM, 81 FR at 88532.

¹⁰⁴ 1-800 CONTACTS (NPRM Comment #3898). Data is based on a SSI online survey of 500 contact lens wearers in 2015. NPRM, 81 FR at 88532.

¹⁰⁵ CooperVision, Inc. (NPRM Comment #3841). *See also* Coalition for Patient Vision Care Safety (NPRM Comment #3883) (“the quality of evidence is not sufficient to support the need for this requirement”).

¹⁰⁶ American Academy of Ophthalmology (WS Comment #2971) (“It is our opinion that evidence should not include industry-sponsored surveys, seeking a specific

According to two prescriber associations, evidence submitted by 1-800 CONTACTS should not be deemed reliable because the submitter is a “stakeholder” rather than a disinterested party and has a history of aggressively seeking competitive advantages.¹⁰⁷ The American Optometric Association (“AOA”) further noted that Consumer Action—a non-profit consumer advocacy organization—has received corporate financial support from, among others, 1-800 CONTACTS.¹⁰⁸

The AOA also asserted that consumer surveys may be unreliable because they are based on patient-reported data and—as the Commission has previously recognized—patients might not always understand that they are entitled to a copy of their prescription only after their contact lens fitting has been fully completed.¹⁰⁹ To rebut these surveys

result, to propel a specific narrative for their benefit.”); American Optometric (WS Comment #3303) (“We question the legitimacy of the information on alleged non-compliance that 1-800 CONTACTS has provided to the Commission.”).

¹⁰⁷ American Academy of Ophthalmology (WS Comment #2971); American Optometric Association (WS Comment #3303). In particular, the AOA argues that surveys conducted on behalf of 1-800 CONTACTS are not credible because: (1) The FTC has previously sued 1-800 CONTACTS for anti-competitive practices against other contact lens retailers (*see* <https://www.ftc.gov/enforcement/cases-proceedings/141-0200/1-800-contacts-inc-matter>); (2) 1-800 CONTACTS supports online vision examinations and thus might have a financial interest in discrediting brick-and-mortar optometrists; and (3) the Arizona Board of Optometry concluded that many complaints about prescriber non-compliance that 1-800 CONTACTS filed with the board were unfounded. *See also* Bhadra (WS Comment #801) (“I find it disingenuous that these online retailers have flooded the public with fake news that ODs are not giving patients their contact lens prescriptions.”).

¹⁰⁸ American Optometric Association (WS Comment #3303).

¹⁰⁹ *Id.* *See also* CooperVision, Inc. (NPRM Comment #3841) (stating Commission overstates evidence of noncompliance by not distinguishing between initial visits to prescribers and subsequent contact lens fittings in which the

and demonstrate that prescribers are complying, the AOA submitted a survey of fifty-seven “high-volume optometrists,” in which 93% said “yes” when asked, “Do you follow Federal law and provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting?”¹¹⁰

As the Commission acknowledged in its NPRM, all surveys have limitations with respect to methodology and evidence, and, in this instance, the Commission does not treat any one survey as definitive. Patients may sometimes misremember details of a particular encounter with a prescriber, and prescribers may be mistaken about the particulars of a given clinical encounter or about the frequency with which they do or do not release prescriptions. For the most part, the submitted surveys do not include independent objective tests of patient or prescriber recollections. In addition, survey responses may be sensitive to the ways in which questions are framed.

Despite what some commenters recommend, however, the Commission does not dismiss survey evidence based solely on the source of its submission. While the Commission is cognizant of the interests of submitting parties, the Commission examines the underlying survey data and methodology to gauge a survey’s usefulness. In the case of the consumer surveys, which were conducted by established third-party polling firms, the submitters provided the Commission with the underlying questions, responses, and

prescription is finalized); NPRM, 81 FR at 88530-31 (noting that consumers are not not always aware of when they are entitled to their prescriptions).

¹¹⁰ American Optometric Association (WS Comment #3303, App. B). This survey appears to have been conducted by the AOA itself rather than an outside polling firm. It is not clear from the AOA’s submission how the fifty-seven optometrists were selected for the survey, what it means to be a “high volume” optometrist, or why high volume optometrists were chosen.

statistical data, as well as details about survey methodology. Based on its review of the submitted material, the Commission finds that the two new consumer surveys represent an improvement over previously submitted consumer surveys. In particular, the new surveys include an option for respondents to acknowledge that they do not recall whether they received their prescriptions and use the term “paper copy” rather than “hard copy,” a term the Commission has previously noted some patients may not understand. The number of consumers polled is also larger than some previous surveys. The Commission further recognizes that the new surveys are generally consistent with the findings of previously-submitted surveys, and that multiple surveys conducted by different sources at different times with similar results bolster the credibility of each individual survey. The Commission also has not received any consumer-survey data rebutting these findings or indicating that consumers consistently receive their prescriptions in satisfactory numbers. The Commission therefore accords the overall submitted consumer-survey data significant weight.

In contrast, the Commission finds the AOA-submitted survey of prescribers less useful as a tool to assess compliance with the prescription-release requirement. The Commission has several concerns. Besides concerns about the small sample size (fifty-seven) and lack of detail as to how prescriber respondents were recruited, the Commission notes that the way the question is phrased¹¹¹ allows prescribers to truthfully answer that they provide patients with a copy of their prescription even if they do not do so for *every* patient, and even if they only do so when the patient requests one.

¹¹¹ “Do you follow Federal law and provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting?”

Moreover, the wording of the survey question makes it highly unlikely a prescriber would admit to not releasing prescriptions. As noted (in a different context) in the NPRM, asking a respondent if he or she is aware of their rights or obligations under the law can skew responses, since respondents may be unwilling to admit they are ignorant of the law or violate it.¹¹² In this instance, prescribers also have a clear incentive to say they follow Federal law even if they do not (whereas consumers do not have a clear incentive to say that prescribers are not providing them with their prescriptions). Based on the wording and framing of the question in the AOA survey, the Commission is surprised that even 7% of prescribers answered that they do not provide patients with their prescriptions, a result that, if extrapolated to the population of prescribers, would still mean that every year more than 2.7 million consumers are denied their prescriptions—and their ability to comparison-shop for more affordable contact lenses—in violation of the law.¹¹³

Apart from the three surveys, no other commenter submitted empirical evidence of automatic-release compliance or consumer awareness.¹¹⁴ Several commenters, nonetheless, strongly opined that the Commission lacks “compelling evidence” that the

¹¹² See NPRM, 81 FR at 88532.

¹¹³ This calculation is based on estimates that there are currently 41 million contact lens wearers in the United States and that each patient gets one contact lens fitting a year. See *supra* note 101.

¹¹⁴ At the CLR Workshop, some audience members commented that in their state, the prescription release rate was 100%. Commission staff asked that this data be provided, but it never was. See CLR Panel V Tr., *supra* note 50, at 23. Another commenter, Lens.com, commented that more than half of its customers “report that optometrists still do not provide prescriptions as required by law.” (NPRM Comment #2358). However, Lens.com could not provide the Commission with information about how it surveyed its customers and exactly what consumers reported, so the Commission has not relied on this evidence.

signed acknowledgment is needed¹¹⁵ and said they are “unaware” of significant compliance problems among eye-care professionals.¹¹⁶ Numerous prescribers also declared that, personally, they consistently release prescriptions to patients after each contact lens fitting, and believe their colleagues do the same.¹¹⁷ Several prescribers were also firm in their belief that patients are fully aware they have a right to their prescription,¹¹⁸ with some noting that advertising and marketing from third-party sellers

¹¹⁵ McGrew (WS Comment #713). *See also, e.g.*, American Society of Cataract and Refractive Surgery (WS Comment #3142); Davies (WS Comment #3307); Utah Ophthalmology Society (NPRM Comment #2586); American Academy of Ophthalmology (NPRM Comment #3657); CooperVision, Inc. (NPRM Comment #3841).

¹¹⁶ *See, e.g.*, Cooperman (NPRM Comment #2382); American Academy of Ophthalmology (NPRM Comment #3657); American Society of Cataract and Refractive Surgery (NPRM Comment #3820); American Optometric Association (NPRM Comment #3830); Wisconsin Academy of Ophthalmology (NPRM Comment #4152); Kentucky Academy of Eye Physicians and Surgeons (NPRM Comment #4276).

¹¹⁷ *E.g.*, Palys (WS Comment #560); Widmann (WS Comment #618); Nixon (WS Comment #687); Bausback (WS Comment #708); Lo (WS Comment #856); Hanian (WS Comment #1196); Carkner (WS Comment #1287); Myers (WS Comment #1322); Leung (WS Comment #1600); Randle (WS Comment #2171); Stamm (WS Comment #2512); Swan (WS Comment #2843); Olson (WS Comment #2970); Wisniewski (NPRM Comment #1769). Over sixty prescribers also submitted identical, or nearly identical, comments which included the following statement, “First, I would like to make clear that I comply with the requirements of the Fairness to Contact Lens Consumers Act (FCLCA) and the corresponding Contact Lens Rule by providing copies of contact lens prescriptions to contact lens wearing patients at the end of the contact lens fitting process.” *E.g.*, Shepherd (WS Comment #483); Alexander (WS Comment #468); Morton (WS Comment #488); Skrdla (WS Comment 492); Smith (WS Comment #493); Hertneky (WS Comment #494); Eklund (WS Comment #502); Buchanan (WS Comment #520); Borden (WS Comment #865); Bryan (WS Comment #987); (Redmond (WS Comment #989).

¹¹⁸ *E.g.*, Lonsk (WS Comment #596); Friederich (WS Comment #614); Highsmith (WS Comment #690); Bedsole (WS Comment #1024); Phillips (WS

help remind patients of their rights.¹¹⁹ Many prescribers thus proclaimed that the signed-acknowledgment proposal was a waste of resources, both for prescribers and the Commission,¹²⁰ and called it a “solution in search of a problem.”¹²¹ Other commenters said that even if it is true that a small number of prescribers do not comply with the automatic-release requirement, the proposed acknowledgment requirement would be, in effect, “punishing the masses for the sins of the few.”¹²²

Prescriber assertions about overwhelming compliance with the automatic-release requirement are undermined somewhat by the large number of prescriber commenters who misstated the Rule and said that they “offer” prescriptions to their patients or provide

Comment #1151); Sumner (WS Comment #1332); Hill (NPRM Comment #3561).
#3561).

¹¹⁹ California Academy of Eye Physicians and Surgeons (NPRM #4269) (online retailers are “not shy” about letting consumers know they have a right to their prescriptions). *See also* Dinh (WS Comment #1653); Ulc (WS Comment #2347).

¹²⁰ *See, e.g.*, To (WS Comment #597); DeKinder (WS Comment #625); Bausback (WS Comment #708).

¹²¹ *E.g.*, Kaminski (WS Comment #607); Bank (WS Comment #653); Melman (WS Comment #667); Nixon (WS Comment #687); Hamilton (WS Comment #781); Martin (WS Comment #1168); McMahon (WS Comment #1868); Randle (WS Comment #2171); Jones (WS Comment #3079); Cervantes (WS Comment #3125); Khong (WS Comment #3435). *See also e.g.*, Larson (WS Comment #716); Ambler (WS Comment #2329); Fritsch (WS Comment #2543); Hornstein (WS Comment #2666).

¹²² McKinnis (WS Comment #786). *See also, e.g.*, Wesley (WS Comment #835); Kline (WS Comment #852); Holcomb (WS Comment #872); Edwards (WS Comment #884); Boyce (WS Comment #1466); Woodward (NPRM Comment #273); McLaughlin (NPRM #1365); Blankenship (NPRM Comment #2117); Armed Forces Optometric Society (NPRM Comment #2884); Sonsino (NPRM Comment #3783); Sterna (NPRM Comment #3892).

them “when requested,” rather than provide them automatically after each fitting.¹²³ Ten state ophthalmology associations commented that the signed acknowledgment is unnecessary because eye doctors in their states are providing patients with their prescriptions “*when requested* in full compliance with the Contact Lens Rule”¹²⁴ (emphasis added). Both the Act and the Rule specifically require that a prescription be provided to each patient “whether or not requested by the patient,” and the Commission does not have authority to amend the statute or disregard this obligation.

b. Verifications as Evidence of Lack of Prescription Release

Many prescribers also contend that the Commission erred in its NPRM finding that the large number of contact lens sales conducted via verifications is evidence of lack of prescription release. According to these commenters, the number of verifications does not reflect lack of prescription release since some consumers may lose their copies and some online sellers promote the ease (for the consumer) of the verification method.¹²⁵ In

¹²³ See, e.g., Moore (WS Comment #544); Heiby (WS Comment #694); Larson (WS Comment #716); Krisciunas (WS Comment #1085); Pebley (WS Comment #1261); Horibe (WS Comment #3242); Mitsoglou (NPRM Comment #480); Frieman (NPRM Comment #2589); Cooper (NPRM Comment #2673).

¹²⁴ Utah Ophthalmology Society (NPRM Comment #2586); South Dakota Academy of Ophthalmology (NPRM Comment #2588); Michigan Society of Eye Physicians and Surgeons (NPRM Comment #4165); Florida Society of Ophthalmology (NPRM Comment #4197); Iowa Academy of Ophthalmology (NPRM #4199); Oklahoma Academy of Ophthalmology (NPRM Comment #4204); Pennsylvania Academy of Ophthalmology (NPRM Comment #4214); Indiana Academy of Ophthalmology (NPRM Comment #4233); Massachusetts Society of Eye Physicians and Surgeons (NPRM Comment #4270); Kentucky Academy of Eye Physicians and Surgeons (NPRM Comment #4276).

¹²⁵ American Optometric Association (NPRM Comment #3830) (sellers promote verification as an easy way to get refills).

contrast, some sellers stated that from a business standpoint, they prefer and encourage patients to present prescriptions rather than rely on verification, since it is faster for the consumer and less costly for the seller.¹²⁶ 1-800 CONTACTS, for instance, promotes presentation at checkout as a way for consumers to get their lenses more quickly, and has run promotional campaigns offering consumers a discount on lens orders if they would send in a copy of their prescription.¹²⁷ Additionally, several commenters, including some prescribers, agreed that a signed acknowledgment would likely reduce the percentage of sales via verification, indicating that some percentage of consumers are not receiving their prescriptions at their contact lens fitting.¹²⁸ Nevertheless, the Commission recognizes that it can be more cumbersome for a consumer to locate and upload a prescription than to simply type in the name of their prescriber and their prescription information—which they can obtain from their contact lens boxes—and thus some consumers may opt for verification even though they did receive a copy of their prescription. The Commission is also aware that some online contact lens sellers do not currently have a mechanism for patients to present their actual prescriptions, and rely solely on verification. Thus, while the Commission will still consider the large

¹²⁶ See FTC, *The Contact Lens Rule and the Evolving Contact Lens Marketplace*, Panel IV: Examining the Verification Process Tr. at 6-7 (Mar. 7, 2018), https://www.ftc.gov/system/files/documents/public_events/1285493/panel_iv_examining_the_verification_process.pdf [hereinafter CLR Panel IV Tr.] (statement of Jennifer Sommer); *id.* at 6-7, 22 (statement of Cindy Williams).

¹²⁷ *Id.* at 6-7.

¹²⁸ See, e.g., CLR Panel V Tr., *supra* note 50, at 9 (statement of David Cockrell that it would absolutely reduce the number of verifications, but would not eliminate them, since patients often lose their prescription copies); National Association of Optometrists and Opticians (WS Comment #3208); Costco Wholesale Corporation (NPRM Comment #4281).

percentage of third-party contact lens sales conducted via verification¹²⁹ as suggestive of prescriber failure to release prescriptions, the Commission will accord it less weight than it did in the NPRM.

c. The Dearth of Consumer Complaints to the FTC as Evidence of Prescriber Compliance

Several commenters made the point that, in proportion to the total number of contact lens users in the United States, there have been relatively few consumers—only a few hundred—who actually filed complaints with the Commission about prescribers’ failing to release prescriptions, and since 2007, only fifty-five prescribers have received FTC warning letters about possible non-compliance.¹³⁰ According to these commenters—the American Optometric Association, in particular—the small percentage of complaining consumers and Commission warning letters indicates that prescribers, for the most part, are complying with the automatic prescription-release requirement.¹³¹

¹²⁹ NPRM, 81 FR at 88531 (estimated at roughly three-quarters of third-party sales).

¹³⁰ American Optometric Association (WS Comment #3303); (American Optometric Association, NPRM Comment #3830). According to AOA’s analysis of consumer complaints filed with the Commission, from 2012-2016, there have been only 309 complaints relating to prescriber failure to release prescriptions, and only .0003% of the 41 million contact lens wearers, approximately 123 patients, filed what the AOA regarded as potentially valid complaints about a prescriber’s failure to release a prescription. *See also, e.g.*, Stubinski (WS Comment #1701); Fritsch (WS Comment #2543); Higley (WS Comment #2857); Tran (WS Comment #3106).

¹³¹ American Optometric Association (WS Comment #3303). *See also e.g.*, Stubinski (WS Comment #1701); Fritsch (WS Comment #2543); Higley (WS Comment #2857); Tran (WS Comment #3106); CLR Panel IV Tr., *supra* note 126, at 23 (statement of David Cockrell that “if it was a real problem for patients, you would have an enormous number of complaints”). The AOA complaint figures were also cited by a number of other commenters, as well as by several legislators who sent letters to the Commission. *See, e.g.*, Cook (WS Comment #7); To (WS Comment #597); Smith (WS Comment #732); Gordon

Other commenters, such as 1-800 CONTACTS,¹³² challenged that assertion and contended that there are many reasons consumers do not file formal complaints each time a prescriber fails to provide a prescription. To support this, 1-800 CONTACTS submitted a report by Stanford University Professor Laurence Baker, which opined that consumers are unlikely to register formal complaints because they (1) may not know they

(WS Comment #1694); Toon (WS Comment #1741); Mattson (WS Comment #1784); #1784); Letter from Twenty-Four Members of the United States House of Representatives Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (Sept. 17, 2018). https://www.ftc.gov/system/files/filings/initiatives/677/congress_letter_to_chairman_simons_re_ftc_contact_lens_rule_9-17-2018.pdf [hereinafter Letter from Twenty-Four Representatives]; Letter from Seven Members of the United States House of Representatives Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (July 27, 2018). https://www.ftc.gov/system/files/filings/initiatives/677/denham_ftc_fclda_code_of_regulations_regarding_contact_lens_prescription.pdf [hereinafter Letter from Seven Representatives]; Letter from Fifty-Four Members of the United States House of Representatives Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (May 10, 2018). https://www.ftc.gov/system/files/filings/initiatives/677/contact_lens_letter_may_10_2018.pdf [hereinafter Letter from Fifty-Four Representatives]; Letter from Senator David Perdue of the United States Senate Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (Nov. 17, 2017), https://www.ftc.gov/system/files/filings/initiatives/677/public_comment_filed_by_senator_david_perdue_in_the_contact_lens_rulemaking.pdf; Letter from Senator John Boozman of the United States Senate Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (Aug. 3, 2017), https://www.ftc.gov/system/files/filings/initiatives/677/boozman_letter_contact_lens_rule_8-3-17.pdf [hereinafter Boozman Letter]; Letter from Fifty-Eight Members of the United States House of Representatives Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (July 24, 2017), https://www.ftc.gov/system/files/filings/initiatives/677/r511995_contact_lens_rule_letter_from_58_representatives_7-24-17.pdf [hereinafter Letter from Fifty-Eight Representatives].

¹³² 1-800 CONTACTS (WS Comment #3207).

are entitled to a copy of the prescription, (2) may not know who to complain to in the event they do not receive their prescription, (3) may be reluctant to create ill-will between them and their doctor, and (4) may calculate that the time and effort of registering a complaint outweigh any benefit they are likely to obtain.¹³³

The Commission understands and recognizes the prescriber-commenters' position that there are relatively few consumer complaints, but believes that consumer complaints, on their own, are a poor reflection of prescriber compliance or non-compliance with the Rule. The Commission has gleaned, through its extensive experience with consumer complaints and deceptive practices, that the vast majority of injured or impacted consumers do not file complaints with the government. According to a 2004 FTC report, only 8.4% of U.S. fraud victims complained to an official source, with only 1.4% complaining to the FTC.¹³⁴ Likewise, the FTC's 2011 Fraud Survey reported that 25.6 million Americans were victimized by fraud that year,¹³⁵ yet the FTC received only 1.3 million fraud complaints.¹³⁶ Furthermore, with the notable exception of the

¹³³ Laurence C. Baker, "Analysis of Costs and Benefits of the FTC Proposed Patient Acknowledgment and Recordkeeping Amendment to the Contact Lens Rule," 11 (2017), https://www.ftc.gov/system/files/summaries/initiatives/677/meeting_summary_for_the_contact_lens_rulemaking_proceeding.pdf [hereinafter Baker Analysis].

¹³⁴ Keith B. Anderson, FTC, "Consumer Fraud in the United States: An FTC Survey" 80 (2004), <http://www.ftc.gov/reports/consumer-fraud-united-states-ftc-survey>.

¹³⁵ Keith B. Anderson, FTC, "Consumer Fraud in the United States, 2011: The Third FTC Survey" 18 (2013), https://www.ftc.gov/sites/default/files/documents/reports/consumer-fraud-united-states-2011-third-ftc-survey/130419fraudsurvey_0.pdf.

¹³⁶ This includes all the complaints about identity theft, which are sometimes catalogued differently than fraud. FTC, "Consumer Sentinel Data Book for January – December 2011" 5 (2012),

Telemarketing Sales Rule (often referred to as “Do Not Call”), consumer complaints about FTC rule violations are even more uncommon, perhaps because they require that consumers know what an FTC rule specifies and how it has been violated.¹³⁷ Indeed, of the many consumer commenters to the NPRM—some fifty-one of whom are cited above¹³⁸—who recounted personal stories in which they, or a family member, faced obstacles obtaining their prescription, not one of them appears to have registered a complaint with the FTC.¹³⁹ While the Commission regards consumer complaints as extremely valuable and informative, it is aware that they often represent just the tip of the iceberg.

<https://www.ftc.gov/sites/default/files/documents/reports/consumer-sentinel-network-data-book-january-december-2011/sentinel-cy2011.pdf>.

¹³⁷ See generally, *id.*; FTC, “Consumer Sentinel Network Data Book for January-December 2016” (2017), https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-january-december-2016/csn_cy-2016_data_book.pdf. Consumer reticence to complain, particularly to a government entity, is well documented. See Marc A. Grainer et al., “Consumer Problems and Complaints: a National View,” 6 *Advances in Consumer Res.* 494 (1979) (noting that “only a small, vocal minority of consumers complain about the problems they experience,” and even fewer (less than 10% of complaints) complain to the government), <http://acrwebsite.org/volumes/9603/volumes/v06/NA-06>. See also John Goodman & Steve Newman, “Understand Customer Behavior and Complaints,” *Quality Progress*, Jan. 2003), at 51 (finding that for problems that resulted in a relatively minor inconvenience or a small loss of money, only 3% of consumers complained), http://web.ist.utl.pt/~ist11038/CD_Casquilho/PRINT/qp0103goodman.pdf.

¹³⁸ See *supra* notes 87-90.

¹³⁹ The Commission has been unable to locate any prior complaints about prescription release filed by any of the consumer commenters to the NPRM, but complaint records typically only go back five years, and thus the Commission cannot ascertain with absolute certainty whether any of them ever registered a complaint in the past.

Furthermore, as evidenced by the aforementioned consumer surveys, many contact lens wearers (46-60%) do not realize they are entitled to receive their prescription, and thus would not even be aware that an incident about which they should complain had occurred, and many others might be unaware of where to direct a complaint when they do not receive a prescription. While many prescriber commenters assert that consumers know their rights, the Commission has not received empirical evidence contradicting the consumer surveys.

Lastly, even consumers who are aware that they have a right to their prescription are unlikely to file complaints with the Commission if they ultimately receive their prescription *after they have asked for them*. From their perspective, they have resolved their problem and may perceive little benefit to themselves from filing a government complaint. Consumers may also not want to risk antagonizing their doctors or subjecting their eye-care providers to legal penalties. Thus, for evaluating Contact Lens Rule compliance—more so than for some other Commission circumstances—the low rate of consumer complaints is less probative of the scope of the problem than consumer survey evidence.¹⁴⁰

Relying on consumers to remedy their own injury by asking for their prescriptions, however, is problematic. Many consumers are uncomfortable asking for prescriptions, since it signals to the prescriber that they plan to purchase lenses elsewhere.¹⁴¹ Many consumers have a good relationship with their prescribers and do not

¹⁴⁰ Consumer surveys may also be more reliable since consumers questioned at random are less likely to have a personal interest in stating that they did not receive their prescription.

¹⁴¹ See *supra* note 91.

want to do something that might be viewed as disloyal. Others may not want to openly acknowledge that they are concerned about the cost of purchasing contact lenses. Moreover, relying on patients to ask for their prescriptions effectively re-writes the FCLCA requirement that prescribers release prescriptions automatically, and amends it to release-upon-request. This would directly contravene Congressional intent and the text of the Act, which specifically states that prescriptions are to be given “whether or not requested by the patient.”¹⁴² When the Commission considered such a change with respect to prescription release under the Eyeglass Rule (which the Commission does have the authority to amend), the Commission repeatedly rejected such an approach as inappropriate since it shifts the burden of prescription-release enforcement to the consumer.¹⁴³

3. Comments Concerning Whether a Proposed Signed Acknowledgment Is Needed for Better Enforcement and Auditing of the Rule

In its December 2016 NPRM, the Commission noted that a signed acknowledgment would increase the Commission’s ability to assess and verify

¹⁴² 15 U.S.C. 7601(a)(1).

¹⁴³ See Eyeglass I, 43 FR at 23998 (stating that relying upon release-upon-request is problematic because many consumers are unaware of their right to a prescription, and because the right should be “immunized from an evidentiary squabble over whether the consumer actually did or did not request the prescription”); Final Trade Regulation Rule, Ophthalmic Practice Rules 54 FR 10285, 10286-87 (Mar. 13, 1989) [hereinafter Eyeglass II] (rejecting a proposal to change the Rule to release-upon-request and finding a “continuing need” for automatic release). See also Contact Lens Rule, 69 FR at 40492 (discussing a commenter proposal to allow prescribers to not release the prescription or release it “for informational purposes only” if the patient has purchased a full year’s supply of contact lenses at the time of the examination, and rejecting it because “such an exception would be contrary to the Act’s express requirement that consumers receive a copy of their prescription at the completion of a contact lens fitting”).

compliance with the Rule.¹⁴⁴ Several commenters agreed, suggesting that the signed-acknowledgment proposal is necessary because the prescription-release requirement is currently difficult or impossible to enforce.¹⁴⁵ According to one commenter, prescribers have little incentive to comply with automatic release because compliance could result in lost sales, and absent some evidentiary record, an FTC enforcement action is extremely unlikely.¹⁴⁶ Another commenter noted that while the Commission has sent warning letters in response to complaints about lack of prescription release, the Commission has yet to bring an enforcement action or seek fines against a prescriber for failure to release contact lens prescriptions.¹⁴⁷ According to some commenters, the Commission needs an auditable process in order to enforce the Rule and the FCLCA.¹⁴⁸ To demonstrate how the current Rule lacks teeth, one commenter, 1-800 CONTACTS, commented that it conducted a follow-up “secret shop” of twenty-one of the forty-five prescribers who

¹⁴⁴ NPRM, 81 FR at 88532.

¹⁴⁵ See, e.g., Information Technology and Innovation Foundation (NPRM Comment #2848); Arizona State Rep. Heather Carter (NPRM Comment #3193); Semelsberger (NPRM Comment #3856); 1-800 CONTACTS (NPRM Comment #3898).

¹⁴⁶ Warby Parker (NPRM Comment #3867).

¹⁴⁷ 1-800 CONTACTS (NPRM Comment #3898). The Commission has brought one case against a prescriber for failure to release eyeglass prescriptions in violation of the Eyeglass Rule, and resolved the suit with a consent decree and \$10,000 penalty. *United States v. Doctors Eyecare Ctr. Inc.*, No. 96-cv-012224-D (N.D. Tex. June 25, 1996). It is also worth noting that warning letters are typically sent in response to consumer complaints, and, as noted *supra*, for a number of reasons, consumers are unlikely to complain to the Commission when they do not receive their prescriptions.

¹⁴⁸ See Information Technology and Innovation Foundation (NPRM Comment #2848); 1-800 CONTACTS (NPRM Comment #3898); Costco Wholesale Corporation (NPRM Comment #4281). See also CLR Panel III Tr., *supra* note 75, at 12 (“there needs to be a mechanism for enforcement”).

received FTC warning letters in 2016, and found that even after receiving these warnings, eighteen still failed to automatically release a prescription after completion of a contact lens fitting.¹⁴⁹ Some commenters also suggested that a signed record would actually help prescribers by giving them a way to prove that they provided the prescription, and thus prevent consumers from incorrectly alleging that a prescriber violated the law.¹⁵⁰

Other commenters, however, suggested that the Commission could do a better job of enforcing the current release requirement instead of adding a signed-acknowledgment requirement.¹⁵¹ One commenter suggested that instead of the signed acknowledgment, the Commission should conduct its own “secret shops” of prescriber offices and fine those who fail to release prescriptions.¹⁵²

Several prescribers also suggested that the signed-acknowledgment requirement itself would be difficult to enforce¹⁵³ or that it was unlikely that prescribers who do not currently comply with prescription release would comply with the signed-acknowledgment requirement.¹⁵⁴ Similarly, some prescribers doubted whether

¹⁴⁹ Baker Analysis, *supra* note 133, at 10.

¹⁵⁰ CLR Panel V Tr., *supra* note 50, at 27 (statements of Linda Sherry); Consumers Union (NPRM Comment #3969).

¹⁵¹ *See e.g.*, Bernard (WS Comment #588); Click (WS Comment #876).

¹⁵² Pearl (WS Comment #824).

¹⁵³ Missouri Optometric Association (NPRM Comment #1208).

¹⁵⁴ *See, e.g.*, Pearl (WS Comment #824); Koch (WS Comment #855); Holcomb (WS Comment #872); Edwards (WS Comment #884); Alwes (WS Comment #998); Jones (WS Comment #2778); Contact Lens Association of Ophthalmologists (NPRM Comment #4259); California Academy of Eye Physicians and Surgeons (NPRM Comment #4269).

consumers would read the signed-acknowledgment document and thus questioned its use for education purposes.¹⁵⁵

4. Comments About the Burden of the Signed-Acknowledgment Proposal

A significant number of commenters felt that the Commission underestimated the burden that the signed-acknowledgment requirement would impose on prescribers, and said the actual burden would be much more “substantial.”¹⁵⁶ According to commenters, the Commission’s estimate¹⁵⁷ did not fully recognize the time it would take to train office staff, answer consumers’ questions, and create, produce and store the acknowledgment

¹⁵⁵ CLR Panel V Tr., *supra* note 50, at 9 (statements of Zachary McCarty); Gasparini (WS Comment #825); Schweiger (WS Comment #993).

¹⁵⁶ American Academy of Ophthalmology (NPRM Comment #3657). *See also*, e.g., American Society of Cataract and Refractive Surgery (NPRM Comment #3820) (“will have significant cost implications”); CLR Panel V Tr., *supra* note 50, at 6 (statement of David Cockrell) (“I think it creates a very significant burden.”); Rohler (NPRM Comment #377); Stott (NPRM Comment #687).

¹⁵⁷ The Commission's estimate was forty-one million minutes per year, based on an estimate of 41 million contact lens wearers and one minute to present each patient with the form, obtain a signature, and scan or store the record. NPRM, 81 FR at 88557. The Commission stated that in all likelihood, the burden would actually be far less, since the Commission did not credit the reduction in verification burden that would likely occur once additional consumers were in possession of their prescriptions. Additionally, not all contact lens wearers obtain eye exams every year. In 2017, for instance, there were approximately 34 million contact lens eye exams in the U.S. CLR Panel I Tr., *supra* note 72, at 5 (statements of Steve Kodey). If the number of actual exams had been used to calculate the burden, this would have reduced the estimated burden to 34 million minutes. *See also* 1-800 CONTACTS (NPRM Comment #3898) (estimating that the average exam frequency for contact lens patients is 15 months, citing <https://www.clspectrum.com/issues/2016/november-2016/four-strategies-for-practice-growth>); CLR Panel IV Tr., *supra* note 126, at 3 (statements of Cindy Williams) (stating that evidence indicates the majority of contact lens wearers get an exam once every 12-16 months).

form for three years.¹⁵⁸ The National Association of Optometrists and Opticians (“NAOO”) predicted the acknowledgment requirement would add five minutes to each transaction “because of the need to explain the reason for the signature to the patient,”¹⁵⁹ and stressed that “storage of the myriad pieces of paper is not a small burden.”¹⁶⁰

Several prescribers predicted they would incur thousands of dollars in staff time, printing, and electronic records costs, although most did not provide a detailed basis for their estimates.¹⁶¹ Some commenters also questioned why the Commission was imposing a paper-storage requirement when so many physicians—at the urging of health authorities—are moving toward electronic records, and spending significant amounts of money to make that transition.¹⁶² Others said they already make the prescription available electronically via patient portals, so this would just generate unnecessary paper waste.¹⁶³

¹⁵⁸ See, e.g., National Association of Optometrists and Opticians (WS Comment #3208); Toepfer (NPRM Comment #652); Slusser (NPRM Comment #149); Armed Forces Optometric Society (NPRM Comment #2884); American Society of Cataract and Refractive Surgery (NPRM #3820); American Optometric Association (NPRM Comment #3830); California Optometric Association (NPRM Comment #3845).

¹⁵⁹ National Association of Optometrists and Opticians (NPRM Comment #3851).

¹⁶⁰ *Id.*

¹⁶¹ See, e.g., Wright (WS Comment #743); Wesley (WS Comment #835); Norman (WS Comment #1285); Paulsen (WS Comment #1335); Dice (WS Comment #1585); Loomis (WS Comment #3300); California Optometric Association (NPRM #3845).

¹⁶² E.g., Akers (WS Comment #577); Rule (WS Comment #775); Schindler (WS Comment #1160); Ball (WS Comment #2861).

¹⁶³ E.g., Nau (WS Comment #683); Carvell (WS Comment #1021). See also Chuang (WS Comment #864).

A number of commenters predicted that the burden would force prescribers to raise patient fees to cover increased administrative costs.¹⁶⁴ Some also felt it was unfair that prescribers, who currently shoulder a larger financial share than sellers of the costs imposed by the Rule, would now be responsible for even more.¹⁶⁵ Some commenters said that by imposing this new burden, it would be harder for prescribers to compete with third-party sellers, and thus the proposal could hinder competition rather than foster it, and some prescribers might have to stop selling lenses.¹⁶⁶ Many prescribers also criticized the proposed signed acknowledgment because they said it would not improve patient health or address what they believe are questionable practices by third-party retailers that put patients' eye health at risk.¹⁶⁷ Many of these commenters suggested that

¹⁶⁴ *See, e.g.*, Mitchell (WS Comment #238); Anders (WS Comment #479); Bjork (WS Comment #591); Giusto (WS Comment #740); Reed (WS Comment #749); Smith (WS Comment #1245); Paulsen (WS Comment #1335); Hamilton (WS Comment #2017); Joe (WS Comment #2340); Webster (WS Comment #2515); Ritter (WS Comment #2888); American Optometric Association (NPRM Comment #3830).

¹⁶⁵ *See* Utah Ophthalmology Society (NPRM Comment #2586); American Optometric Association (NPRM Comment #3830).

¹⁶⁶ *See, e.g.*, Koch (WS Comment #855); Willingham (WS Comment #858); Heltsley (WS Comment #1028); American Optometric Association (NPRM Comment #3830); Teed (NPRM Comment #4232).

¹⁶⁷ *See, e.g.*, Wright (WS Comment #743) (“Instead of going after doctors that take an oath, are held to high standards and depend on excellent patient care reputation to retain patients, the FTC should be going after the unscrupulous contact lens sellers that put profits far ahead of patient eye health concerns”); Satjawatcharaphong (WS Comment #1030) (“There is no justification for targeting eye doctors . . . while the Commission allows retailers who blatantly violate the law to operate unchecked.”); Vosseteig (WS Comment #1205) (“These proposed changes are NOT in the best interests in the patient, and are attacking optometry, instead of the retailers who consistently and constantly abuse the unenforced rules already in place. Do not target eye doctors! New paperwork and document storage requirements are NOT going to protect the patient, but will only add cost and time to an already broken health system.”). *See also* McLoughlin (WS Comment #1311); Utah Ophthalmology Society (NPRM Comment #2586); American

the Commission re-approach the Rule review with patient safety as the number one priority.¹⁶⁸

A few commenters also said the new requirement would add a burden to consumers, since they would not want to sign another form¹⁶⁹ or might have to return to their prescribers' offices to sign the acknowledgment receipt, whereas currently some contact lens fittings are finalized remotely (via phone, text, or email) after the patient takes home trial lenses for a few days.¹⁷⁰ Other commenters contested this assessment, stating that the percentage of consumers who complete their contact lens fitting remotely is small (by one estimate just 9%), and that prescribers who complete a fitting remotely could satisfy the signed-acknowledgment requirement by retaining proof that they transmitted the actual prescription to the patient.¹⁷¹

Society of Cataract and Refractive Surgery (NPRM Comment #3820); California Optometric Association (NPRM Comment #3845); Simsarian (NPRM Comment #3902); Foster (NPRM Comment #3981); Nakano (NPRM Comment #4353).

¹⁶⁸ Utah Ophthalmology Society (NPRM Comment #2586).

¹⁶⁹ Kampa (NPRM Comment #3042); Mecham (NPRM Comment #3419); Dang (NPRM Comment #3508); Warner (NPRM Comment #3533).

¹⁷⁰ Fortier (NPRM Comment #363); Dingley (NPRM Comment #342); Wisconsin Academy of Ophthalmology (NPRM Comment #4152).

¹⁷¹ 1-800 CONTACTS (NPRM Comment #3898, Ex. B). Results are based on an online panel study of 753 optometrists between December 12, 2016 and January 4, 2017. *See also* CLR Panel V Tr., *supra* note 50, at 11 (statements of David Cockrell that he would be “really surprised” if less than 80%-90% of contact lens fittings are completed in person); Simple Contacts (NPRM Comment #3479) (requirement could be satisfied remotely with “little additional effort”); Opternative (NPRM Comment #3785) (“they can be sent and completed either electronically or via hardcopy in the office at the end of a fitting and added to a patient’s existing medical record, which most states require to be kept for at least three years”).

On the issue of burden, the AOA submitted a third-party survey and analysis conducted by Avalon Health Economics (the “Avalon Report”), which reported that optometrists expect it will take 3.12 minutes to explain to each patient the purpose of the signed acknowledgment, 3.41 minutes to answer questions from patients who seek more information, and 13.31 minutes of training to teach staff how to correctly address patient concerns about the acknowledgment (although only 44% of optometrists said additional training would be necessary).¹⁷² According to the AOA, the analysis shows that the cost of implementing the signed-acknowledgment proposal could be as high as \$18,795 for a practice with one optometrist, and as high as \$49,913 for a practice with three optometrists.¹⁷³ Approximately 85% of this estimated burden, however, came not from training, explaining, or answering questions about the signed acknowledgment, but rather from the general cost of “total administrative time associated with adhering to the rules, regulations and policies regarding the operation of your practice.”¹⁷⁴ In other words, the bulk of the burden derived not from the new signed-acknowledgment requirement, but

¹⁷² American Optometric Association (NPRM Comment #3830). According to the AOA, the survey was disseminated to approximately 1000 optometrists, of whom 130 responded. The survey asked them to describe how much time it takes them to introduce a new patient engagement process and conduct periodic assessments of such a process, and how much time they anticipate they and their staff would spend answering questions and explaining the purpose of the signed acknowledgment to patients. It also asked them for the “total administrative time associated with adhering to the rules, regulations and policies.”

¹⁷³ American Optometric Association (NPRM Comment #3830).

¹⁷⁴ *Id.*

from adhering to rules and regulations in general, including existing rules and regulations.¹⁷⁵

After its own review of the Avalon Report, the Commission doubts its reliability and usefulness. Of greatest concern is that the bulk of the estimated burden is derived not from the signed-acknowledgment proposal, but rather from responses to the survey's open-ended question regarding total indirect costs of adhering to government regulations. As noted, these encompass regulations that are already in place and already taking prescriber adherence time, but may be unrelated in any way to the Commission's proposal. Furthermore, the survey also asked prescribers to predict whether patients would have questions, rather than surveying patients themselves as to whether they would have questions. Moreover, the relatively small sample of optometrists who responded to the survey (130) knew the sponsor and purpose of the survey beforehand. In fact, the AOA had urged its members to comment on the NPRM and provided them with a sample letter declaring that the Commission's NPRM burden estimate did not sufficiently account for "ongoing staff training" and the "additional step in the patient engagement process."¹⁷⁶ Thus, Avalon survey respondents may have been unduly

¹⁷⁵ The AOA burden estimate was also cited by numerous other commenters as evidence that the acknowledgment proposal would be extremely burdensome for prescribers, and disproportionate to the harm caused by prescriber failure to release prescriptions. *See, e.g.*, Letter from Seven Representatives, *supra* note 131; Letter from Fifty-Four Representatives, *supra* note 131; Boozman Letter, *supra* note 131; Letter from Fifty-Eight Representatives, *supra* note 131.

¹⁷⁶ *E.g.*, Mass Mail Campaign (NPRM Comment #283) (1,415 submissions). *See also, e.g.*, Shaw (NPRM Comment #314); Schwartz (NPRM Comment #321); Yin (NPRM Comment #326); Singh (NPRM Comment #340); Stahl (NPRM Comment #355); Moore (NPRM Comment #365); Brozzo (NPRM Comment #366); Rohler (NPRM Comment #377); Woo (NPRM Comment #400); Heeg (NPRM Comment #407); Le (NPRM Comment #416); Lemke (NPRM Comment #441); Durham (NPRM Comment

influenced to inflate the burden of complying with existing regulations and the proposed new one. Based on these and other concerns,¹⁷⁷ the Commission cannot accord significant weight to many of the survey's findings or cost estimates, although it will still consider whether to include training time in its determination of the overall burden and need for the proposal.

In marked contrast to the views of prescribers, other commenters called the Commission's signed-acknowledgment proposal a measured approach that would be easy to administer and impose a relatively minor burden.¹⁷⁸ According to the consumer advocacy organization Consumers Union, "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

#473); Mueller (NPRM Comment #513); Williams (NPRM Comment #411); Kirsch (NPRM Comment #495); Bond (NPRM Comment #497); Palys (NPRM Comment #538); Kanevsky (NPRM Comment #555); Nordwall (NPRM Comment #576); Johnson (NPRM Comment #613); Bate (NPRM Comment #647); Toepfer (NPRM Comment #652); Korley (NPRM Comment #653); Wegener (NPRM Comment #665); Melman (NPRM Comment #676); Williams (NPRM Comment #703); Ballard (NPRM Comment #756); Cass (NPRM Comment #757).

¹⁷⁷ The analysis did not account for the fact that 16% of optometrists do not believe consumers will have additional questions about the signed acknowledgment. The survey also does not supply information on the mean and variance of the open-ended question regarding time. If any respondents significantly overestimated the time spent adhering to rules, those figures would distort the overall average, particularly since only 130 optometrists participated.

¹⁷⁸ See e.g., Information Technology & Innovation Foundation (NPRM Comment #2848); Citizen Outreach (NPRM Comment #3247); Thompson (NPRM Comment #3302); Searles (NPRM Comment #3304); Simple Contacts (NPRM Comment #3479); Coalition for Contact Lens Consumer Choice (NPRM Comment #3718); Opternative (NPRM Comment #3785); Attorneys General of 20 States (NPRM Comment #3804); Consumers Union (NPRM #3969); National Taxpayers Union (NPRM #4262).

while also making it easier for eye doctors to show compliance.”¹⁷⁹ Likewise, other commenters stated that such a requirement should be easy to administer, particularly if prescribers use an electronic device to present the acknowledgment and record the signature electronically.¹⁸⁰ Other commenters felt that the signed acknowledgment would be similar to the HIPAA acknowledgment that prescribers are already obtaining from each patient, and thus would not cause an excessive burden.”¹⁸¹

Some commenters questioned prescribers’ estimates for how long it would take to explain the signed acknowledgment to each consumer.¹⁸² 1-800 CONTACTS submitted a third-party survey that reported that on average, it took consumers twelve seconds to read the proposed two-sentence acknowledgment statement, 90% of those surveyed

¹⁷⁹ Consumers Union (NPRM Comment #3969). *See also* Mouzon (NPRM Comment #2121) (“This requirement would add only a minimal paperwork burden on optometrists, but it could have a major impact on protecting the rights of consumers. It will also help keep prices low, which is important to my family”); Truman (NPRM Comment #3285) (“This isn’t too much work to ask of optometrists and it will make sure everyone will be able to make that choice [of where to buy contacts].”)

¹⁸⁰ Information Technology & Innovation Foundation (NPRM Comment #2848); Thompson (NPRM Comment #3302); Simple Contacts (NPRM Comment #3479).

¹⁸¹ Costco Wholesale Corporation (NPRM Comment #4281); Richter (NPRM Comment #2706).

¹⁸² 1-800 CONTACTS (WS Comment #3207); CLR Panel V Tr., *supra* note 50, at 7 (statement of Linda Sherry that she does not believe that consumers would have a lot of questions about signed-acknowledgment statement). *See also* National Association of Optometrists and Opticians (NPRM Comment #3851) (estimating it might add 5 minutes or more per transaction, but also stating, “Doctor’s offices typically do a quick explanation of the form(s) to be signed and our experience is that patients routinely accept that explanation and sign the form without too much thought or discussion”).

understood the purpose of the signed acknowledgment, and only 4% had any questions or comments they would ask about it.¹⁸³

Some commenters also suggested that the increased burden from the signed acknowledgment would be lessened or even outweighed by a reduced verification burden because with more patients in possession of their prescriptions and able to present them to sellers, fewer verifications would be necessary.¹⁸⁴ 1-800 CONTACTS submitted a cost-benefit analysis that concluded that since prescribers and sellers spend considerably more time to comply with the Rule using verification¹⁸⁵ than they do when consumers present prescriptions for purchase, a relatively modest reduction in the number of verifications could have a significant impact on overall compliance costs.¹⁸⁶ According

¹⁸³ 1-800 CONTACTS (WS Comment #3207); Baker Analysis, Ex. B, *supra* note 133, https://www.ftc.gov/system/files/summaries/initiatives/677/meeting_summary_for_the_contact_lens_rulemaking_proceeding.pdf (SSI online survey of 500 respondents).

¹⁸⁴ *E.g.*, National Association of Optometrists and Opticians (WS Comment #3208) (“increased access to prescriptions and ease in securing additional copies of one’s prescription will reduce the number of verification requests and make the fulfillment process easier and more accurate”); 1-800 CONTACTS (NPRM Comment #3898); Consumers Union (NPRM Comment #3969) (increase in patients with their prescriptions “should significantly reduce the number of prescriptions that require verification”); Costco Wholesale Corporation (NPRM Comment #4281). *See also* CLR Panel V Tr., *supra* note 50, at 9 (statements of David Cockrell that it would reduce the number of verifications but would not eliminate them).

¹⁸⁵ The Commission has estimated that prescribers’ offices spend five minutes per verification request, based on information provided by the American Optometric Association. Agency Information Collection Activities; Submission for OMB Review, 81 FR 62501 (Sept. 9 2016) [hereinafter PRA Assessment]. The Commission has also estimated that sellers spend five minutes per verification request, and one minute on recordkeeping in non-verification circumstances (to preserve the prescription when presented by a patient). *Id.*

¹⁸⁶ Baker Analysis, *supra* note 133, at 12-17.

to this analysis, a reduction in verifications of 9% could be sufficient to offset the entire burden of the acknowledgment proposal.¹⁸⁷ The analysis further predicted, based on current consumer behavior, that the proposed amendment was likely to reduce the number of verifications by 15.9% and thus likely to offset much of the cost.¹⁸⁸

The Commission has some concerns about the analysis performed for 1-800 CONTACTS, since Dr. Baker used certain assumptions that differ from what the Commission has traditionally used in its calculation of the verification burden.¹⁸⁹ The Commission undertook a similar analysis using Dr. Baker's assumption regarding the percentage of consumers who would present prescriptions to sellers, but using

¹⁸⁷ *Id.* The estimate is based on the NPRM PRA Assessment estimate of the signed-acknowledgment compliance cost of \$10.8 million, and an assumption that 30% of consumers who currently do not receive their prescription would receive them due to the proposed requirement. This calculation is further based on the premise that prescribers are the ones who take the time to respond to verification calls, which is how the FTC has traditionally calculated the verification burden. *See* PRA Assessment, *supra* note 184, at 62501. If the burden were calculated with the assumption that prescribers' office staff handle verification calls rather than prescribers, the verification burden cost would be much less (since staff typically have a much lower hourly wage than prescribers), and consequently, the reduction in verifications would have to be 21% to offset that burden, according to Dr. Baker. Baker Analysis, *supra* note 133, at 16.

¹⁸⁸ *Id.* This calculation uses (1) an assumption that consumers make two contact lens purchases per year which would otherwise (in the absence of prescription presentation) require verification, and (2) the assumption, based on current consumer behavior, that approximately 38.6% of consumers in possession of their prescription would present them to sellers.

¹⁸⁹ For example, Dr. Baker assumed two verifications per customer per year, whereas the Commission has typically assumed just one. In addition, the Commission's burden calculation typically limits its estimate of the minutes prescribers spend responding to verification calls to only those calls that they respond to, where Dr. Baker bases his burden estimate on five minutes for each verification call, regardless of whether it requires prescriber action. *See* PRA Assessment, *supra* note 185, at 62501; Agency Information Collection Activities; Proposed Collection; Comment Request, 81 FR 31938, 31939-40 (May 20, 2016); Baker Analysis, *supra* note 133, at 12-17.

assumptions more closely mirroring those used in the Commission's prior Public Record Collection analysis, and calculated that the full cost of the signed acknowledgment might be offset by a 22.9% reduction in verifications.¹⁹⁰ The Commission considers this a relatively rough estimate and does not accord it substantial weight, however, since the calculation relies on a significant number of assumptions, not all of which may be accurate. The calculation also does not take into account any of the benefit to consumers of having their prescriptions and being able to choose from among competing providers; the savings consumers might achieve by purchasing lower-priced lenses; the improvements to health and safety due to a reduction in errors associated with invalid prescriptions currently verified through passive verification; and the Commission's ability to assess and verify compliance with the Rule.¹⁹¹

5. Comments on the Text of the Proposed Acknowledgment Form

Some commenter opposition to the Commission's proposal focused on the text of the acknowledgment form. In particular, some prescribers took issue with the proposed requirement that the acknowledgment form include the statement, "I understand I am free to purchase contact lenses from the seller of my choice."¹⁹² According to prescribers, this

¹⁹⁰ As noted, this uses the assumption from the Commission's PRA Assessment that prescribers handle verification calls. If that assumption is changed to an assumption that prescribers' staff handle all of the verification calls, the overall cost of the verification burden falls, and consequently the percentage of verification reductions needed to offset the \$10.4 million cost of the signed acknowledgment rises to between 43-50%, depending upon whether staff time spent verifying prescriptions but not responding to sellers is included in the calculation.

¹⁹¹ NPRM, 81 FR at 88533.

¹⁹² *See, e.g.*, Highsmith (WS Comment #651); Parikh (WS Comment #764).

language makes it appear that doctors who sell contact lenses have been misleading their patients and overcharging them, and actively encourages consumers to buy their lenses elsewhere.¹⁹³

While many commenters criticized the proposed language, few suggested alternative wording. One commenter, however, suggested adding the language “valid anywhere” to the prescription itself rather than on an acknowledgment form.¹⁹⁴ Another commenter, Consumers Union, suggested keeping the proposed wording but adding a third sentence to the acknowledgment, stating, “I also understand that my having the copy of my prescription means I can give a copy to the seller I choose.”¹⁹⁵ 1-800 CONTACTS said it supported the Commission’s proposed language because it would make it more likely patients would be given the prescription earlier in the process and before they purchased lenses from their prescriber.¹⁹⁶

6. Alternative Proposals to the Signed-Acknowledgment Proposal

¹⁹³ See, e.g., CLR Panel V Tr., *supra* note 50, at 25 (statement of David Cockrell that it implies that doctors have done something wrong); Phillips (WS Comment #701) (“What other industry is required in their place of business to hand a customer a sheet of paper informing the customer you can buy these items elsewhere? Obviously people know there are different choices to get contacts—but why are we being forced to point people away?”); Johnson (WS Comment #755) (“Now I’m supposed to have them sign a document implying that I’m some kind of shady character. When patients lose trust in their doctor, medical care is damaged.”); Hanian (WS Comment #1196) (disclosure “has the impression in the public of making Eye Care Professionals look guilty of non-release”); Frazier (NPRM Comment #2653); Kentucky Optometric Association (NPRM Comment #3174).

¹⁹⁴ Wisconsin Academy of Ophthalmology (NPRM Comment #4152).

¹⁹⁵ Consumers Union (NPRM Comment #3969).

¹⁹⁶ 1-800 CONTACTS (NPRM Comment #3898).

Some commenters suggested that instead of a signed acknowledgment, the Commission should provide better guidance and increased education.¹⁹⁷ Many commenters suggested, as an alternative, requiring that prescribers post a sign advising patients of their right to their prescription, and said this would help educate consumers without adding as much of a burden for prescribers.¹⁹⁸ According to the AOA, signage is a common tool used to educate patients and consumers in a variety of settings.¹⁹⁹ Furthermore, commenters noted that the state of California already requires that prescribers post just such a sign, and some said the signage was working to remind the public of its rights.²⁰⁰ The AOA submitted a third-party online survey showing that California contact lens wearers strongly support the requirement and believe the law helps enable patients to find the best prices on contact lenses.²⁰¹

¹⁹⁷ CooperVision, Inc. (NPRM Comment #3841). *See also, e.g.*, Kochik (WS Comment #729) (“it might be better to mandate that a placard be clearly displayed that states that you are entitled to a copy of your contact lens prescription upon completion of the exam, or run an advertising campaign”); American Optometric Association (NPRM Comment #3830).

¹⁹⁸ *E.g.*, CLR Panel V Tr., *supra* note 50, at 12 (statements of David Cockrell); To (WS Comment #597); Smith (WS Comment #732); Schott (WS Comment #1739); Toon (WS Comment #1741); Gibson (WS Comment #1889); Gilthvedt (WS Comment #2205); Health Care Alliance for Patient Safety (WS Comment #3206); American Optometric Association (NPRM Comment #3830); Gridley (NPRM Comment #4150); Letter from Twenty-Four Representatives, *supra* note 131; Letter from Seven Representatives, *supra* note 131; Letter from Fifty-Four Representatives, *supra* note 131; Letter from Fifty-Eight Representatives, *supra* note 131.

¹⁹⁹ American Optometric Association (WS Comment #3303).

²⁰⁰ *Id.*; Lo (WS Comment #856).

²⁰¹ American Optometric Association (WS Comment #3303). The survey presented 1000 consumers with a copy of the signage requirement and asked, among other things, “As a contact lens wearer, do you support this law?” to which 96% opted for the answers “definitely support” or “support.” Ninety-three percent said the signage

In contrast, other commenters said a sign would be less effective than a signed acknowledgment since consumers might not notice a sign amid other signs and notifications at a prescriber's office, and since a signage requirement might have no effect on the likelihood that doctors release prescriptions without patients having to ask for them.²⁰² In a survey submitted by 1-800 CONTACTS, 74% of consumer respondents said they are more likely to pay attention to a document presented to them than to a posted sign, while only 5% said they were more likely to pay attention to a posted sign.²⁰³ Others noted that unless a prescriber maintained a record of release, determining whether a prescription had, in fact, been released, would remain a challenge for the Commission.²⁰⁴ At the Commission's CLR Workshop, there was also discussion as to whether enforcement of the signage requirement could itself be difficult, since in the absence of a sign, consumers would not know to complain, or who to complain to, and the only way to verify compliance with the signage requirement would be for the

requirement either "helps" or "definitely helps" patients find the best prices on lenses. The survey also asked to what extent respondents agree or disagree with the following statement, "This law is the best way to ensure that contact lens wearers are as informed as possible about their contact lens purchasing options," and gave the respondents four options, "completely agree," "agree," "disagree" and "completely disagree." Eighty-eight percent selected either "completely agree" or "agree."

²⁰² CLR Panel V Tr., *supra* note 50, at 12-13 (statements of Linda Sherry); 1-800 CONTACTS (NPRM Comment #3898); *see also* NPRM, 81 at 88534.

²⁰³ Baker Analysis, Ex. B, *supra* note 133, at 9 (SSI online survey of 500 respondents).

²⁰⁴ *See e.g.*, Information Technology & Innovation Foundation (NPRM Comment #2848).

Commission to perform numerous spot checks across the country.²⁰⁵ Similarly, a panelist and moderator both mentioned that informal spot checks in California have found that such signs are not universally posted in accordance with state law,²⁰⁶ although another panelist noted that when his organization looked at eye-care office compliance, the offices “passed the test.”²⁰⁷ As none of these “spot checks” can be considered scientific or thorough investigations, the Commission will not accord any of them any weight.

The Commission does not have empirical data about prescriber compliance with the signage requirement in California. However, an analysis of consumer survey evidence provided by Survey Sampling International (submitted by 1-800 CONTACTS) indicates that regardless of signage, Californians do not automatically receive their prescriptions in substantially greater numbers than residents of states without a signage requirement.²⁰⁸ According to the 2015 and 2017 survey evidence from SSI, the percentage of residents in California who receive their prescription in accordance with the CLR is only 2% higher than the nationwide rate, and 20-25% of California residents never received their prescription at all,²⁰⁹ even though the signage requirement has been in effect in California since 1994.²¹⁰

²⁰⁵ CLR Panel V Tr., *supra* note 50, at 14-15; *id.* at 13 (statements of Linda Sherry).

²⁰⁶ *Id.*

²⁰⁷ *Id.* at 13 (statements of Joseph Neville).

²⁰⁸ 1-800 CONTACTS (WS Comment #3207, Ex. A).

²⁰⁹ *Id.* One of the SSI surveys (October 2015) found that the percentage of consumers who did not receive their prescription but subsequently asked for it and immediately received it is higher in California by 13%, a statistically significant amount, which could indicate that some consumers are seeing the sign and thus remembering that

One commenter suggested that instead of requiring a signed acknowledgment, the prescription itself could have a notice instructing consumers that they are free to purchase lenses at the retailer of their choice.²¹¹ This proposal might help to educate consumers, but, if imposed by itself, would likely have no effect on the percentage of prescriptions that are released to consumers. In fact, it might reduce that percentage if prescribers are hesitant to give consumers a document reminding them they can buy their lenses elsewhere.

One commenter, the NAOO, suggested that rather than specifying the precise terms of a signed acknowledgment, the Commission should require proof of compliance with the prescription-release requirement but allow the prescriber to select the method of proof from several accepted methods.²¹² According to the NAOO, allowing any of several forms of proof would provide a degree of flexibility—thus reducing prescriber

they have a right to their prescriptions. However, the more recent SSI survey (January 2017), which surveyed twice as many consumers, only reported a 3% difference between California and nationwide in this regard, which does not indicate that the signage is prompting large numbers of people to ask for their prescriptions.

²¹⁰ California actually has two statutes that require signage regarding consumers' rights to their prescriptions. The first, 16 CCR 1566, applies to prescribers and has been in effect since 1994. A second statute, Cal. Bus. & Prof. Code 2554, went into effect in 2016, and extended the signage requirement to opticians who enter into business with prescribers. In 1-800 CONTACTS' comment, the company identified the incorrect statute for purposes of making a before-and-after comparison. 1-800 CONTACTS (WS Comment #3207). The Commission does not have survey evidence of California prescription-release practices from before the 1994 signage requirement, and such data would be unhelpful in any event since the Contact Lens Rule did not exist at that point.

²¹¹ Jolly (WS Comment #790). *See also* Wisconsin Academy of Ophthalmology (NPRM Comment #4152).

²¹² National Association of Optometrists and Opticians (WS Comment #3208). *See also* CLR Panel V Tr., *supra* note 50, at 22 (statements of Joseph Neville).

burden—while still providing the Commission with more effective enforcement and verification ability than it has today.²¹³ The NAOO suggested that a prescriber who could not produce credible evidence of prescription release would face a rebuttable presumption of noncompliance.²¹⁴

The NAOO proposed that accepted forms of proof of prescription release would include: a separate signed acknowledgment (as proposed in the NPRM); a patient-signed acknowledgment of prescription receipt on a prescriber-retained copy of the prescription; a patient-signed acknowledgment of prescription receipt on a customer's purchase receipt; a copy of and transmission receipt of a fax of the prescription to the patient; email and text retention of the sent prescription, including a digital image of the prescription, evidencing the correct address or number for the patient, along with a delivery receipt of sending; portal acknowledgment and evidence of the prescription download; and other forms of retention, whether paper or electronic not yet contemplated, that the Commission can approve in the future based on an adequate showing.²¹⁵ According to the NAOO, these choices would allow prescribers to tailor the acknowledgment to their practices, reduce unnecessary paper and storage issues, and yet

²¹³ *Id.* See also National Association of Optometrists and Opticians (NPRM Comment #3851) (“While many may elect to use a paper or electronic form, others may opt for some form of portal acknowledgment, email or text acknowledgment or other method not yet determined. In this way there is some flexibility for the prescriber, depending on tools used in the practice.”).

²¹⁴ *Id.*

²¹⁵ National Association of Optometrists and Opticians (WS Comment #3208).

still provide the Commission with an enforcement mechanism to ensure that prescribers are complying.²¹⁶

The NAOO also suggested an exemption for prescribers who do not sell contact lenses, since they lack a financial incentive to withhold a prescription.²¹⁷ Some other commenters, however, opposed this, stating that it implied that doctors who chose to sell lenses were unethical, and further that it might be difficult to determine whether doctors—particularly those co-located with an optical retailer—have any kind of direct or indirect financial interest in the sale of lenses.²¹⁸

C. Additional Discussion and Proposal

The Commission has reviewed and considered the thoughts and concerns expressed in the more than 7,000 comments submitted in response to its NPRM proposal. Many of the comments were helpful and provided insight into the effectiveness of the current Rule's automatic prescription release provision, the need for amending that provision, the potential burden on providers of doing so, and possible alternatives to the Commission's NPRM proposal.

²¹⁶ CLR Panel V Tr., *supra* note 50, at 13-14, 22, 25 (statements of Joseph Neville).

²¹⁷ *Id.* at 25-26 (statements of Joseph Neville). Such an exemption was also supported by a few other commenters, such as 1-800 CONTACTS, which noted that this would reduce the overall burden on prescribers without reducing benefits for consumers. 1-800 CONTACTS (WS Comment #3207).

²¹⁸ *See* CLR Panel V Tr., *supra* note 50, at 26 (statements of David Cockrell) (“How in the world could you look at every commercial contract and know whether that doc who isn’t physically selling them is incentivized in any other way, whether it’s a decrease in the rent space, whether it’s advantage in something else.”); *id.* at 26 (statements of Linda Sherry that it would be simpler to have one law for everyone).

The Commission also emphasizes that it has great respect for the nation's eye-care professionals, and recognizes the unique contribution they provide in helping America's consumers see clearly and enjoy quality eye health. Congress determined that the benefits patients enjoy from these services are enhanced when they can buy from third-party sellers, and that requiring the automatic release of prescriptions at the completion of the contact lens fitting is the best way to ensure consumer choice. Congress directed the Commission to implement and enforce that requirement, and if the Act and Rule are not functioning as intended, the Commission is obligated to address the deficiency.

After consideration of the comments and evidence at its disposal, the Commission believes that the overall weight of the evidence in the rulemaking record is compelling, and firmly establishes that the Act and Rule are not working as Congress intended. It is evident that a majority of consumers—between 56-65%²¹⁹—are not receiving their contact lens prescriptions automatically as required by law, and millions of consumers are not receiving them at all.²²⁰ This is evident from the surveys previously discussed in the NPRM, as well as the two new consumer surveys and additional corroborating evidence.

While the Commission reiterates that any one survey might not be treated as definitive, the fact that several different surveys over the course of several years have found similar levels of non-compliance is significant. Additional evidence of noncompliance includes the persistently high verification numbers and consumer

²¹⁹ *See supra* Section IV B(2)(a).

²²⁰ *Id.*

accounts of failure to release. Moreover, the existing regulatory structure in the U.S., which bars a consumer from obtaining contact lenses without a prescription while permitting prescribers to sell what they prescribe, creates regulatory-based economic incentives for some prescribers to not release prescriptions, or to not release them unless requested by the consumer.²²¹

Furthermore, the Commission has not seen credible empirical evidence that contradicts the evidence that prescribers are not automatically releasing prescriptions. For reasons explained in its earlier discussion, the Commission does not regard the relatively small number of consumer complaints as indicative of prescriber compliance. While many prescribers attest—via the AOA prescriber survey and their own comments—that they personally always provide patients with prescriptions, and the Commission takes these personal declarations into account, they do not rebut the empirical evidence that a substantial number of consumers are not receiving their prescriptions automatically as required by law. Similarly, the evidence in the record supports the conclusion that many consumers are still unaware of their right to their prescription.²²² The Commission therefore continues to believe that compliance with the automatic prescription release provision could, and should, be substantially improved.

The Commission also continues to believe, as it has found in the past,²²³ that consumers

²²¹ See Information Technology & Innovation Foundation (NPRM Comment #2848) (noting the long history of the optometry industry to use its gatekeeper power to limit patients' ability to purchase lenses from outside sources, and the existing imbalance in that U.S. consumers still need prescribers to give them a prescription in order for them to purchase lenses).

²²² See *supra* Section IV B(2)(a).

²²³ Contact Lens Rule, 69 FR 5440 (Feb. 4, 2004); Eyeglass I, 43 FR at 24002.

are subject to substantial economic loss attributable to the inability to comparison shop when they do not possess their prescriptions, and that significant harm to competition exists when prescribers do not comply with the prescription-release requirement. When consumers' ability to comparison shop is diminished, the normal competitive pressures on the eye-care industry to offer competitive prices—or the combination of prices, features, and services most in demand—are themselves diminished.²²⁴

Furthermore, as noted in its NPRM, the Commission believes that the potential benefit of increasing the number of patients in possession of their prescriptions remains substantial: increased flexibility and choice for consumers; a reduced verification burden for prescribers and sellers; a reduced likelihood of errors associated with incorrect, invalid, or expired prescriptions and, consequently, improved patient safety; and a reduction in the number of failed attempts at verification or attempts to verify with the wrong prescriber.²²⁵

1. A Confirmation from the Consumer Is Necessary for Enforcement and Monitoring

Additionally, the Commission is convinced that some form of retained documentation is necessary to improve the Commission's enforcement and monitoring ability. As commenters noted, the Commission currently faces notable challenges in enforcing the Rule since typically the only evidence is the word of a complaining

²²⁴ Fed. Tr. Comm'n, "The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study," 45-46, 50 (2005), <https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf>.

²²⁵ NPRM, 81 FR at 88532-34.

consumer against that of the prescriber.²²⁶ This fact has played a role in the lack of enforcement over the last ten years. Under the current Rule, to investigate a complaint and bring an enforcement action, the Commission might be required to issue a Civil Investigative Demand for the names and contact information of a prescriber's recent patients (perhaps within the past two months), and then survey or interview them to ascertain whether they received their prescriptions. The Commission might also have to conduct investigational hearings with prescribers' office staff to determine if there was any proof that prescriptions had been provided. Such an investigation would be resource-intensive for the Commission and costly, time-consuming, and disruptive for a prescriber, even if the Commission never ultimately brought an enforcement action.

The current lack of enforcement, in conjunction with the fact that so few consumers file complaints when they have not received their prescription, is likely a significant contributing factor in why less than half of all patients receive their prescription automatically as required by law. Prescribers, whether intentionally or not, can fail to release prescriptions yet risk very little, since if a patient asks for the prescription and subsequently receives it, the consumer is unlikely to file a complaint.

While some commenters questioned whether prescribers who do not comply with prescription release would comply with the acknowledgment requirement, the Commission notes that the difference between the two requirements is that there would be a verifiable method to check the latter. If the Commission has concerns about a prescriber's compliance, the Commission can simply request to see the patient

²²⁶ See *supra* Section IV B(3).

acknowledgment, and that should resolve most questions as to whether the prescriber did or did not provide a prescription.

As for commenters who complained that the proposed acknowledgment does not directly improve patients' health and safety, or address so-called questionable practices by third-party sellers,²²⁷ that assertion even if accurate, is irrelevant, because the acknowledgment proposal is not intended to do so. Other parts of the Rule are designed to focus on verification and prescription alteration, both of which may affect patient health and safety. The prescription-release component of the Rule is designed to enhance consumer choice, and the Commission's proposed acknowledgment is targeted to achieve that goal. And while it may be true, as some commenters have asserted, that not every single consumer would read the acknowledgment form, the Commission believes that enough patients would read a document handed to them and asked to sign to make such a requirement beneficial (particularly if it increases the number who receive their prescriptions). As noted *supra*, a survey of consumers found that a significant majority were more likely to pay attention to a document given to them than to a posted sign.²²⁸ Furthermore, the contention that consumers will not read the acknowledgment form runs contrary to the comments of many prescribers who predict that consumers will ask a lot of questions after reading the form.

2. The Burden Is Relatively Small and Outweighed by the Benefits

²²⁷ See *supra* note 167 and accompanying text.

²²⁸ Baker Analysis, Ex. B, *supra* note 133, at 9.

The Commission also finds that the evidentiary record does not establish that the burden to obtain a signature and retain a single sheet of paper or electronic record is as extreme as that forecast by many prescribers. As the Commission noted in the NPRM, the majority of states already require that optometrists maintain records of eye examinations for three years, and maintaining an additional piece of paper should not take more than a few seconds of time, as well as inconsequential, or *de minimis*, amount of record space.²²⁹ This recordkeeping burden can be further reduced to the extent that prescribers adopt, or have adopted, electronic-health record systems where patient signatures can be recorded electronically and inputted automatically into the electronic record.²³⁰ The Commission also believes that while the precise offset resulting from reduced verifications may be difficult to predict with precision, there would undoubtedly be some offsetting benefits for both sellers and prescribers.²³¹

The argument put forth in some comments that the cost of the Rule's burden falls disproportionately on prescribers, and that this proposal aggravates that imbalance, is not persuasive. In the first place, the signed-acknowledgment proposal is intended to remedy lack of compliance with the automatic-release provision *by prescribers*. Furthermore, while Congress recognized the health issues associated with selling contact lenses without a prescription, the FCLCA was enacted primarily because of prescribers'

²²⁹ NPRM, 81 FR at 88557.

²³⁰ *Id.* at 88534.

²³¹ *See supra* Section IV B(4).

widespread failure to release and verify prescriptions,²³² and Congress set out nearly all of the requirements and corresponding burdens imposed on prescribers and sellers. The primary inquiry for the Commission is to determine whether the Rule is functioning to ensure compliance with the Act. The Commission's focus is to find the most effective and least burdensome way to achieve compliance with the Rule and the Act, and thereby benefit consumers.

While prescribers predicted that consumers would have many questions about having to sign a receipt for their prescription, the only submitted empirical survey of consumer understanding of the proposal found that just 4% of consumers surveyed had questions about the acknowledgment form, and it took consumers, on average, a mere twelve seconds to read it. And as one commenter noted, consumers are accustomed to tasks such as this.²³³ Indeed, many pharmacists require patients to acknowledge that they do not have any questions upon receiving a prescription; package services require signature upon delivery; schools require signed permission slips; businesses and physicians' offices require visitors to sign in; and, as some commenters noted, patients are accustomed to signing acknowledgment forms signifying they are in receipt of a provider's HIPAA notice of privacy practices.²³⁴

²³² H.R. Rep. No. 108-318 at 4-5. *See also* 69 FR at 40492 (quoting FCLCA co-sponsor Rep. F. James Sensenbrenner, Jr., stating that the intent of the Act is "to allow consumers to receive their contact lens prescriptions so they can easily shop around to buy their lenses from any number of suppliers.").

²³³ *See* CLR Panel V Tr., *supra* note 50, at 7 (statements of Linda Sherry that she did not think it would raise a lot of questions from consumers).

²³⁴ Costco Wholesale Corporation (NPRM Comment #4281). *See also* Searles, NPRM Comment #3304) (stating that from his experience as a pharmaceutical doctor, he

The HIPAA acknowledgment requirement²³⁵ faced some similar objections prior to implementation, including complaints that it would be burdensome, present difficulties when patients and doctors are not face-to-face, and be more difficult and costly to implement than signage.²³⁶ The U.S. Department of Health and Human Services, however, determined that a signed acknowledgment would require just ten seconds to hand out and ten seconds to obtain a patient's signature.²³⁷ HHS did not determine that additional time was needed for explaining the need for the patient's signature, answering questions from the patient, or scanning or storing the signed acknowledgment.²³⁸

The HIPAA signed acknowledgment differs from the Commission's proposal in a few ways, however. In particular, HHS did not specify a particular form for its patient acknowledgment, but rather left it up to providers to determine what type of acknowledgment—so long as it was signed by the patient²³⁹—would work best for them and their practice.²⁴⁰ In this manner, the HIPAA acknowledgment requirement more closely resembles the proposal by the National Association of Optometrists and Opticians

finds it difficult to understand how some eye doctors would find it difficult to maintain a file of signatures).

²³⁵ 45 CFR 164.520 (c)(2)(ii).

²³⁶ Standards for Privacy of Individually Identifiable Health Information, 67 FR 53182, 53240-43 (Aug. 14, 2002) (implementing 45 CFR 164.520(c)(2)(ii)).

²³⁷ *Id.* at 53240-43, 53260-61. HHS also calculated three cents per signed acknowledgment for the cost some doctors might incur for the paper. *Id.* at 53256.

²³⁸ *Id.* at 53256.

²³⁹ “[T]he Department would not consider a receptionist's notation in a computer system to be an individual's written acknowledgment.” *Id.* at 53242.

²⁴⁰ *Id.*

in that it provides the prescriber with greater flexibility to adapt the acknowledgment to best suit his or her practice.²⁴¹ HHS also rejected the idea of relying on signage or providing the notice only upon request, since it determined that the burden of enforcing an important right afforded to individuals by the rule should not be placed on the individual.²⁴²

3. Analysis and Proposal

The Commission likewise does not view signage as an appropriate or effective alternative to ensure that patients receive their prescriptions as required by law. As discussed in the NPRM, signage offers some of the benefits of a signed acknowledgment in that it would notify some consumers of their rights.²⁴³ On the other hand, it is likely that in the particular environment of a doctor's office, fewer consumers would learn of their rights from a sign than from being handed a document, particularly a document consumers are asked to sign. It is worth noting that when California first considered requiring prescription-release signage, the California Optometric Association opposed it because it felt that "[t]urning optometrists' offices into bulletin boards is not the

²⁴¹ See *supra* Section IV B(6).

²⁴² 67 FR at 53242-43. Perhaps due in part to its written acknowledgment, non-compliance with the HIPAA requirement to provide patients with privacy notices has not been a significant issue, and HHS is now in the preliminary stages of evaluating whether a written acknowledgment is still needed. Regulatory Agenda, 83 FR 27126 (June 11, 2018), <https://www.gpo.gov/fdsys/pkg/FR-2018-06-11/pdf/2018-11239.pdf>. The fact that covered health care providers do not have a powerful incentive to withhold privacy notices may also play a role in compliance with the HIPAA privacy-notice release requirement, in contrast to the CLR requirement to release prescriptions.

²⁴³ NPRM, 81 FR at 88534. Unlike a "secret shop" to determine prescriber compliance with prescription release, spot checks of signage could be accomplished with significantly less time and expense.

answer.... What if the patient doesn't read the notice?"²⁴⁴ Moreover, since a sign would not require a prescriber, or prescriber's staff, to interact with each patient about the prescription, it would serve as less of a reminder to them to provide patients with their prescriptions. And, as noted previously, although it might be relatively straightforward (although very time consuming) for the Commission to verify and enforce the signage requirement through spot checks, such a requirement would do little to assist the Commission in verifying or enforcing compliance with the automatic prescription release provision itself. Confirming that a prescriber has posted a sign does little or nothing to establish whether the prescriber is releasing prescriptions to patients.²⁴⁵

Similarly, the Commission finds the aforementioned survey of California residents relatively unhelpful. The issue is whether signage increases prescription-release, not whether residents support the law or believe a sign helps them find the best prices for contact lenses. Notably, California consumers were not asked if they saw or remembered seeing a sign at their prescribers' office, whether they typically receive their prescriptions after a contact lens fitting, or whether they thought a signed-acknowledgment requirement would be a more effective way to ensure that they receive a

²⁴⁴ California Optometry Association, Comment on the Proposed Changes to Chapter 15 of Title 16 of the California Code of Regulations, *in* State of California Board of Optometry, Rulemaking File, section VIII (1994) (calling the idea of a signage requirement "truly an example of over regulation").

²⁴⁵ In its comment, the American Optometric Association agreed that this concern was accurate but noted that it was "equally accurate that under the current Rule, the completion of a robocall to verify a prescription does not ensure that a seller addressed a prescriber's correction to a verification request, or that the seller has not sold lenses to the patient that should not have been provided." American Optometric Association (WS Comment #3303). It is not clear to the Commission why potential compliance issues in one aspect of a law should justify overlooking noncompliance in another.

prescription.

Using signage to ensure that patients obtain their prescriptions also requires that patients see the signs and invoke their prescription rights. Yet as noted in the discussion of consumer complaints, relying on patients to ask for their prescriptions is problematic. Many consumers might not see the sign, while others may be uncomfortable asking their prescribers for their prescriptions. And relying on patients to ask for their prescriptions again puts the onus on consumers to enforce the Rule and essentially amends the automatic-release requirement to release-upon-request, in contravention of the text of the FCLCA.²⁴⁶

Nonetheless, the Commission is receptive to prescriber concerns about the burden of the signed-acknowledgment requirement. The Commission is willing to consider alternatives that might reduce the burden and lessen any interference with the doctor-patient relationship, while at the same time maintaining much of the effectiveness and enforceability of the proposed signed acknowledgment. To this end, the Commission believes that allowing prescribers to choose from several different ways of confirming prescription release—including via portals, email delivery, and signed prescription or purchase receipts—and draft their own prescription-confirmation language will provide greater flexibility without markedly undermining the Commission’s enforceability objective.²⁴⁷ Such a change should also reduce the cost of the requirement, since prescribers will, if they choose, be able to incorporate the confirmation into an existing

²⁴⁶ See also *Eyeglass I*, 43 FR at 23998; *Eyeglass II*, 54 FR at 10286-87.

²⁴⁷ This proposal is similar to that recommended by the National Association of Optometrists and Opticians. National Association of Optometrists and Opticians (WS Comment #3208).

document that they would store in any event, or, so long as agreed to by patients, release the prescription to a portal without having to provide a paper copy.²⁴⁸ In addition, by allowing flexibility with the text of the patient confirmation, prescribers can draft one in such a way that they believe consumers will be less likely to draw an inference that prescribers have done something wrong.

At the same time, the Commission does not wish to burden prescribers with the task of formulating adequate confirmation language if they prefer to use the language the Commission previously proposed: “My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting.” Such language would satisfy the proposed requirement. In any case, while prescribers are free to provide their own language, the receipt must confirm that the patient received a prescription and cannot include additional information proscribed by the Rule, such as liability waivers or agreements to purchase lenses from the prescriber.

The Commission therefore proposes to modify its prior proposal for a signed-acknowledgment requirement by instead proposing a more flexible Confirmation of Prescription Release provision, which would require that prescribers either obtain a patient acknowledgment—whether on a separate form or on a copy of the patient’s

²⁴⁸ Some commenters expressed concern that allowing release to a portal to satisfy the confirmation requirement would undercut the educational aspect of the signed-acknowledgment proposal and provide prescribers with an “easy way to evade their obligations and frustrate the intent of the Rule.” 1-800 CONTACTS (NPRM Comment #3898). *See also* Consumers Union (NPRM Comment #3969) (stating that an electronic copy of a prescription should supplement but not substitute for providing a patient with a paper copy). However, the Commission believes that portal release achieves most of the benefits of a paper confirmation with a reduction in burden, and thus is an acceptable alternative. In order to utilize a portal for delivery of the prescription, the prescriber must obtain verifiable affirmative consent from the patient.

prescription or sales receipt²⁴⁹—or retain evidence that the prescription was provided to the patient via electronic means. The prescriber would be required to maintain evidence of the Confirmation of Prescription Release for at least three years, and make such evidence available upon request by the Commission.

Furthermore, the Commission accepts the suggestion that the requirement should apply only to prescribers who have a financial interest in the sale of contact lenses, which could create an incentive to withhold a prescription.²⁵⁰ The Commission does not believe that such an exemption is unworkable from the standpoint of determining whether a financial interest exists,²⁵¹ nor that the exemption will somehow impart to consumers the message that prescribers who sell contacts are unethical, as some commenters have feared. Overall, the Commission believes that the new proposal will retain most of the benefits of the prior signed-acknowledgment proposal, but will cause less disruption and fewer burdens for prescribers.

The Commission therefore requests comments on its modified proposal to amend § 315.3 to add a Confirmation of Prescription Release, require evidence of Confirmation

²⁴⁹ A prescriber who elects to comply with the Confirmation of Prescription Release requirement by providing a patient acknowledgment on a sales receipt must comply with any other requirements that might apply to such sales receipts.

²⁵⁰ A patient who wants contact lenses, but visits a prescriber who does not sell contact lenses (or does not have a financial interest in the sale of contact lenses), does so for the purpose of obtaining a prescription. The failure of the prescriber to provide the prescription under such circumstances would provide no benefit to the prescriber while likely alienating the patient.

²⁵¹ The proposal defines “financial interest” to include an association, affiliation, or co-location with a contact lens seller. The Commission is soliciting comments on what other types of arrangements might constitute a disqualifying indirect financial interest in the sale of contact lenses.

of Prescription Release be maintained for at least three years, and make such evidence available to the Commission upon request.

V. Requiring Prescribers to Respond to Requests for an Additional Copy of a Prescription Within Forty Business Hours

In the NPRM, the Commission clarified that the Act and the Rule require that prescribers provide patients or their agents with additional copies of prescriptions upon request.²⁵² This interpretation is consistent with the language and intent of the Act—improving prescription portability while protecting consumer health.²⁵³ By receiving a copy after making the requests themselves or authorizing sellers to make the requests, consumers can purchase contacts without the verification process. Additionally, if a patient were not to receive his or her prescription under § 315.3(a)(1), the patient would be able to request a copy later. Although the Commission did not propose amending the Rule in the NPRM, it sought comment on this clarification.

A. Obtaining an Additional Copy of a Prescription

Several commenters supported the Commission’s interpretation that the Rule and Act allow patients to request additional copies of their prescriptions.²⁵⁴ An increase in

²⁵² NPRM, 81 FR at 88536. This interpretation is consistent with prior Commission guidance. FTC Staff Opinion Letter to the American Optometric Association Providing Guidance Regarding How Contact Lens Prescribers Should Respond to Requests for Patients’ Contact Lens Prescriptions, Pursuant to the Fairness to Contact Lens Consumers Act and the Contact Lens Rule (Oct. 4, 2006), <https://www.ftc.gov/public-statements/2006/10/requests-contact-lens-prescribers-provide-patients-contact-lens>.

²⁵³ NPRM, 81 FR at 88536.

²⁵⁴ Institute for Liberty (NPRM Comment #2690); The Coalition for Contact Lens Consumer Choice (NPRM Comment #3718); Comments of the Attorneys General of 20 States (NPRM Comment #3804); National Association of Optometrists and Opticians (NPRM Comment #3851); Warby Parker (NPRM Comment # 3867); Consumers Union

the number of consumers in possession of their prescriptions could improve the accuracy of the prescription information given to sellers, reduce the number of verification requests, and make sales quicker.²⁵⁵ Commenters also suggested limitations on how long a prescriber would have to respond to the request, including eight business hours (similar to the period for responding to a verification request),²⁵⁶ two business days,²⁵⁷ and five business days.²⁵⁸

B. Analysis and Proposal

Based on the comments received, the Commission believes that the Rule should be amended to ensure that patients' agents can obtain additional copies of prescriptions in a timely manner.²⁵⁹ A time limitation for prescribers to respond to such requests would

(NPRM Comment #3969); Contact Lens Association of Ophthalmologists (NPRM Comment #4259) (“We have no objection to requiring prescribers to provide additional copies of prescriptions to a patient upon request, and suspect that this will reduce the burden of verification requests.”); Costco Wholesale Corporation (NPRM Comment #4281).

²⁵⁵ National Association of Optometrists and Opticians (NPRM Comment #3851); 1-800 CONTACTS (NPRM Comment #3898) (“With a prescription on file, 1-800 is able to ship orders faster—orders can be processed within 14 minutes of the time the order is placed” and can sell lenses throughout the duration of the prescription without any verification requests.).

²⁵⁶ National Association of Optometrists and Opticians (WS Comment #3208).

²⁵⁷ Opternative (NPRM Comment #3785); Contact Lens Association of Ophthalmologists (NPRM Comment #4259).

²⁵⁸ American Academy of Ophthalmology (WS Comment #2971); 1-800 CONTACTS (NPRM Comment #3898).

²⁵⁹ As noted in the NPRM, patients can act as their own agent and request a duplicate copy of their prescription. NPRM, 81 FR at 88536.

promote quicker responses and, in turn, allow patients to purchase contacts sooner.²⁶⁰ However, because patients should have already received an initial copy of their prescriptions under § 315.3(a)(1), the Commission believes that a longer response period, such as the forty business hours recommended by the American Academy of Ophthalmology, is more appropriate.²⁶¹ To complete the transaction sooner, a seller could instead verify the prescription with the prescriber in accordance with § 315.5. When evaluating a prescriber's compliance, the Commission would consider any extenuating circumstances that may have prevented a prescriber from providing the requested copy within forty business hours, including vacation or illness. To assist in monitoring compliance, the Commission believes that prescribers should be required to note the prescription requests and responses in patient records. Therefore, the Commission seeks comments on its proposed modification, including how much time prescribers should have to respond to a request and what records, if any, a prescriber must keep to document the request and response.

VI. Additional Requirements for Sellers Using Automated Telephone Verification Messages

²⁶⁰ 1-800 CONTACTS states that in 2016 it requested approximately 558,000 prescriptions from prescribers and received the prescription around 46% of the time. 1-800 CONTACTS (NPRM Comment #3898). Ninety percent of prescribers who responded provided the copy of the prescription within two calendar days. *Id.* By contrast, a panelist stated that Walmart had been successful in obtaining a copy of the prescription within the same business day after calling the prescriber and did not believe that any requirement to respond was necessary. CLR Panel IV Tr., *supra* note 126, at 20 (statements of Jennifer Sommer).

²⁶¹ (WS Comment #2971). If a patient who did not receive a prescription after completion of a contact lens fitting requests a copy at a later time, the prescriber must respond to this request immediately as required by § 315.3(a)(1). This would not be considered a request under § 315.3(a)(3).

In the NPRM, the Commission discussed comments concerning sellers' use of calls with pre-recorded messages, including computer-generated messages ("automated telephone messages"), to communicate verification requests.²⁶² Among other concerns with the verification process,²⁶³ commenters stated that such automated messages were difficult to understand, were confusing, or did not provide all of the information required to be a valid request.²⁶⁴ In response, the Commission noted that the Act expressly permits telephone communication for verification and believed it would be contrary to Congressional intent to prohibit use of automated technology for the purpose of prescription verification.²⁶⁵ The Commission emphasized, however, that all calls and messages must fully comply with applicable Rule requirements in order for the verification request to be valid.²⁶⁶ For example, requests delivered at a volume or cadence not capable of being understood by a reasonable person or missing required information would be invalid.²⁶⁷ The Commission sought additional information on

²⁶² NPRM, 81 FR at 88538-39.

²⁶³ *Id.* at 88537-45.

²⁶⁴ *Id.* at 88538-39.

²⁶⁵ *Id.* at 88540; Contact Lens Rule, 69 FR 40489.

²⁶⁶ *Id.* An invalid verification request does not commence the eight-business-hour period. Contact Lens Rule, 69 FR at 40497. Sellers must also comply with all state and federal statutes and regulations relating to automated telephone calls and messages, since neither the Act nor the Rule preempts other such requirements in this context.

²⁶⁷ *See* Contact Lens Rule, 69 FR at 40490 (stating that to qualify as a "completed" verification message under the Rule, a communication by telephone would require either directly reaching and speaking with the intended recipient or "clearly leaving a voice message on the telephone answering machine of the intended recipient setting forth all of the required information.").

possible modifications to the Rule that, short of prohibition, could address prescribers' concerns related to automated telephone messages.²⁶⁸

A. Issues with Automated Telephone Verification Messages

In response, the Commission received many comments concerning automated telephone messages. Some commenters viewed such messages as an efficient method of transmitting verification requests,²⁶⁹ while others stated that incomplete or incomprehensible messages were common, which burdened prescribers' businesses and posed health risks to patients who might receive incorrect lenses.²⁷⁰ Commenters also expressed concerns that: (1) The Rule does not specify how an automated telephone verification request must be communicated or structured;²⁷¹ (2) a prescriber who receives an automated message may not have an opportunity to seek clarification;²⁷² and (3) automated telephone messages do not provide sufficient records for monitoring

²⁶⁸ NPRM, 81 FR at 88541.

²⁶⁹ 1-800 CONTACTS (WS Comment #3207); National Association of Optometrists and Opticians (WS Comment #3208); Consumers Union (NPRM Comment # 3969).

²⁷⁰ *See, e.g.*, Fuller (WS Comment #531); Wheadon (WS #648); Wright (WS #743); Jolly (WS #790); Swanson (WS Comment #868); McKee (WS Comment #1290); Fandry (WS Comment #1458); Hill (WS Comment #1755); Gibson (WS Comment #1889); Hemler (WS Comment #2312); Doyle (WS Comment #2657); Tan (WS Comment #3108); Hosaka (WS Comment #3137); McCaslin (WS Comment #3228); Yu-Davis (WS Comment #3410); Burke (WS Comment #3439); CLR Panel IV Tr., *supra* note 126, at 8, 15.

²⁷¹ American Society of Cataract and Refractive Surgery (WS #3142); Consumers Union (NPRM #3969).

²⁷² Contact Lens Institute (WS Comment #3296).

compliance.²⁷³ One commenter, the National Association of Optometrists and Opticians, proposed adding requirements to the Rule that would specify how telephone verification messages would occur and what records would be maintained, including requiring that the seller's name be provided, the communication be delivered in a cadence, pronunciation, and volume that a reasonable English-speaking person could understand, and the recording be preserved if the telephone call contained a pre-recorded message.²⁷⁴

B. Analysis and Proposal

Congress included the verification process in an effort to balance the interests of consumer health and prescription portability.²⁷⁵ Although telephone is a common method of verification,²⁷⁶ the Commission does not have empirical data showing the frequency of incomplete or incomprehensible automated telephone messages²⁷⁷ or that a phone call

²⁷³ *Id.*; Health Care Alliance for Patient Safety (WS Comment #3206); CooperVision, Inc. (NPRM Comment #3841).

²⁷⁴ National Association of Optometrists and Opticians (WS Comment #3208).

²⁷⁵ NPRM, 81 FR at 88543.

²⁷⁶ One seller makes approximately 100,000 automated-verification calls per week. 1-800 CONTACTS (NPRM Comment #3898). *See also* CLR Panel IV Tr., *supra* note 126, at 8 (statements of Tim Steinemann that most of the requests to his office are received by fax, but that automated calls are also used).

²⁷⁷ The Commission has received many anecdotal comments from eye-care prescribers mentioning difficulties with understanding automated telephone calls. *See supra* note 270; CooperVision, Inc. (WS Comment #3077). One eye-care provider estimated that the verification request error rate ranged from 25% to 60%. CLR Panel IV Tr., *supra* note 126, at 8-9 (statements of Tim Steinemann). However, this rate included errors unrelated to incomplete or incomprehensible automated telephone calls, such as use of expired prescriptions or calls to the incorrect doctor. *Id.* Other commenters do not believe that automated phone calls pose a significant burden. *See* National Association of Optometrists and Opticians (WS Comment #3208) ("From our members' general perspective, there are only a few issues with the use of automated calls, which tend to be infrequent to any particular prescriber's office"). *See also* 1-800 CONTACTS

with an automated message is necessarily less reliable than one with a live person.²⁷⁸

However, the Commission recognizes the burden on prescribers²⁷⁹ and potential health risk to patients²⁸⁰ from incomplete or incomprehensible automated telephone messages.²⁸¹ Prescribers have an important role in safeguarding the health of their patients, and improper use of contact lenses could be harmful.²⁸² An effective

(NPRM Comment #3898) (based on its internal data, the average prescriber receives one telephone verification request per week, which lasts 101 to 149 seconds); Consumers Union (NPRM Comment #3969) (“[I]t does not appear that the incidence of these automated-verification calls is high enough to constitute a significant burden.”).

²⁷⁸ 1-800 CONTACTS (WS Comment #3207) (“Requiring live agents to read the entire verification request would only increase costs and lower compliance without any offsetting benefits to consumers.”); Consumers Union (NPRM Comment # 3969) (“Eye doctor offices should 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.”).

²⁷⁹ CLR Panel IV Tr., *supra* note 126, at 9 (statements of Tim Steinemann saying that he could spend twenty or thirty minutes reviewing a verification request when there are discrepancies).

²⁸⁰ Coalition for Patient Vision Care Safety (NPRM Comment #3883).

²⁸¹ Some commenters have encouraged the Commission to prohibit automated telephone messages from being used for verification requests or allow prescribers to select a preferred method. *See, e.g.*, Health Care Alliance for Patient Safety (WS Comment #3206); Coalition for Patient Vision Care Safety (NPRM Comment #3883); Johnson & Johnson Vision Care, Inc. (NPRM Comment #4327). However, for the reasons stated in the NPRM, the Commission declines to restrict sellers from using automated telephone messages. NPRM, 81 FR at 88540-41.

²⁸² *See, e.g.*, Contact Lens Institute (WS Comment #3296); Tan (WS Comment #3108); Hopkins (WS Comment #3235); Coalition for Patient Vision Care Safety (NPRM Comment #3883); The Optometric Physicians of Washington (NPRM Comment #4145); Indiana Academy of Ophthalmology (NPRM Comment #4233). *See infra* note 327 (discussing the potential health risks related to improper contact lens use).

verification process relies on prescribers being able to understand the automated messages and, if necessary, respond to sellers to prevent improper sales.²⁸³

Based on comments received and staff's experience reviewing a number of automated-verification messages, the Commission believes that to improve the verification process, § 315.5 of the Rule should be amended to require that if a seller verifies a prescription through calls that use, in whole or in part, an automated message, it must: (1) Record the entire call;²⁸⁴ (2) commence the call by identifying it as a request for a prescription verification; (3) provide the information required by § 315.5(b) in a slow and deliberate manner and at a reasonably understandable volume;²⁸⁵ and (4) give the prescriber the option to repeat this information. These changes will help prescribers better recognize and understand verification requests made with automatic telephone messages and reduce their burden, allow consumers to receive the correct lenses more

²⁸³ See Contact Lens Institute (WS Comment #3296) (stating that “the reliability of this system depends entirely on the accuracy and completeness of the transmission of the verification request and the ready availability to the prescriber of effective means for responding to the request if the request is either incomplete or the purported prescription is invalid”); CLR Panel IV Tr., *supra* note 126, at 8 (statements of Tim Steinemann) (“Many of those robocalls are unintelligible or cut off. We have no way of responding or even verifying the information.”).

²⁸⁴ Sellers must record the actual calls that occurred and not simply the electronic copies of the automated messages that should have been played. If, for instance, a prescriber's office hangs up in the middle of an automated message, the recording should capture this.

²⁸⁵ Section 315.2 would be modified to add definitions of “reasonably understandable volume” and “slow and deliberate manner.” These requirements are consistent with prior FTC guidance, which noted that automated telephone messages must be delivered at a volume and cadence that a reasonable person can understand. See FTC, FTC Facts for Business, Complying with the Contact Lens Rule at 6 (Aug. 2005), <https://www.ftc.gov/system/files/documents/plain-language/bus63-complying-contact-lens-rule.pdf>.

quickly, and provide the Commission with a way to monitor sellers' compliance with the Rule.²⁸⁶ Importantly, a verification request made using a call with an automated telephone message that does not meet the proposed requirements would be considered an invalid request.²⁸⁷ Therefore, the Commission seeks comments on its proposed modification, including the feasibility of recording the entire call and making the message repeatable at the prescriber's option.²⁸⁸

VII. Seller Alteration of Contact Lens Prescriptions

A. Background

The FCLCA's clear purpose is to provide contact lens consumers with their prescriptions so they can shop at the seller of their choice. However, the FCLCA requires sellers to sell lenses "only in accordance with a contact lens prescription" and prohibits sellers from altering contact lens prescriptions.²⁸⁹ Under the Act, a consumer's ability to shop and a seller's ability to sell only extends to the lens prescribed by an eye-

²⁸⁶ The Commission also proposes modifying § 315.5 to require that sellers maintain these recordings, similar to other records, for at least three years.

²⁸⁷ In some situations, a seller may not realize that its request is invalid. To prevent dispensing potentially incorrect lenses, the Commission encourages prescribers to contact sellers, when possible, to inform them of invalid verification requests. NPRM, 81 FR at 88540-41. For incomplete requests, the Commission encourages prescribers, to the extent possible, to provide the missing information to sellers. *Id.*

²⁸⁸ The Commission notes that some states require two-party consent to record telephone calls and that determining compliance with state law taping requirements is the responsibility of the seller. Since the Rule permits verification requests to be made via live telephone call, email, and fax, sellers who face obstacles related to these requirements have other options.

²⁸⁹ 15 U.S.C. 7603.

care prescriber, or an identical contact lens.²⁹⁰ The Rule follows the Act on its prohibition of contact lens alteration.²⁹¹

In previously assessing the issue of alteration in the NPRM,²⁹² the Commission reviewed comments received in response to the FTC’s 2015 Request for Comment about illegal alteration and a 2015 online survey submitted by Johnson & Johnson Vision Care, Inc. that purportedly showed a high incidence of illegal alterations.²⁹³ For reasons detailed in the NPRM, the Commission could not rely on that survey.²⁹⁴ Since the Rule already prohibited alteration and the Commission did not receive reliable empirical evidence on the frequency of illegal alterations, the Commission concluded that no changes were necessary, but indicated that it would review evidence of illegal substitutions and investigate as appropriate.²⁹⁵

B. Comments

In response to the NPRM and the workshop notice, the Commission received numerous detailed comments describing instances of, and adverse outcomes arising from,

²⁹⁰ Contact Lens Rule, 69 FR at 40503.

²⁹¹ 16 CFR 315.5(e); *see also id.* 315.5(a) (indicating that a “seller may sell contact lenses only in accordance with a contact lens prescription[.]”).

²⁹² Alteration can occur in a number of ways. One way would be for a seller who is presented with a copy of a prescription to substitute another brand for that specified on the prescription. Another way would be for a seller to submit a verification request for a brand listed on a prescription, but fill the prescription with another brand of lenses following verification. A third way would be for a seller to submit a brand for verification other than what is listed on a patient’s prescription.

²⁹³ NPRM, 81 FR at 88551-52.

²⁹⁴ *Id.*

²⁹⁵ *Id.*

illegal substitutions. Commission staff also re-examined its complaint database and engaged in its own review of websites offering contact lenses for sale. As a result, the Commission is reconsidering its earlier determination.

Many manufacturers, prescribers, and optometry groups—through written comments and at the FTC’s workshop examining the Rule and the marketplace—expressed strong support for the continued prohibition of prescription alteration. These entities noted that contact lenses are classified as restricted medical devices regulated by the FDA,²⁹⁶ are not interchangeable, and should not be treated as commodities.²⁹⁷ The commenters were emphatic about the need for a contact lens fitting performed by an eye-care prescriber,²⁹⁸ resulting in a prescription listing the manufacturer or brand of the

²⁹⁶ Health Care Alliance for Patient Safety (WS Comment #3206); Contact Lens Institute (WS Comment #3296); Alcon (WS Comment #3339); *see also* FTC, The Contact Lens Rule and the Evolving Contact Lens Marketplace, Panel II: Contact Lens Health and Safety Issues Tr. at 6 (Mar. 7, 2018) (statements of Malvina Eydelman explaining FDA regulation of contact lenses); https://www.ftc.gov/system/files/documents/public_events/1285493/panel_ii_contact_lens_health_and_safety_issues.pdf [hereinafter CLR Panel II Tr.].

²⁹⁷ Leung (WS Comment #1600); Ng (WS Comment #1753); Jones (WS Comment #3012); Johnson & Johnson Vision Care, Inc. (WS Comment #2231); Contact Lens Institute (WS Comment #3296); Ellenbecker (WS Comment #3357); Anderson (NPRM Comment #127); Boyer (NPRM Comment #2681); Henahan (NPRM Comment #3365).

²⁹⁸ *See, e.g.*, CLR Panel II Tr., *supra* note 296, at 11 (statements of Edward Chaum) (“[A]ll patients who wear contact lenses should have an appropriate contact lens fitting by an eye care professional.”); *id.* at 13-14 (statements of Carol Lakkis discussing the importance of an evaluation after a lens has been worn for some time); FTC, The Contact Lens Rule and the Evolving Contact Lens Marketplace, Panel VI: Looking Ahead Tr. at 5 (statements of Peter Menziuso explaining a prescriber determines a brand based on the physiology, anatomy, and lifestyle of the patient, and the material, edge design, modality, optical zones, and wetting agent of the lens) https://www.ftc.gov/system/files/documents/public_events/1285493/panel_vi_looking_ah_ead.pdf [hereinafter CLR Panel VI Tr.]; Shepherd (WS Comment #483); McLemore (WS

selected lens.²⁹⁹ The Contact Lens Institute, an association of contact lens manufacturers, explained that a contact lens fitting must be the basis for the initial and ongoing prescription and wear of contact lenses and “because a contact lens is placed directly on the eye, the physiological response [] must be monitored to ensure safe wear.”³⁰⁰ Dr. Malvina Eydelman of the FDA explained that different brands of lenses, even those with the same technical measurements, such as base curve and diameter, do not fit the same and therefore need to be evaluated on the patient’s eyes to determine whether they are appropriate for that patient.³⁰¹ Dr. Eydelman’s statement that “the current clinical care paradigm does not support substitution of contact lens brands without a clinical evaluation” bolsters the Commission’s continued adherence to the Rule’s prohibition on illegal alteration.³⁰²

Comment #1270); McKee (WS Comment #1290); Ng (WS Comment #1753); Ballard (WS Comment #3027).

²⁹⁹ The Rule defines a contact lens prescription to include the power, and the material or manufacturer or both, of the prescribed contact lens. 16 CFR 315.2. In practice, it appears many prescriptions list the manufacturer’s brand, which refers to the entire device, and from which a seller can determine the manufacturer.

³⁰⁰ Contact Lens Institute (WS Comment #3296).

³⁰¹ CLR Panel II Tr., *supra* note 296, at 13.

³⁰² *See* CLR Panel II Tr., *supra* note 296, at 8. Dr. Eydelman also noted that additional research is needed to support clinical equivalency between lens brands. *Id.* Other panelists presented their views that greater substitution should be permitted or at least explored. *See* CLR Panel VI Tr., *supra* note 298, at 5-6. *See also* 1-800 CONTACTS (WS Comment #3207) (brand selection is more about economics than physiology and consumers would benefit from greater brand choice).

With some noting that this occurred frequently,³⁰³ prescribers expressed concern that some patients were wearing different lenses than those they had prescribed, which they had not evaluated on their patients' eyes.³⁰⁴ Many prescribers detailed harm that resulted from wearing unprescribed lenses, including headaches, corneal neovascularization, corneal ulcers, and other irreversible and vision threatening diagnoses.³⁰⁵ Others commented on the general risks that may result from wearing lenses

³⁰³ McBride (WS Comment #659) (online retailers constantly switch lenses); A. McKee (WS Comment #730) (not uncommon); E. McKee (WS Comment #1290) (on a regular basis); Costabile (WS Comment #2320) (many violations); Kerns (WS Comment #2573) (three patients this week in non-prescribed brands); Heinke (WS Comment #2744) (hundreds over the last fifteen years); McGahen (WS Comment #2935) (“so many patients?”); Ballard (WS Comment #3027) (constant); Plasner (WS Comment #3085) (frequent); Milner (WS Comment #3255) (common); Jankowski (WS Comment #3407) (dozens each year); Glazier (NPRM Comment #265) (weekly); Henahan (NPRM Comment #3365) (consistent and pervasive violation by filling prescriptions that have expired, by substituting contact lenses for another brand); McAleese (NPRM Comment #3383) (numerous patients over the past ten years with the wrong brand, parameters, or filled by using an expired prescription).

³⁰⁴ Shepherd (WS Comment #483); Foutz (WS Comment #512); McVicker (WS Comment #517); Polizzi (WS Comment #519); Morse (WS Comment #536); Bernard (WS Comment #588); Sun (WS Comment #692); Larson (WS Comment #716); McKee (WS Comment #730); Gitchell (WS Comment #759); Dillehay (WS Comment #822); Nowakowski (WS Comment #827); Yoder (WS Comment #830); Molamphy (WS Comment #853); McKee (WS Comment #1290); Bandy Jr. (WS Comment #1593); Leung (WS Comment #1600); Mintchell (WS Comment #1705); Kendrick (WS Comment #1725); Ng (WS Comment #1753); Seyller (WS Comment #1797); McMahon (WS Comment #1868); Bowers (WS Comment #2291); Costabile (WS Comment #2320); Bearden (WS Comment #2685); McGahen (WS Comment #2935); Olson (WS Comment #2970); Ballard (WS Comment #3027); Raymond (WS Comment #3090); Richmond (WS Comment #3255); Glazier (NPRM Comment #265); Luy (NPRM Comment #2051); Boyer (NPRM Comment #2681); *see also* American Optometric Association (WS Comment #3303, App. F) (including prescriber reports of sellers engaging in illegal alteration).

³⁰⁵ *See, e.g.*, Gitchell (WS Comment #759) (discomfort and red eyes to patients needing corneal transplants); Molamphy (WS Comment #853) (blood vessels growing in cornea); Leung (WS Comment #1600) (harm); Mintchell (WS Comment #1705) (ocular problems); Kerns (WS Comment #2573) (three patients with significant corneal

that have not been fit by prescribers.³⁰⁶ Dr. Carol Lakkis of Johnson and Johnson Vision Care, Inc. stated that “finding the appropriate lenses for [patients’] eyes doesn’t just provide them with overall comfort [], but more importantly, it can minimize the negative impact on their eye health.”³⁰⁷ A number of state ophthalmology associations commented that “poorly fit lenses can cause corneal ulcers and infections resulting in permanent vision loss.”³⁰⁸ One comment, a version of which was submitted by approximately 1,000 commenters, many of whom were prescribers, implored the FTC to consider enforcement mechanisms or revisions to the Rule that address illegal substitutions.³⁰⁹

neovascularization); Bearden (WS Comment #2685) (irreversible and vision threatening); Heinke (WS Comment #2744) (headaches); McGahen (WS Comment #2935) (many patients with sight threatening corneal ulcers); Raymondi (WS Comment #3090) (red, dry eyes and blurry vision); White (WS Comment #3210) (sight threatening corneal ulcers); Theroux (WS Comment #3350) (corneal keratitis infection); Glazier (NPRM Comment #265) (infections); Boyer (NPRM Comment #2681). *See also* American Optometric Association (WS Comment #3303, App. F) (including prescriber reports of harm from, *inter alia*, illegal alteration).

³⁰⁶ *See, e.g.*, Johnson & Johnson Vision Care, Inc. (WS Comment #555); McLemore (WS Comment #1270); Easton (WS Comment #1333); Dice (WS Comment #1585); Staab (Comment #1597); Roth (WS Comment #1806); Rodriguez (WS Comment #1807); Olson (WS Comment #2970); Ballard (WS Comment #3027); Plasner (WS Comment #3085).

³⁰⁷ CLR Panel II Tr., *supra* note 296, at 9.

³⁰⁸ Indiana Academy of Ophthalmology (NPRM Comment #4233). *See also* Pennsylvania Academy of Ophthalmology (NPRM Comment #4214); Idaho Society of Ophthalmology (NPRM Comment #4167); Florida Society of Ophthalmology (NPRM Comment #4197); Oklahoma Academy of Ophthalmology (NPRM Comment #4204);

³⁰⁹ *See, e.g.*, Wolfe (WS Comment #780); Whitaker (WS Comment #997); Carvell (WS Comment #1021); Pam Satjawatcharaphong (WS Comment #1030); Marler (WS Comment #1181); Brandenburg (WS Comment #1376); Fruchtmann (WS Comment #1392); Bui (WS Comment #1562); Tashner (WS Comment #1594); Mintchell (WS Comment #1705); Engle (WS Comment #1721); Spivack (WS Comment #1778); Thau

Prescribers blamed third-party sellers,³¹⁰ those who sell their own brand of lenses direct-to-consumer,³¹¹ and online sellers more generally,³¹² as the primary sources of prescription alteration. Some asserted that certain sellers are only interested in their financial bottom line and not in their customers' eye health.³¹³ Specifically, many prescribers complained that a number of sellers are not complying with—or are even abusing—the prescription verification process to unlawfully alter prescriptions and sell

(WS Comment #1909); Yamamoto (WS Comment # 2053); Bloodgood (WS Comment #2200); Persson (WS Comment #2418); Hanna (WS Comment #2537); Sugianto (WS Comment #2546); Zellers (WS Comment #2559); Hom (WS Comment #2655).

³¹⁰ Some commenters refer to third-party sellers as the source of the problem, without specific reference to online sellers. *See, e.g.*, McKee (WS Comment #1290); Bowers (WS Comment #2291); Costabile (WS Comment #2320); Plasner (WS Comment #3085).

³¹¹ Brenden (WS Comment #600); Jones (WS Comment #644); Martorana (WS Comment #677); Sandberg (WS Comment #693); Cox (WS Comment #797); Marrotte (WS Comment #806); Young (Comment #812); Dillehay (WS Comment #822); Nowakowski (Comment #827); Derryberry (WS Comment #833); Alwes (Comment #998); Dugger (Comment #1238); Staab (Comment #1597); Leung (WS Comment #1600); Begeny-Mahan (WS Comment #1702); Ng (WS Comment #1753); Roth (WS Comment #1806); Rodriguez (WS Comment #1807); McMahon (WS Comment #1868); Steinhauser (Comment #1937); Olswing (WS Comment #2686); Weaver (Comment #2726); Ballard (WS Comment #3027); Nason (WS Comment #3086); Raymondi (WS Comment #3090); Tan (WS Comment #3108); Horibe (WS Comment #3242); Theroux (WS Comment #3350).

³¹² Palys (WS Comment #560); McBride (WS Comment #659); Sun (WS Comment #692); McGrew (Comment #713); Larson (Comment #716); Marrotte (WS Comment #806); Branstetter (WS Comment #2235); Mintchell (WS Comment #1705); Kendrick (WS Comment #1725); Seyller (WS Comment #1797); Jones (WS Comment #3012); Bearden (WS Comment #2685); McGahen (WS Comment #2935); Olson (WS Comment #2970); Smith (WS Comment #3024); Nason (WS Comment #3086); White (WS Comment #3210); Szabo (WS Comment #3348); Bottjer (WS Comment #3378).

³¹³ McBride (WS Comment #659); Larson (WS Comment #716); McKee (WS Comment #1290); Plasner (WS Comment #3085); Nason (WS Comment #3086).

lenses that are not prescribed or not identical to those prescribed.³¹⁴ A number of prescribers alleged that sellers of their own brand of lenses routinely rely on prescribers not responding to verification requests (*i.e.* passive verification) as part of their business model to “fill non-existent prescriptions with their own brand of generic lenses.”³¹⁵ In addition to these comments, other prescribers stated that they have never fit, and thus never would have prescribed, certain brands of lenses,³¹⁶ and therefore consumers could only obtain them through seller alteration, either without any attempt at verification, or via passive verification.

Concerns about passive verification resulting in patients receiving contact lenses for which they have no prescription are not new, and were considered when Congress passed the FCLCA³¹⁷ and in the NPRM in 2016.³¹⁸ What is new, however, is the

³¹⁴ *See, e.g.*, Sandberg (WS Comment #693); Swanson (WS Comment #868); Alwes (WS Comment #998); Dugger (WS Comment #1238); Hill (WS Comment #1755); Gibson (WS Comment #1889); Henry (WS Comment #2194); Wacker (WS Comment #2814); Nason (WS Comment #3086); Hosaka (WS Comment #3137); Contact Lens Institute (WS Comment #3296); Yu-Davis (WS Comment #3410); Scullaw1 (WS Comment #3492); *see also* Rose (WS Comment #2841) (optician); Tan (WS Comment #3108) (staff in optometrist office).

³¹⁵ Silverman (WS Comment #805); Marrotte (WS Comment #806); Young (WS Comment #812); Koch (WS Comment #855); Alwes (WS Comment #998); Dugger (WS Comment #1238); Olswing (WS Comment #2686); *see also* Dillehay (WS Comment #822) (stating one online supplier explained how they set up their business to use passive verification to switch lenses to their own brand).

³¹⁶ Vo (WS Comment #301); Yu-Davis (WS Comment #3410); *see also* Cox (WS Comment #797) (“Almost no doctors fit these archaic lenses”); Derryberry (WS Comment #833) (“I do not know any physicians who prescribe these lenses.”).

³¹⁷ *See, e.g.*, FCLCA Subcomm. Hearing, *supra* note 15 (statements of Howard Beales, Federal Trade Commission); *Id.* (statements of J. Pat Cummings, American Optometric Association) (“And the problem with passive verification is that people will get contact lenses without a prescription.”).

emergence of business models that rely exclusively, or almost exclusively, on passive verification as a means to substitute their own brand of daily contact lenses. Under these business models, sellers advertise directly to consumers, often through Facebook or other social media platforms,³¹⁹ and often sell their lenses through subscription services. Several of these companies sell one type of lens only, made from a single material, with one modality, base curve, and diameter.³²⁰ Some consumers who have been prescribed toric lenses for astigmatism or multifocal lenses have ordered and received lenses from these sellers, unaware at the time they order that the sellers do not offer appropriate lenses for them.³²¹ The only information some sellers request from consumers about their contact lens prescription is the desired power(s) of the lenses, and the websites for some do not include a mechanism for consumers to upload their actual prescription. Rather, these sellers ask consumers to provide prescriber information and represent that they will check with, or verify, the prescription with the prescriber.³²² Sellers may then contact the

³¹⁸ NPRM, 81 FR at 88543.

³¹⁹ McVicker (WS Comment #517) (explaining that she ordered contact lenses for the first time after seeing an ad on Facebook); McMahon (WS Comment #1868) (stating that patient heard about seller on Facebook).

³²⁰ *See, e.g.*, McMahon (WS Comment #1868) (stating one seller sells only one lens with one material, one base curve, one diameter, and one replacement schedule).

³²¹ Approximately 16% of contact lens wearers wear toric lenses, with another 12% wearing multifocal lenses. Vision Council, U.S. Optical Market Eyewear Overview 11 (2018), https://www.ftc.gov/sites/default/files/filefield_paths/steve_kodey_ppt_presentation.pdf. *See also* Easton (WS Comment #1333) (changing from a toric lens to a spherical lens can give eyestrain, headaches, and poor vision).

³²² *See, e.g.*, McVicker (WS Comment #517) (consumer stating checkout form indicated seller would check with optometrist to verify prescription).

prescriber with a verification request that includes the power of the consumer's lenses, but substitutes the seller-manufacturer's name as the brand of lens.³²³ Should a prescriber fail to invalidate such a verification request within eight business hours (as dictated by the Rule), the seller may believe it is authorized to ship that month's lenses, and subsequent subscription orders for a year or two, depending on state prescription expiration limits.

The Commission is concerned about the misuse of passive verification to substitute a different brand and manufacturer of lenses. If a seller knows or should know that a verification request includes a different brand and manufacturer than that prescribed by the prescriber, the verification request is not valid and does not commence the eight-business-hour verification period.³²⁴ In such circumstances, the seller is not selling contact lenses "in accordance with a contact lens prescription."³²⁵ The purpose of passive verification under the Act was "to ensure that consumers are not caught in the competitive tug-of-war between doctors and third party sellers for the sale of contact

³²³ *E.g.*, Silverman (WS Comment #805) (substitution to "generic" lenses occurring via passive verification); Marrotte (WS Comment #806) (same); Koch (Comment #855) (same); Alwes (WS Comment #998) (same); Dugger (WS Comment #1238) (same); Olswing (WS Comment #2686) (same); *see also* Dillehay (WS Comment #822) (stating one online supplier explained how it set up its business to use passive verification to switch lenses to its own brand).

³²⁴ If the seller is relying on information provided by the consumer in response to a request that the consumer provide the manufacturer or brand listed on the consumer's prescription, and the consumer provides inaccurate information, the verification request would be inaccurate, and the prescriber would be obligated to correct the inaccuracy. 16 CFR 315.5(d).

³²⁵ 16 CFR 315.5(a).

lenses.”³²⁶ The tug-of-war referred to was over the sale of the prescribed lens, not over which party would determine the brand of lens consumers should wear. Any attempt to substitute another lens, including a seller’s own brand, for the prescribed lens thwarts the purpose of the Act, which is to allow sellers to sell contact lenses as prescribed by the consumer’s eye-care provider. Although the Commission has anecdotal reports of eye injury to patients from wearing lenses that were not prescribed for them, the Commission does not have definitive evidence of the incidence of such injury.³²⁷

C. Analysis and Proposals

Although the Commission does not possess systematic empirical evidence of the full extent of this type of illegal substitution,³²⁸ it believes such activity is growing

³²⁶ H.R. Rep. No. 108-318, at 5.

³²⁷ Some reports in the literature suggest that purchasing contact lenses from unregulated sources, *i.e.*, sources that would not include a contact lens fitting, may be a risk factor for microbial keratitis and other serious adverse events, but these reports fail to control for various confounding factors. See Graeme Young et al., “Review of Complications Associated With Contact Lenses From Unregulated Sources of Supply,” 40(1) *Eye & Contact Lens* 58, 62 (2014) (most risk factors noted in case reports were absence of lens fitting and education concerning usage and hygiene); William H. Schweizer et al., “The European Contact Lens Forum (ECLF)—The Results of the CLEER-Project,” 34 *Contact Lens Anterior Eye*, 293, 295 (unregulated sourcing of plano contact lenses resulted in more cases of corneal staining, corneal neovascularization, and vision threatening signs). At the contact lens workshop, experts disputed whether countries with less stringent contact lens regulations experienced more serious adverse events related to contact lens wear as compared to countries with more stringent regulations, such as the United States. Compare CLR Panel II Tr., *supra* note 296, at 10 (statements of Carrol Lakkis that unregulated Asian markets have higher rates of infection), *with id.* at 16 (statements of Edward Chaum that “in countries in which FDA regulations do not exist, and they are less regulated, the incidence is the same”).

³²⁸ At the workshop, Dr. Steinemann presented an informal survey, finding error rates in prescription verification requests ranging from 25% to 60% depending on the office. CLR Panel IV Tr., *supra* note 126, at 8-9. The greatest inaccuracy, according to Dr. Steinemann, was for expired prescriptions, though this survey also captured inaccurate prescriptions. *Id.* Although informative anecdotally, the Commission cannot

quickly and is large enough to merit action. Moreover, the Commission is aware that more sellers have been entering the market to sell their own brands of lenses directly to consumers, and this, along with the large number of complaints and anecdotal reports of instances of alteration by online sellers—some of which describe vision-threatening injuries—necessitate modifications to the Rule.

Some commenters recommended fundamentally restructuring the Rule’s prescription verification framework to close passive verification loopholes that allow lenses to be dispensed without a valid prescription.³²⁹ This recommendation fails to recognize that the verification framework is prescribed in the FCLCA. Moreover, the Commission believes that it can address some of the concerns about selling lenses

rely on such a small informal sample as empirical evidence of the prevalence of illegal alteration. The Commission also cannot rely on the survey results submitted by the American Optometric Association in which some of its members responded to the following question: “How many of your patients do you believe are obtaining lenses from Internet retailers after the prescription has expired or are obtaining lenses that are different from what has been prescribed?,” as empirical evidence. American Optometric Association (WS Comment #3303, App. B). First, prescriber entries of “zero,” “1-10,” “11-20,” “21-30,” “31+,” and “no value” give no indication of what percentage of the prescriber’s patients are believed to have experienced issues; also, these results are not time limited so it is not clear if the numbers provided are within the last year or some other period. In addition, the question combines the issues of obtaining lenses with expired prescriptions and obtaining lenses that were different from the prescribed lenses; accordingly, the Commission cannot isolate the prevalence of the practice of substitutions to different lenses. Further, even if the prescriber was referring to alteration, the question refers to lenses “different from” the prescribed lens, and it is unclear whether a lens purchased that is identical to the prescribed lens would be included in the results, and thus whether the results may include permissible alterations.

³²⁹ See, e.g., Northsight Vision Care Center (WS Comment #1196) (proposing an end to passive verification, and instead requiring that patients provide sellers with a copy of their prescription); Golden (WS Comment #1353) (“need to move from a passive verification process to an active one where contact lenses can not [*sic*] be sold unless approved by a doctor”); American Society of Cataract and Refractive Surgery (WS Comment #3142) (extending the eight-business-hour time-period for passive verification to five business days).

without a prescription without making changes to the verification framework itself.

Aside from the modifications related to calls that use automated messages discussed in Section VI in this SNPRM, for the reasons discussed in the NPRM,³³⁰ the Commission is not proposing changes to the verification framework.

The Commission is concerned with what appears to be the use of prescription verification to change consumers from their prescribed lens to another brand of lens entirely. Therefore, the Commission proposes two amendments to the Rule, which should increase prescription presentation to sellers and decrease the number of invalid verification requests made to prescribers.³³¹ Both further the purpose and intent of the Act.

1. Seller Requirement to Accept Prescription Presentation

The first proposed modification, adding a paragraph (g) to § 315.5, requires sellers to provide a clear and prominent method for the patient to present the seller with a copy of the patient's prescription.³³² Such method may include, without limitation, electronic mail, text message, file upload, or facsimile. This proposal would address

³³⁰ NPRM, 81 FR 88537-45.

³³¹ The Commission evaluated the recommendation from Johnson and Johnson Vision Care, Inc. that it stated would ensure patients continue to receive the exact lenses prescribed by their eye doctors. Johnson and Johnson Vision Care, Inc. (WS Comment #2231). It requested that the Commission clarify the current definition of contact lens prescription to make it clear that a prescription must include both the brand and the manufacturer. *Id.* The manufacturer did not explain how the current requirement that a prescription include the material or manufacturer or both is inadequate, and the Commission does not see how such a modification would alleviate the occurrence of illegal alteration for an order where a seller does not present a copy of the prescription and instead, makes a passive verification request.

³³² The amendment would also allow a prescriber to upload a prescription.

prescriber and manufacturer concerns by increasing the number of patients who present online sellers with their prescriptions rather than relying on verification. Indeed, one commenter noted that the verification process is intended to be a “back-up, failsafe means for a retailer to ascertain the accuracy of a prescription ... in the absence of having an actual copy of the prescription.”³³³ Other commenters noted that if more consumers possess their prescriptions, verifications will decrease.³³⁴ But this can only occur if patients can present their prescriptions. While the majority of online sellers currently facilitate patient presentation of a prescription (and may even encourage it), some sellers do not request or even allow it. Their reliance solely on verification defeats the intent of the Act and Rule by limiting patient choice, by making it more likely that patients will receive lenses for which they do not have a prescription, and by disproportionately increasing the Act’s burden on prescribers. Although the Commission cannot require that sellers obtain a copy of a prescription in lieu of verification, should a patient (or prescriber) provide a seller with a prescription for a lens other than, and not identical to, the lens ordered, the seller would thereby be on notice that the patient does not have a prescription for the lens ordered and thus should not, in connection with that order, attempt to verify any lens other than what is, or is identical to, that listed on the prescription. This amendment should thereby reduce the incidences of verification attempts for a non-prescribed lens and the burden on prescribers of responding to such

³³³ Consumers Union (NPRM Comment #3969).

³³⁴ See, e.g., National Association of Optometrists and Opticians (WS Comment #3208); Costco Wholesale Corporation (NPRM Comment #4281); CLR Panel V Tr., *supra* note 50, at 9 (statements of David Cockrell that it would absolutely reduce the number of verifications, but would not eliminate them, since patients often lose their prescription copies).

verification requests. As an added benefit, the requirement to allow prescription presentation will also ensure patient choice and flexibility, and enable patients to receive their lenses more rapidly than they would via the verification method.³³⁵

2. Seller Requirement to Verify Only the Contact Lens Brand or Manufacturer that Consumers Indicate Is on Their Prescriptions

The second proposed modification targets concerns about prescription verification more directly. The proposed modification of § 315.5(f) would define alteration to include a seller's providing, as part of a verification request, a prescriber with a manufacturer other than that specified on a patient's prescription. The proposal includes an exception, however, for when a seller provides a manufacturer that a patient provided to the seller, either on the order form or orally in response to a request for the manufacturer or brand listed on the prescription. In other words, to avail themselves of the exception, sellers must ask their customers to provide the manufacturer or brand listed on their prescription.³³⁶ A seller would not be able to avail itself of the exception by relying on a prepopulated or preselected box, or customers' online searches for a particular manufacturer or brand, as a representation that they have a prescription for that manufacturer or brand. A seller not covered under the exception discussed above who makes a verification request containing a manufacturer other than, and not identical to,

³³⁵ Such prescription presentation can also benefit sellers who can avoid costs associated with prescription verification.

³³⁶ The Rule proposal permits sellers to ask for a brand or a manufacturer, as a consumer may know only the brand, and not the manufacturer, of the prescribed lens. In its verification request, the seller should provide the prescriber with the manufacturer of the lens as required by 16 CFR 315.5(b)(2).

one the consumer has indicated is on his or her prescription, violates the Rule, even if a prescriber subsequently invalidates the request and the lenses are never sold.

Although the proposed amendment is not a fail-safe in avoiding all instances of alteration, it should reduce the instances of sellers altering a consumer's contact lens brand through prescription verification. If the consumer responds to the seller's inquiry by providing a manufacturer or brand other than that on his or her prescription,³³⁷ whether intentionally or not, the seller would not violate the Rule by indicating that manufacturer on a verification request.³³⁸ Thus, the passive verification framework could allow a consumer to obtain lenses other than those prescribed.³³⁹ Congress, however, was aware of this risk when opting for a passive verification framework for the Act.³⁴⁰

³³⁷ If consumers wish to try a different brand of contact lenses than that listed on their prescriptions, sellers can encourage those consumers to contact a prescriber.

³³⁸ It is not clear to what extent consumers realize they may be ordering a different contact lens than the one prescribed. Indeed, one optometrist commented that patients who come in wearing non-prescribed lenses do not understand they purchased something different from what they tried in the office and "probably don't even realize the specificity of a contact lens prescription." Gitchell (WS Comment #759). *See also* Begeny-Mahan (WS Comment #1702) (stating one seller is especially noted for not informing patients that the lenses they are ordering are a substitute for the lens on their written prescriptions). Seller statements that it will check the prescription information with, or verify the prescription information with, consumers' doctors may lead consumers to believe that their prescribers will actively approve the lens ordered, which is not necessarily the case. The Commission will work to provide consumers with greater education on the Rule's passive verification framework.

³³⁹ If a consumer wishes to obtain a contact lens that was not prescribed, there is little the Commission can do other than rely on the prescriber to invalidate the request. *See* CLR Panel IV Tr., *supra* note 126, at 21 (statements of Jennifer Sommer that she is not sure there is a control that can be put in place for these types of consumers).

³⁴⁰ *See, e.g.*, FCLCA Subcomm. Hearing, *supra* note 15 (statements of Howard Beales, Federal Trade Commission); *id.* (statements of J. Pat Cummings, American Optometric Association) ("And the problem with passive verification is that people will get contact lenses without a prescription.").

The Commission does not propose a recordkeeping requirement for sellers in conjunction with its proposal to amend the alteration provision of the Rule. However, should a seller wish to avail itself of the defense that the consumer provided the name of a different, non-identical, manufacturer than that prescribed, the seller will have the burden of producing evidence to support its claim.³⁴¹ The Commission seeks comment on its proposals to enable patients to present prescriptions to sellers and to require sellers to limit verification requests to manufacturers or brands that consumers have indicated are on their prescriptions as ways to reduce the incidence of illegal alterations.

VIII. Request for Comments

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Write “Contact Lens Rule, 16 CFR Part 315, Project No. R511995” on the comment. Your comment, including your name and your state, will be placed on the public record of this proceeding, including, to the extent practicable, the <https://www.regulations.gov> website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online. To

³⁴¹ The Commission declines to prescribe the manner in which sellers collect or maintain this information. However, examples of evidence the Commission would find convincing include: (1) If the consumer provides the name of the manufacturer or brand on the order form, a screenshot of the order page or an email or other electronic exchange of information; and (2) if the consumer states the manufacturer or brand orally, an audio recording of the statement, or a notation of the manufacturer or brand provided, the name of the seller’s representative who obtained the statement, and the date and time of the statement.

make sure that the Commission considers your online comment, you must file it at <https://www.regulations.gov> by following the instructions on the web-based form.

If you file your comment on paper, write “Contact Lens Rule, 16 CFR Part 315, Project No. R511995,” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024. If possible, please submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else’s Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential,” as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2), including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns,

devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comments to be withheld from the public record. Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at <https://www.regulations.gov>, we cannot redact or remove your comment from the FTC Website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the Commission’s website at <https://www.ftc.gov> to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

The Commission invites members of the public to comment on any issues or concerns they believe are relevant or appropriate to the Commission’s consideration of proposed amendments to the Rule. The Commission requests you provide factual data,

and in particular, empirical data, upon which your comments are based. In addition to the issues raised above, the Commission solicits public comment on the costs and benefits to industry members and consumers of each of the proposals as well as the specific questions identified below. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

Questions

A. General Questions on Proposed Amendments: To maximize the benefits and minimize the costs for prescribers and sellers (including small businesses), the Commission seeks views and data on the following general questions for each of the proposed changes described in this SNPRM:

1. What benefits would a proposed change confer and on whom?

The Commission in particular seeks information on any benefits a change would confer on consumers of contact lenses.

2. What costs or burdens would a proposed change impose and on whom?

The Commission in particular seeks information on any burdens a change would impose on small businesses.

3. What regulatory alternatives to the proposed changes are available that would reduce the burdens of the proposed changes while providing the same benefits?

4. What additional information, tools, or guidance might the Commission provide to assist industry in meeting extant or proposed requirements efficiently?

5. What evidence supports your answers?

B. Electronic Delivery of Prescriptions

1. The Commission believes that providing patients with a digital copy of their prescription, in lieu of a paper copy, would satisfy the automatic prescription-release requirement (§ 315.3(a)(1)) if the patient gives verifiable affirmative consent and is able to access, download, and print the prescription. The Commission seeks comment on the benefits or the burdens that the option to provide electronic delivery of prescriptions would confer.

2. Would prescribers choose to satisfy the automatic prescription-release requirement through electronic delivery if permitted by the Rule?

3. Would a patient portal, email, or text message be feasible methods for prescribers to provide digital copies of prescriptions to patients? Are prescribers using any other electronic methods to provide patients with prescriptions?

4. Should prescribers be required to keep any records documenting a patient's verifiable affirmative consent to receive the prescription electronically? If yes, what records should be kept and for how long? Should the documentation specify the electronic method(s) by which the patient has agreed to receive the prescription?

5. What evidence supports your responses?

C. Confirmation of Prescription Release:

1. Would the proposed Confirmation of Prescription Release provision increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

2. Compared to the Commission's prior proposal for a signed acknowledgment, would the proposed Confirmation of Prescription Release provision have more, less, or about the same effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

3. Would the proposed requirement that prescribers would have to maintain evidence of the Confirmation of Prescription Release for at least three years increase, decrease, or have no effect on the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? Why?

4. Compared to the Commission's prior proposal for a signed acknowledgment, would the proposed Confirmation of Prescription Release provision have more, less, or about the same effect on the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? Why?

5. Would the proposed Confirmation of Prescription Release requirement increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

6. Compared to the Commission's prior proposal for a signed acknowledgment, would the requirement of Confirmation of Prescription Release have more, less, or about the same effect on the extent to which patients understand their rights under the Rule? Why?

7. Does the new proposal to allow prescribers to choose from different

delivery methods for the Confirmation of Prescription Release increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

8. Does the new proposal to allow prescribers to devise their own language for the Confirmation of Prescription Release increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

9. Does the new proposal to allow prescribers to satisfy the Confirmation of Prescription Release requirement by (when expressly consented to by the patient) releasing a digital copy of the prescription to the patient, such as via online portal, electronic mail, or text message increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

10. Does the new proposal to allow prescribers to satisfy the Confirmation of Prescription Release requirement by (when expressly consented to by the patient) releasing a digital copy of the prescription to the patient, such as via online portal, electronic mail, or text message increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

11. Does the new proposal to allow prescribers to choose from different delivery methods and devise their own language for the Confirmation of

Prescription Release increase, decrease, or have no effect on the burden placed on prescribers? Why?

12. If prescribers choose to comply with the Confirmation of Prescription Release provision by providing a digital copy of the prescription (if the patient gives verifiable affirmative consent), what costs or burdens are associated with retaining evidence that the prescription was sent, received, or made accessible, downloadable, and printable?

13. Compared to the Commission's prior proposal for a signed acknowledgment, does the new proposed Confirmation of Prescription Release increase, decrease, or place about the same burden on prescribers? Why?

14. Do the potential benefits of the Confirmation of Prescription Release requirement—having more patients in possession of their prescription—outweigh the burden on prescribers of having to provide patients with a Confirmation of Prescription Release and preserve a record for three years? Why or why not?

15. What other factors should the Commission consider to lower the cost and improve the reliability of executing, storing, and retrieving Confirmations of Prescription Release?

16. Are there alternate ways that the Commission has not yet considered in this Rule review to design a signed acknowledgment or Confirmation of Prescription Release requirement that would reduce the burden on prescribers while providing the same, or greater, benefits for consumers? What are they and how do they compare to the current proposal?

17. Are there alternate ways that the Commission has not yet considered

in this Rule review to increase compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? What are they and how do they compare to the current proposal?

18. Are there alternate ways that the Commission has not yet considered in its Rule review to increase the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? What are they and how do they compare to the current proposal?

19. Are there alternate ways that the Commission has not yet considered in its Rule review to increase the extent to which patients understand their rights under the Rule? What are they and how do they compare to the current proposal?

20. Under the Commission's proposal, the confirmation of prescription release and the accompanying recordkeeping provision shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses, including, but not limited to, through an association, affiliation, or co-location with a contact lens seller. Aside from associations, affiliations, and co-locations with contact lens sellers, what other indirect financial interests exist in the sale of contact lenses that should disqualify a prescriber from the proposed exemption?

21. How do contact lens manufacturers compete for consumer business? Do they compete directly for consumers or compete to have eye-care prescribers prescribe their lenses? To what extent do eye-care prescribers choose to prescribe primarily one manufacturer's contact lenses based on financial considerations?

22. What evidence supports your answers?

D. Prescriber Responses to Requests for an Additional Copy of a Prescription

1. The Commission believes that the Act requires that prescribers provide additional copies of contact lens prescriptions to authorized agents of patients.

Should the Commission require that prescribers respond to such requests within a certain period of time?

2. Would forty business hours, which the Commission proposes, be an appropriate amount of time to respond to a request for an additional copy of a prescription?

3. Should a prescriber be required to keep any records to document the request and response? If yes, what records should be kept and for how long?

4. What evidence supports your responses?

E. Automated Telephone Verification Messages

1. The Commission believes that allowing calls that use automated messages for verification requests is consistent with the Act. To address concerns with incomplete and incomprehensible automated messages, the Commission proposes additional requirements for sellers. What benefits or burdens would each proposal involving automated telephone verification messages confer?

2. Would each of the proposed modifications address the concerns raised by prescribers about incomprehensible or incomplete automated messages? If so, how?

3. When using an automated message for a verification request, what are the costs and burdens to sellers of meeting each of the proposed requirements,

especially recording the entire call and making the message repeatable at the prescriber's option?

4. What evidence supports your responses?

F. Illegal Prescription Alteration

1. What percent of contact lens sales consist of illegal alterations?

2. Has the introduction of sellers who sell their own brand of contact lenses directly to consumers affected the incidence of illegal alteration? If so, how?

3. What percent of the overall contact lens market consists of sellers who sell their own brand of contact lenses directly to consumers and is that percentage increasing, decreasing, or staying the same? What percentage of eye-care prescribers prescribe these lenses, and what portion of the prescriptions written are for these lenses?

4. Would the proposed amendment requiring sellers to accept prescription presentation increase, decrease, or have no effect on the incidence of illegal alterations? Why?

5. Would the proposed amendment requiring sellers to accept prescription presentation increase, decrease, or have no effect on the number of verification requests that prescribers must respond to?

6. Under the proposed amendment, a verification request that includes a manufacturer or brand provided by, or identical to that provided by, the consumer would not be deemed an alteration of a prescription. Would this provision

increase, decrease, or have no effect on the incidence of alterations of prescriptions? Why? What risks to patients, if any, would result?

7. What risks, if any, are associated with the substitution of contact lenses different and not identical to the manufacturer or brand of lenses fitted and prescribed by the prescriber? Would the proposed amendment increase, decrease, or have no effect on these risks?

8. In what circumstances does a contact lens prescription indicate a particular material, brand, or manufacturer because of the prescriber's medical judgment about the ocular health of the patient (for example, because the patient's astigmatism requires toric lenses)? Are these circumstances common?

9. When a prescription indicates a material, brand, or manufacturer for reasons other than medical judgment about ocular health, what reasons inform the selection? Is it common for a patient to test the fit of more than one material, brand, or manufacturer before receiving a prescription? When more than one material, brand, or manufacturer can achieve a successful fit, is the consumer able to make an informed choice among competing products?

10. What are the drawbacks, if any, of each proposal regarding illegal alteration of contact lenses?

11. What are the benefits, if any, of each proposal regarding illegal alteration of contact lenses?

12. What is the administrative burden, if any, to sellers, including small sellers, from each of the proposals?

13. Are these proposals necessary to address illegal alteration of contact lenses?

14. Are there alternative proposals that the Commission should consider?

15. What evidence supports your answers?

IX. Communications by Outside Parties to the Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record. *See* 16 CFR 1.26(b)(5).

X. Paperwork Reduction Act

The existing Rule contains recordkeeping and disclosure requirements that constitute "information collection requirements" as defined by 5 CFR 1320.3(c) under OMB regulations that implement the Paperwork Reduction Act ("PRA"), 44 U.S.C. 3501 *et seq.* OMB has approved the Rule's existing information collection requirements. (OMB Control No. 3084-0127).

The proposed modifications to the Rule would require that prescribers either (1) obtain from patients, and maintain for a period of not less than three years, a signed confirmation of prescription release on a separate stand-alone document; (2) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's prescription; (3) obtain from patients, and maintain for a period of not less than three years, a patient's

signature on a confirmation of prescription release included on a copy of a patient's contact lens fitting sales receipt; or (4) provide each patient with a copy of the prescription via online portal, electronic mail, or text message, and for three years retain evidence that such was sent, received, or, if provided via an online-patient portal, made accessible, downloadable, and printable by the patient.

The proposed requirement to collect patient signatures and the associated recordkeeping requirement would each constitute an information collection as defined by 5 CFR 1320.3(c). Accordingly, the Commission is providing PRA burden estimates for them, as set forth below.

A. Estimated Additional Hours Burden

Commission staff estimates the PRA burden of the proposed modifications based on its knowledge of the eye-care industry. The staff believes there will be an additional burden on individual prescribers' offices to generate and present to patients the confirmations of prescription release, and to collect and maintain the confirmations of prescription release for a period of not less than three years.

The number of contact lens wearers in the United States is currently estimated to be approximately 41 million.³⁴² Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 41 million people would read and sign a confirmation of prescription release every year.³⁴³

³⁴² Cope, *supra* note 70, at 866.

³⁴³ In the past, some commenters have suggested that typical contact lens wearers obtain annual exams every 18 months or so, rather than one every year. However, because most prescriptions are valid for a minimum of one year under the Rule, Commission staff will continue to assume conservatively for purposes of PRA burden estimation that patients seek exams every 12 months.

The Commission believes that generating and presenting the confirmation of prescription release to patients will not require significant time. Creating the confirmation of prescription release should be relatively straightforward for prescribers since the Commission's proposal is flexible in that it allows any one of several different modalities and delivery methods to satisfy the requirement, including adding the confirmation to existing documents that prescribers routinely provide (sales receipts) or are already required to provide (prescriptions) to patients. The Commission's proposal is also flexible in that it does not prescribe other details such as the precise content or language of the patient confirmation, but merely requires that, if provided to the patient in-person, the confirmation from the consumer must be in writing. At the same time, the Commission's proposal does not require that prescribers spend time generating their own content for the confirmation, since the Commission has provided draft language that prescribers are free to use to satisfy the requirement, if they so desire. Furthermore, the confirmation proposal is flexible enough to cover situations where a contact lens fitting is completed remotely, since a prescriber can readily satisfy the requirement by various methods, including email, text, or uploading the prescription to a patient portal.

The four proposed options for a prescriber to confirm a prescription release to a patient are set out in § 315.3(c). The first three options (§ 315.3(c)(1)(i)(A), (B), and (C)), which direct a prescriber to provide information to a patient in the form of a confirmation of prescription release, are not disclosures constituting an information collection under the PRA because the FTC has supplied the prescriber with draft

language the prescriber can use to satisfy this requirement.³⁴⁴ However, as noted above, the collection of a patient's signature and the associated recordkeeping required constitutes an information collection as defined by OMB regulations that implement the PRA. Nonetheless, the Commission believes it will require minimal time for a patient to read the confirmation of prescription release and provide a signature. Based on the aforementioned consumer survey about the Commission's prior signed-acknowledgment proposal, it would take consumers, on average, twelve seconds to read the two-sentence acknowledgment.³⁴⁵ Since the new proposed confirmation of prescription release would be significantly shorter than the prior proposed acknowledgment, Commission staff expects that the time required to read and sign such confirmation would be less, perhaps half (six seconds). As noted above, a somewhat similar written acknowledgment requirement under HIPAA was estimated to require ten seconds for the consumer to complete.³⁴⁶ Based on the consumer survey and prior estimate, the Commission allots ten seconds for the consumer to read and provide a signature.

The fourth option, § 315.3(c)(1)(i)(D), does not constitute an information collection under the PRA, since no new information is provided or requested of the patient. Excluding that from consideration and assuming the remaining three options are exercised with equal frequency, three-fourths or 75% of approximately 41 million annual prescription releases otherwise entail reading and signing a confirmation statement.

³⁴⁴ "The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within" the definition of "collection of information." 5 CFR 1320.3(c)(2).

³⁴⁵ *Supra* note 183 and accompanying text. The median was ten seconds.

³⁴⁶ 67 FR at 53261.

Thus, 85,417 hours, cumulatively (75% x 41 million prescriptions yearly x ten seconds each) would be devoted to those tasks.³⁴⁷

Maintaining those signed confirmations for a period of not less than three years should not impose substantial new burden on individual prescribers and their office staff. The majority of states already require that optometrists keep records of eye examinations for at least three years,³⁴⁸ and thus many prescribers who opt to include the confirmation of prescription release on the prescription itself would be preserving that document, regardless. Similarly, most prescribers already retain customer sales receipts for financial recordkeeping purposes, and thus prescribers who opt to include the confirmation of prescription release on the sales receipt also could be retaining that document, regardless. Moreover, storing a one-page document per patient per year should not require more than a few seconds, and an inconsequential, or *de minimis*, amount of record space. As noted above, some prescribers might present the confirmation of prescription release electronically, and such format would allow the confirmation to be preserved without any additional burden. For other prescribers, the new recordkeeping requirement would likely require that office staff either preserve the confirmation in paper format or

³⁴⁷ The FTC has previously accounted for and retains active OMB clearance regarding its separate PRA burden estimates for prescriber release of prescriptions to patients. Those estimates were one minute per prescriber and 683,333 hours, cumulative of the estimated 41 million prescriptions released annually. *See* 81 FR 31398, at 31939 (May 20, 2016); 81 FR 62501, 62501 (Sept. 9, 2016).

³⁴⁸ *See, e.g.*, 246 Mass. Code Regs. sec. 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code sec. 246-851-290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645-182.2(2) (requiring optometrists to maintain patient records for at least five years); Fla. Admin. Code r. 64B13-3.003(6) (requiring optometrists to maintain patient records for at least five years).

electronically scan the signed confirmation and save it as an electronic document. For prescribers who preserve the confirmation electronically, Commission staff estimates that scanning and saving the document would consume approximately one minute.

Commission staff do not possess detailed information on the percentage of prescribers' offices that use paper forms, electronic forms, or that scan paper files and maintain them electronically. Thus, for purposes of this PRA analysis, Commission staff will conservatively assume that *all* prescriber offices require a full minute per confirmation for recordkeeping arising from the proposed modifications.

Excluding from PRA consideration the fourth option, §315.3(c)(1)(i)(D), as there is no signature to obtain or retain, and assuming that prescribers elect the remaining options three-fourths or 75% of the time, the recordkeeping burden for all prescribers to scan and save such confirmations would amount to 512,500 hours (75% x 41 million prescriptions yearly x one minute) per year. Thus, estimated incremental PRA recordkeeping burden for prescribers resulting from the proposed Rule modifications is 597,917 hours (85,417 hours regarding signatures + 512,500 hours regarding their retention).

Arguably, the overall burden of the Rule—including verification costs previously approved by the Office of Management and Budget³⁴⁹—could lessen (or not increase by as much as the incremental burden from the proposed Rule modifications), given potentially offsetting effects presented by the proposed modifications. As noted above, some commenters suggested that the increased burden from the proposed signed-acknowledgment requirement would be lessened or even outweighed by a reduced

³⁴⁹ PRA Assessment, *supra* note 185, at 62501-02; OMB Control No. 3084-0127.

verification burden, because with more patients in possession of their prescriptions and able to present them to third-party sellers, fewer time-consuming verifications would be necessary.³⁵⁰ Based on some commenter and Commission projections, a decrease of between 9%-23% in verifications could be sufficient to offset the entire cost of the signed-acknowledgment proposal.³⁵¹ Since the estimated burden for the confirmation of prescription release proposal is similar to that of the signed acknowledgment,³⁵² and would be expected to have the same offsetting effects, it is possible that the burden of the proposed modification would be offset to a great extent by a reduction in verifications. The Commission requests additional comment on whether and by how much a reduction in verifications would result from the confirmation of prescription proposal.

Since the Confirmation of Prescription Release proposal—in contrast to the Signed-Acknowledgment proposal—exempts prescribers who do not have a direct or

³⁵⁰ *Supra* notes 184-191 and accompanying text.

³⁵¹ Based on the estimated burden for the Commission's prior signed-acknowledgment requirement proposal. *Supra* note 187 and accompanying text.

³⁵² The estimated burden of the proposed confirmation requirement is lower than the signed-acknowledgment burden in terms of time required (597,917 hours for all prescribers and their staff compared to 683,333 hours for the signed-acknowledgment proposal, a decrease of approximately 13 percent). However, the estimated total financial burden is somewhat higher due to increases in average hourly wages for prescribers and staff since 2016, and due to the addition of time—now assigned to prescribers—to obtain a signature, in response to comments and information received subsequent to publication of the NPRM. Because of the higher overall cost, it might require a greater respective decrease in verifications to offset the financial burden. As noted, however, *supra* note 190 and accompanying text, none of the monetary burden-offset calculations takes into account the expected benefit to consumers of having their prescriptions and being able to choose from among competing providers; the savings consumers might achieve by purchasing lower-priced lenses; the improvements to health and safety due to a reduction in errors associated with invalid prescriptions currently verified through passive verification; and the Commission's improved ability to assess and verify compliance with the Rule.

indirect financial interest in the sale of contact lenses, this will also reduce the burden created by the new requirement. The Commission, however, does not currently possess information as to how many prescribers would qualify for the exemption due to a lack of financial interest in the sale of lenses. The Commission therefore has not reduced its PRA burden estimate accordingly and instead requests comment on the percentage of prescribers who would qualify for the proposed § 315.3(c)(3) exemption.

This PRA analysis also does not attempt to assess and estimate hours or cost burden for sellers regarding the proposed Rule modifications that would require those who use automated telephone messages, wholly or in part, to verify a prescription, to record the full call, among other steps associated with that proposed modification. As noted above in the Section VIII. E. (Request for Comments/Automated Telephone Verification Messages), the Commission seeks comments to help inform such estimated burden, to the extent applicable.

B. Estimated Total Labor Cost Burden

Commission staff derives labor costs by applying appropriate hourly cost figures to the burden hours described above. The prescriber task to obtain patient signed acknowledgments theoretically could be performed by medical professionals (e.g., optometrists, ophthalmologists) or support staff (e.g., dispensing opticians, ophthalmic medical technicians). To estimate associated labor costs, staff will conservatively assume that optometrists would perform the task.³⁵³ Applying a mean hourly wage of \$57.26³⁵⁴

³⁵³ It is not certain that this assumption is well-founded. See CLR Panel IV Tr., *supra* note 126, at 8 (statements of David Cockrell that, in his office, the staff handle all the verification calls). Many prescribers may use office staff to handle verification calls, which would result in a significantly lower burden calculation for prescribers' offices

for optometrists to the above-noted estimate of 85,417 hours, resultant aggregate labor costs to obtain patient signatures would be \$4,890,977.

Commission staff assumes that office clerks will typically perform the labor pertaining to the printing, scanning and storing of prescription release confirmations. Applying a mean hourly wage for office clerks of \$16.30 per hour,³⁵⁵ to the above-noted estimate of 512,500 hours, cumulative labor costs for those tasks would total \$8,353,750.

Therefore, combining the aggregate labor costs for both prescribers and office staff to obtain patient signed acknowledgments and preserve the associated records, the Commission estimates the total labor burden of the confirmation of prescription release proposal to be \$13,244,727.

C. Capital and Other Non-Labor Costs

The proposed recordkeeping requirements detailed above regarding prescribers impose negligible capital or other non-labor costs, as prescribers likely have already the necessary equipment and supplies (e.g., prescription pads, patients' medical charts, scanning devices, recordkeeping storage) to act upon those requirements.

The Commission invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency,

than what the Commission previously calculated. Without more empirical data as to who handles most verification requests, however, the Commission will continue to use the estimate for prescribers, even if it might overstate the actual burden.

³⁵⁴ Economic News Release, U.S. Dep't of Labor, Bureau of Labor Statistics, Table 1. National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2017:
<https://www.bls.gov/news.release/ocwage.t01.htm> ("BLS Table 1")

³⁵⁵ BLS Table 1.

including whether the information will have practical utility; (2) the accuracy of the FTC's burden estimates, including whether the methodology and assumptions used are valid (such as whether prescribers or office staff are more likely to collect patient signatures and retain associated recordkeeping); (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collecting information.

Comments on the proposed information collection requirements subject to review under the PRA should additionally be submitted to OMB. Comments can be received from 30 days of publication up to the close of the comment period, but comments to OMB will be most useful if OMB receives them within 30 days of publication. If sent by U.S. mail, comments should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW, Washington, D.C. 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead can also be sent by email to wliberante@omb.eop.gov.

XI. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA")³⁵⁶ requires the Commission to conduct an analysis of the anticipated economic impact of the proposed amendments on small entities.³⁵⁷ The purpose of a regulatory flexibility analysis is to ensure the agency

³⁵⁶ 5 U.S.C. 601-612.

³⁵⁷ The Commission also conducted an RFA analysis of the Rule implementing the Fairness to Contact Lens Consumers Act. 69 FR 40482, 40507 (July 2, 2004).

considers the impacts on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA³⁵⁸ provides that such an analysis is not required if the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.

The Commission does not anticipate that the proposed amendments will have a significant economic impact on small entities, although in the case of prescribers, they may affect a substantial number of small businesses. The proposed amendments affecting prescribers: (1) Allow for electronic delivery of prescriptions as a means for automatic prescription release when agreed to by the patient (and in such cases prescribers must retain evidence for not less than three years that the prescription was sent, received, or made accessible, downloadable, and printable); (2) require prescribers to request that the patient confirm prescription release and to retain such confirmations for a period of not less than three years; and (3) establish a time-frame of forty business hours for prescribers to respond to authorized seller requests for copies of a prescription, and require the prescriber to make a notation in the patient's record when responding to such requests. The proposed amendments affecting sellers require them: (1) When using automated telephone messages to verify prescriptions, to record the entire call (and maintain such recordings for a period of not less than three years), commence the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule, deliver the required information in a slow and deliberate manner and at a reasonably understandable volume, and make the required information repeatable at

³⁵⁸ 5 U.S.C. 605.

the prescriber's option; (2) to accept prescription presentation; and (3) to verify only the contact lens brand or manufacturer that consumers indicate is on their prescriptions.

The Commission believes the burden of complying with these requirements likely will be relatively small. As discussed in the Paperwork Reduction Act section, with respect to the recordkeeping proposal requiring prescribers to maintain signed confirmations, the majority of states already require that optometrists maintain records of eye examinations for at least three years. The proposed amendment would require, at most, one additional page to be maintained as a record, which is likely a minimal burden. The Commission similarly believes that the other proposals impacting prescribers likely present a minimal burden. For example, the proposed requirement for the prescriber to make a notation in a patient's record when responding to an authorized seller or other agent's request for a patient's prescription would require only that the prescriber note the requestor's name and the date and time the prescription was provided. With respect to the burdens on non-prescriber sellers from the amendments affecting them, the Commission has no information that, and does not believe that, they are more than minimal. Further, the number of such sellers that are small entities is not believed to be substantial. Therefore, based on available information, the Commission certifies that amending the Rule as proposed will not have a significant economic impact on a substantial number of small businesses.

Although the Commission certifies under the RFA that the proposed amendment will not, if promulgated, have a significant impact on a substantial number of small entities, the Commission has nonetheless determined it is appropriate to publish an Initial

Regulatory Flexibility Analysis to inquire into the impact of the proposed amendment on small entities. Therefore, the Commission has prepared the following analysis:

A. Description of the Reasons the Agency Is Taking Action

In response to public comments, the Commission is proposing amendments to allow for electronic delivery of prescriptions as a means for automatic prescription release and to require a confirmation of prescription release, as ways to ensure that patients are receiving a copy of their contact lens prescriptions at the completion of their contact lens fittings. In further response to the public comments, the Commission is proposing a time-frame of forty business hours for prescribers to respond to seller or other authorized agent requests for copies of a prescription to ensure that patients' agents can obtain additional copies of prescriptions in a timely manner. The Commission is proposing additional seller requirements for the use of automated telephone verification messages to help prescribers better understand, and reduce the burden of, verification requests; to allow consumers to receive the correct lenses more quickly; and to provide the Commission with a way to monitor sellers' compliance with the Rule. Lastly, in response to public comments and after a review of websites selling contact lenses online, the Commission is proposing that sellers be required to accept prescription presentation and to verify only the contact lens brand or manufacturer that consumers indicate is on their prescriptions as a means to limit the frequency of illegal alterations. The corresponding recordkeeping requirements for these proposals, retaining these records for no less than three years, are necessary for the FTC to enforce the Rule.

B. Statement of the Objectives of, and Legal Basis for, the Proposed Amendments

The objective of the proposed amendments is to clarify and update the Rule in accordance with marketplace practices. The legal basis for the Rule is the Fairness to Contact Lens Consumers Act.³⁵⁹ The Act authorizes the Commission to implement its requirements through the issuance of rules.

C. Small Entities to Which the Proposed Amendments Will Apply

Prescribers of contact lenses are affected by the proposed amendments concerning the option for electronic delivery of prescriptions as a means for automatic prescription release, confirmation of prescription release, and the imposition of a forty-business hour time frame for responding to authorized requests for additional copies of prescriptions. The Commission believes that many prescribers will fall into the category of small entities (*e.g.*, offices of optometrists with less than \$7.5 million in average annual receipts).³⁶⁰ Determining a precise estimate of the number of small entities covered by the Rule's prescription-release requirements is not readily feasible because most prescribers' offices do not release the underlying revenue information necessary to make this determination.³⁶¹ Based on its knowledge of the eye-care industry, staff believes that a substantial number of these entities likely qualify as small businesses. The Commission seeks comment with regard to the estimated number or nature of such small business entities, if any, for which the proposed amendments would have a significant impact.

Non-prescriber sellers of contact lenses are affected by the proposed amendments

³⁵⁹ 15 U.S.C. 7601-7610.

³⁶⁰ See U.S. Small Business Admin., "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," (eff. Feb. 26, 2016), https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

³⁶¹ 5 U.S.C. 601(6).

concerning the additional requirements for using an automated telephone verification message, requirements to accept prescription presentation, and requirements to verify only the contact lens brand or manufacturer that consumers indicate is on their prescriptions.³⁶² Based on its knowledge of the industry, staff believes that the number of these entities that likely qualify as small businesses (less than \$20.5 million in average annual receipts) is not likely to be substantial.³⁶³ The Commission seeks comment with regard to the estimated number or nature of such small business entities, if any, for which the proposed amendments would have a significant impact.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed to Comply

1. Amendments Affecting Prescribers

The proposed amendment relating to confirmation of prescription release requires that prescribers obtain from patients, and maintain for a period of not less than three years, a confirmation that patients received their contact lens prescriptions at the completion of their contact lens fittings. If the prescriptions were provided to the patients digitally, the prescriber must maintain, for a period of not less than three years, evidence that the prescriptions were sent, received, or made accessible, downloadable and printable.

³⁶² Most prescribers who sell lenses do so after fitting the patient with the prescribed lens, and thus, do not rely on prescription verification. The amendments affecting sellers pertain to verification or prescription presentation and do not pertain to these sales. As a result, the Commission does not consider prescribers in its estimated burden for the proposals affecting sellers.

³⁶³ See U.S. Small Business Admin., “Table of Small Business Size Standards Matched to North American Industry Classification System Codes” (Feb. 26, 2016), https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

The small entities potentially covered by these proposed amendments will include all such entities subject to the Rule. The professional skills necessary for compliance with the Rule as modified by the proposed amendments will include office and administrative support supervisors to create the language and format of the confirmation and clerical personnel to collect signatures from patients and maintain records, or in the case of digital prescriptions, retain evidence that the prescription was sent, received, or made accessible, downloadable and printable. Compliance may include some minimal training time as well. The Commission has provided language that prescribers can use which, should a prescriber elect to use such language, negates the burden of deriving appropriate language. The Commission believes the burden imposed on small businesses by these requirements is relatively small, for the reasons described previously in Section X of this document. The Commission invites further comment and information on these issues, including estimates or data on specific compliance costs that small entities might be expected to incur.

The proposed amendment relating to providing a designated agent with an additional copy of a prescription requires the prescriber respond within forty business hours of receipt of the request, and note in the patient's record the name of the requester and the date and time that the prescription was provided to the requester. The professional skills necessary for compliance with the Rule as modified by the proposed amendment will include office and administrative support supervisors to respond to the request within forty business hours, whereas before there was no time limit for responding to the request. The office and administrative support supervisors will also need to make the required notations in the patient's records. As noted, the required

notation would be limited to the name of the requester and the date and time the prescription was provided to the requester. Although the Rule does not require that prescribers retain the notations, the Commission expects prescribers would make and retain such notations in the ordinary course of their business and thus believes the proposal would not create much, if any, additional burden. The Commission invites further comment and information on these issues, including estimates or data on specific compliance costs that small entities might be expected to incur.

2. Amendments Affecting Sellers

To the extent, if any, that non-prescriber sellers are small entities, the proposed amendments relating to changes in verifications made through automated telephone messages require sellers to record the entire call, commence the call by identifying it as a request for prescription verification made in accordance with the Rule, deliver the information in a slow and deliberate manner and at a reasonably understandable volume, and make the information repeatable at the prescriber's option. For calls that use an automated message verification system, sellers must retain the complete call recording for at least three years.

The Commission believes that most small sellers who are covered by the Rule, if any, are unlikely to have undergone or to undergo the expense associated with creating and maintaining an automated telephone system for verification requests. Instead, such sellers comply with the Rule by receiving copies of prescriptions from patients, or making verification requests to prescribers via fax, email, or live telephone calls. Should a small seller already have an automated system for verification, the additional burden presented by the new proposal to commence the call by identifying it as a call made in

accordance with the Contact Lens Rule should be minimal because they are already in compliance, or if not, need only to modify the verification recording once. Further, automated messages, if already made in accordance with the FTC's prior guidance that they be delivered at a volume and cadence that a reasonable person can understand³⁶⁴ would comply with the new proposal that all such messages be at a "reasonably understandable volume" and delivered in a "slow and deliberate manner." The Commission therefore does not believe this proposal adds any additional burden to sellers. Should a small seller already use automated messages for verification, it may need to modify its system to comply with the proposal that it make the required information repeatable at the prescriber's option. The Commission does not believe the associated costs from this change would be more than minimal.

The proposal also requires sellers to record calls that use automated messages in their entirety and to retain them for no less than three years. Should a small seller already verify prescriptions through calls that use automated messages and not currently record the calls, it would need to commence recording them. In addition, such sellers would need to retain these calls for not less than three years. The Commission is unaware of the cost of recording and storing these calls. The Commission invites comment on the frequency with which small sellers use automated telephone messages for verification and the costs associated with the proposals pertaining to these messages, including whether existing verification systems include the capability to record and the capacity for storage, and the costs associated with recording the calls and maintaining the recordings for no less than three years.

³⁶⁴ See *supra* note 285.

To comply with the proposed amendment relating to the requirement that sellers provide a clear and prominent method for the consumer and prescriber to present the seller with a copy of the patient's prescription, a small seller would need to update its website to inform consumers about the ability to provide the seller with a prescription, or alternatively, if an order occurs via telephone or in person, to verbally inform the consumer about the ability to provide the seller with a prescription. The professional skill or time necessary for this task would include personnel with the skills required to update the website and the time it takes to update the website, or if the information is relayed over the phone or in person, the additional time for an employee of the seller to inform a consumer that he or she is able to provide a prescription, and the method by which a consumer can do so. These proposals may also require training time for staff. The seller would also need to provide a mechanism for a consumer to provide the prescription to the seller. Although the seller could create a mechanism for the consumer to upload the prescription to a website, it could instead rely on a consumer sending an email, fax, or text message with a digital copy of the prescription. Because a seller almost certainly has an existing account that accepts texts, faxes, or emails, the Commission believes there is little additional burden of complying with this part of the proposal.

Both the Fairness to Contact Lens Consumers Act and the Rule prohibit illegal alteration of a prescription. The proposed modification would clarify that illegal alteration occurs when a seller submits a verification request to a prescriber that includes a manufacturer or brand other than the manufacturer or brand prescribed by the prescriber unless the seller obtained the inaccurate manufacturer or brand information from the

customer in response to a request for such information. Manufacturer or brand information will largely be obtained via website, telephone, or in person. The professional skill or time necessary for this task would include personnel with the skills required to update the website and the time it takes to update the website, or if the information is relayed over the phone or in person, the additional time for an employee of the seller to obtain and record the information. Such employees would also need to be trained on this requirement. Although there is no associated compliance requirement set forth in the Rule, the Commission is aware that without the evidence that the manufacturer or brand provided on the verification request was the one provided by the customer, the seller would not be able to avail itself of the exception to illegal alteration. As a result, the Commission should consider the associated compliance burden. As many contact lens sales by non-prescriber sellers occur online, the burden of retention of the record may be minimized by the ability to keep electronic sales records. For sales that occur via telephone or in person, the seller would be required to create and maintain a log or similar document containing the relevant information. The Commission believes that sellers retain order records in the ordinary course of business and any additional compliance steps resulting from this proposal may be minimal. Nevertheless, the Commission invites comment on the compliance costs from these proposals that small sellers might be expected to incur.

E. Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any other federal statutes, rules, or policies duplicating, overlapping, or conflicting with the proposed amendments, but as noted previously, the majority of states already require that optometrists—of which many are

most likely small businesses—maintain records of eye examinations for at least three years. The Commission invites additional comment on this issue.

F. Significant Alternatives to the Proposed Amendments

1. Alternatives for Amendments Affecting Prescribers

For the proposed amendment regarding confirmation of prescription release, the Commission has not proposed any specific small entity exemption or other significant alternatives. The Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendments. Nonetheless, the Commission believes the proposed requirements provide prescribers and sellers with maximum flexibility in complying with the Rule, while still achieving the Rule's objectives. For example, the Commission modified its prior proposal regarding confirmation of prescription release to provide options in the form of delivery; a prescriber may request a patient sign a statement confirming prescription release on a prescriber-retained copy of a contact lens prescription or examination receipt, or on a separate piece of paper. Further, whereas the prior proposal dictated the language prescribers must use, this proposal provides language a prescriber may use, but ultimately leaves that decision to the prescriber. As discussed above, the proposed recordkeeping requirement likely involves minimal burden and prescribers would be permitted to maintain records in either paper or electronic format. The recordkeeping burden could also be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and inputted automatically into the electronic record. To lower

the costs of this recordkeeping requirement, prescribers also could scan signed paper copies of the acknowledgment form and store those forms electronically. Moreover, this proposal, should prescribers wish, and patients agree, permits prescribers to release prescriptions electronically, including via text, email, or online portal, which should simplify the recordkeeping of prescription release. In addition to the aforementioned alternatives that are included in the proposal itself, the Commission seeks comment on the need, if any, for alternative compliance methods to reduce the economic impact of the Rule on small entities.

The Commission has not proposed any specific small entity exemption or other significant alternatives for its proposal requiring prescribers to respond to authorized agent requests for additional copies of prescriptions within forty hours and noting in the record the requestor and when the prescriber responds to the request. The Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendment.

If the comments filed in response to this SNPRM identify small entities affected by the proposed amendments, as well as alternative methods of compliance that would reduce the economic impact of the proposed amendments on such entities, the Commission will consider the feasibility of such alternatives and determine whether they should be incorporated into the final Rule.

2. Alternatives for Amendments Affecting Sellers

With respect to the proposals relating to automated telephone messages, the Commission has not proposed any specific small entity exemption or other significant

alternatives. The Commission notes that small sellers are not required to place verification requests through calls that use automated messages. The Rule permits sellers to make verification requests via live calls, fax, or email, and thus sellers, including small sellers who wish to avoid any burden imposed by the new requirements, may consider alternative methods.

In terms of its requirement that sellers accept prescriptions presented by customers, the Commission notes that a seller may meet this requirement by accepting such prescriptions via email or text, both mechanisms that small sellers likely already have set up as part of their existing businesses.

The Commission has not proposed any specific small entity exemption or other significant alternatives for its proposal requiring sellers to verify only the brand or manufacturer listed on a customer's prescription. As previously indicated, the Commission recognizes that all sellers, including small sellers, must request, whether orally or via website, the brand or manufacturer that is listed on the customer's prescription, and that sellers must retain records of the information provided by the customer. The Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendment.

If the comments filed in response to this SNPRM identify small entities affected by the proposed amendments, as well as alternative methods of compliance that would reduce the economic impact of the proposed amendments on such entities, the

Commission will consider the feasibility of such alternatives and determine whether they should be incorporated into the final Rule.

Proposed Rule Language

List of Subjects in 16 CFR Part 315

Advertising, Medical devices, Ophthalmic goods and services, Trade practices.

Under 15 U.S.C 7601-7610 and for the reasons discussed in the preamble, the Federal Trade Commission proposes to amend title 16 of the Code of Federal Regulations part 315 as follows:

PART 315—CONTACT LENS RULE

1. The authority citation for part 315 is revised to read as follows:

AUTHORITY: 15 U.S.C. 7601-7610.

2. Amend § 315.2 by adding in alphabetical order the definitions for “Provide to the patient a copy”, “Reasonably understandable volume”, and “Slow and deliberate manner” to read as follows:

§ 315.2 Definitions.

* * * * *

Provide to the patient a copy means giving a patient a copy of his or her contact lens prescription on paper or, if offered by the prescriber and preferred by the patient as evidenced by the patient’s verifiable affirmative consent, making a digital copy of the prescription available by electronic means that can be accessed, downloaded, and printed by the patient, including via text message, electronic mail, or a posting on an online patient portal.

Reasonably understandable volume means at an audible level that renders the message intelligible to the receiving audience.

Slow and deliberate manner means at a rate that renders the message intelligible to the receiving audience.

3. Amend § 315.3 by revising paragraphs (a)(1) and (2), adding paragraph (a)(3), revising paragraphs (b)(1) through (3), and adding paragraph (c) to read as follows:

§ 315.3 Availability of contact lens prescriptions to patients.

(a) * * *

(1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription;

(2) Shall, as directed by any person designated to act on behalf of the patient, verify the contact lens prescription by electronic or other means; and

(3) Shall, upon request, provide any person designated to act on behalf of the patient with a copy of the patient's contact lens prescription by electronic or other means within forty (40) business hours of receipt of the request. A prescriber shall note in the patient's record the name of the requester and the date and time that the prescription was provided to the requester.

(b) * * *

(1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (3) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;

(2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (3) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or

(3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1), (2), or (3) of this section.

(c) *Confirmation of prescription release.* (1)(i) Upon completion of a contact lens fitting, the prescriber shall do one of the following:

(A) Request that the patient acknowledge receipt of the contact lens prescription by signing a statement confirming receipt of the contact lens prescription;

(B) Request that the patient sign a prescriber-retained copy of a contact lens prescription that contains a statement confirming receipt of the contact lens prescription;

(C) Request that the patient sign a prescriber-retained copy of the receipt for the examination that contains a statement confirming receipt of the contact lens prescription;
or

(D) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message) in compliance with paragraph (a)(1) of this section, retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable.

(ii) If the prescriber elects to confirm prescription release via paragraph (c)(1)(i)(A), (B), or (C) of this section, the prescriber may, but is not required to, use the statement, “My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting” to satisfy the requirement.

(2) A prescriber shall maintain the records or evidence required under paragraph (c)(1) of this section for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(3) Paragraphs (c)(1) and (2) of this section shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses, including, but not limited to, through an association, affiliation, or co-location with a contact lens seller.

4. Amend § 315.5 by:

- a. Redesignating paragraphs (d), (e), (f), and (g) as paragraphs (e), (f), (h), and (i), respectively;
- b. Adding new paragraph (d);
- c. Revising newly redesignated paragraph (f);
- d. Adding new paragraph (g);
- e. Adding paragraph (h)(2)(iii); and
- f. Revising newly redesignated paragraph (i).

The additions and revisions read as follows:

§ 315.5 Prescriber verification.

* * * * *

(d) *Automated telephone verification messages.* If a seller verifies prescriptions through calls that use, in whole or in part, an automated message, the seller must:

- (1) Record the entire call;
- (2) Commence the call by identifying it as a request for prescription verification made in accordance with the this part;

(3) Deliver the information required by paragraph (b) of this section in a slow and deliberate manner and at a reasonably understandable volume; and

(4) Make the information required by paragraph (b) of this section repeatable at the prescriber's option.

* * * * *

(f) *No alteration of prescription.* A seller may not alter a contact lens prescription. In the context of prescription verification, alteration includes, but is not limited to, providing the prescriber with the name of a manufacturer or brand other than that specified by the patient's prescription, unless such name is provided because the patient entered it on the seller's order form when asked for the manufacturer or brand listed on the patient's prescription, or the patient orally gave the seller the name in response to a request for the manufacturer or brand listed on the patient's prescription.

Notwithstanding the preceding sentences, a seller may substitute for contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(g) *Seller requirement to accept prescription presentation.* A seller shall provide a clear and prominent method for the patient and prescriber to present the seller with a copy of the patient's prescription. Such method may include, without limitation, electronic mail, text message, file upload, or facsimile.

(h) * * *

(2) * * *

(iii) If the communication occurs via telephone and uses an automated message, the complete recording required pursuant to paragraph (d)(1) of this section.

* * * * *

(i) *Recordkeeping requirement—Saturday business hours.* A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for a request for a copy of the prescription specified in § 315.3(a)(3) or for verification specified in paragraph (c)(3) of this section shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

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