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 July 29, 2019.

ADDRESSES: Interested parties may file a comment online or by 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, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.


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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 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 must only be 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 the prescriber to verify the prescription when the consumer presents to the seller by the patient or a designated agent or verifies the prescription by direct communication with the prescriber. The Rule further sets out 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. The Rule also incorporates the Act’s prescription of state and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification.\(^8\)

**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 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, 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,\(^14\)

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\(^3\) 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.
\(^8\) 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).

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many prescribers continued to withhold prescriptions for contact lenses.\(^15\) This, and other prescriber practices (such as requiring liability waivers, refusing 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.”\(^17\)

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\(^15\) 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 FCCA Subcomm. Hearing] (statement of Ami Gadhia, 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 to 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.” FCCA Subcomm. Hearing, supra note 15 (statements of Rep. W.J. Tauzin (La.)).

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\(^16\) H.R. Rep. No. 108–318 at 4; FCLCA Subcomm. Hearing, supra note 15 (statements of Howard Beales, Jonathan Cohen, 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 to pharmacies, mail order, and other alternative sellers. Id.

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\(^17\) 16 CFR 315.5(b).
Third-party sellers are thus forced to compete for the sale of lenses with the 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 seller has verified the patient’s prescription with the prescriber.23 Sellers also are prohibited from altering 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 seller has verified the patient’s prescription with the prescriber.23

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 that the correct prescription; or (3) the prescriber does not communicate with the seller within eight business hours of the seller’s request 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, after a review of comments, surveys, and other submitted information, and its own enforcement experience, the Commission determined that the overall weight of the evidence demonstrated a

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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 'stakeholder on contact lens competition.”
22 Contact Lens Rule, 69 FR 40482.
23 16 CFR 315.3(a).
24 16 CFR 315.3(e).
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’’) and 16 U.S.C. 7601(b)(3) (must, as directed by authorized party, “provide or verify the prescription”).
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.”).
31 Contact Lens Rule, 69 FR at 40498.
32 FCLCA Subcomm. Hearing, supra note 15 (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).
34 Comment figures are approximations because identical comments are sometimes submitted more than once.
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. To achieve this, the Commission issued a Notice of Proposed Rulemaking (“NPRM”) on December 7, 2016 that proposed to add a signed-acknowledgment requirement. 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 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 comments 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.

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.

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,” 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; (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 sellers to 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. Prescribers could post, and patients could obtain, prescriptions online. With an electronic copy, patients could provide prescriptions more easily to sellers when purchasing lenses. In turn, this potentially would reduce the volume of requests by sellers for verification or additional copies of the prescription. 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-release requirement.

A. Use of Patient Portals by Prescribers and Patients

In response, several commenters noted the benefits and supported the use of patient portals. Through a portal, patients would have greater access to their prescriptions and would have electronic copies to send to sellers. However, commenters also expressed concerns that: (1) Online portals are not available to (2) patients may not be aware of the portal or may have difficulty accessing or printing medical documents online; and (3) prescribers and patients prefer paper copies. 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.

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. It would be inconsistent for the Act and Rule to permit prescribers to provide WS 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, the prevalence of portals among eye-care providers is unclear. However, portal usage could increase as patients become more comfortable in interacting with their medical providers online and portal capabilities improve.

Several eye-care providers already offer copies of prescriptions through patient portals or other electronic means, including e-mail.

42 Id.

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 #3472); American Optometric Association (NPRM Comment #3898); Consumers Union (NPRM Comment #3969).


46 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).

47 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.].


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).

50 See, e.g., Eklund (WS Comment #502); Reed (WS Comment #749); Cittel (WS Comment #759); Andrews (WS Comment #1014); Carvell (WS Comment #1014); Cecili (WS Comment #1021); Cecili (WS Comment #1892); Kuryan (WS Comment #3472); Hopkins (NPRM Comment #164); Wilson (NPRM Comment #1310); Kuryan (WS Comment #1892); Andrus (NPRM Comment #3345); and American Academy of Ophthalmology (NPRM Comment #3657) ("For practices that utilize electronic medical record systems, patients can..." ).
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. Importantly, the choice is not 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. 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 copy in lieu of a paper copy request a copy of their prescription and [be] issued one electronically. Many practices also utilize portals to fill prescription requests.”

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 burdensome, the Commission’s proposed change does not require that patients be able to send prescriptions to sellers through the 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. Id. at 88535. 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”).

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 forms, other than the address or letterhead of the prescriber, would be placed on the acknowledgment form. 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 their right to receive them. The Commission acknowledged that none of the comments or surveys, in and of itself, could be considered definitive, and acknowledged that there are inherent limitations to survey evidence. 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.

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); evidence that consumers are still unaware of their right to their prescriptions; the ongoing pattern of consumer complaints and anecdotal reports of failure to release prescriptions; 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 obligated under state law. 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. 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.

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. 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. The Commission determined that the cumulative effect of increased automatic-release compliance would thus be lower costs and improved

54 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.
55 NPRM, 81 FR at 88535. NPRM, 81 FR at 88531–32.
56 Id.
57 Id.
58 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.
63 Id.
64 Id. at 88533.
65 Id.
66 Id. at 88532.
67 Id.
convenience and flexibility for patients, sellers, and prescribers, as well as increased accuracy of prescriptions presented 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 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 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

77 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).78

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 #987) (recognizing the “inherent conflict of interest” and noting that the FCLCA was made necessary by “the unique nature of the contact lens marketplace”).
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 their prescriptions automatically after a contact lens fitting.83 A comment from the Attorneys General for 20 States,84 for example, said that they “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 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 bureau 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

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”); Morahito (WS Comment #1135) (“This is a slap in the face of good people whose only crime is being self-sufficient.”); Holt (WS Comment #1375) (“having a patient sign a piece of paper that 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”);
83 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 #1301).
84 E.g., Institute for Liberty (WS 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 #1969).
86 Id.
87 See, e.g., Keck (WS Comment #22); Mattix (WS Comment #28); Arthur (WS Comment #47); Barrett (WS Comment #259); Tyree (WS Comment #123); Fielding (WS Comment #176); Tennison (WS Comment #428); Lambrecht (WS Comment #448); Copley (WS Comment #513); Moses (WS Comment #675); Subowicz (WS Comment #926); Brotz (WS Comment #939); Bonner (WS Comment #962); 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); Kraimann (NPRM Comment #1847); Valley (NPRM Comment #1853); Dieckow (NPRM Comment #1869); Zeledon (NPRM Comment #1852); Diedrich (NPRM Comment #1856); Berry (NPRM Comment #1860); Montagnino (NPRM Comment #1866); Hochberg (NPRM Comment #1878); Bogner (NPRM Comment #1881); Raszczuk (NPRM Comment #1904); Fraza (NPRM Comment #1907); Vasquez (NPRM Comment #1917); Megraw (NPRM Comment #1933); Kasal (NPR Comment #1937); Strobel (NPR Comment #1940); Quinlog (NPR Comment #1963); Sommerville (NPR Comment #1966); Stanton (NPR Comment #2001); Austin (NPR Comment #2022); Cotten (NPR Comment #2024); Buhlman (NPR Comment #2045); Miller (NPR Comment #2062); Robertson (NPR Comment #2124); Capuano (NPR Comment #2722); Martinez (NPR Comment #2804); Woolfet (NPR Comment #3131); Thomson (NPR Comment #3421).
88 Rushton (NPRM Comment #2649).
89 Hamilton (NPRM Comment #1835).
90 Acton (NPRM Comment #2070).
91 E. Montague (WS Comment #875); Brotz (WS Comment #939); Calk (WS Comment #984); Fridleyn (WS Comment #988); Gonzales (WS Comment #1417); Vasquez (NPRM Comment #1917); Austin (NPRM Comment #2022); Ng (NPRM Comment #1289); James (NPRM Comment #4029).
92 St. Louis (NPRM Comment #3531); 1–800 CONTACTS (NPRM Comment #3988). See also, e.g., League of United Latin American Citizens (NPRM Comment #3326) (“Consumers who do not an 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 fitting.98 The other survey, submitted by Consumer Action, reported that just 44% of consumers received

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 currently aware of their right to copies of their prescriptions, creating information asymmetry” between consumers and prescribers).
93 Monpe (NPRM Comment #4277).
94 See, e.g., Barrett (WS Comment #259); Pasucchi (WS Comment #403); Bie (WS Comment #902); Randall (WS Comment #912); Rasczyk (WS Comment #930); Elliott (WS Comment #930); Skyland (WS Comment #944); Palmer (WS Comment #956); Miller (WS Comment #1055); McBride (WS Comment #1088); Wilber (WS Comment #1162); Subach (WS Comment #1364); Kraimann (NPRM Comment #1847); Boue (NPRM Comment #1806); Sallier (NPRM Comment #1808); Zeledon (NPRM Comment #1852); Vasquez (NPRM Comment #1917); Herron (NPRM Comment #1982); Tardif (NPRM Comment #2011); Burlingham (NPRM Comment #3115).
95 Ballou (NPRM Comment #3331).
96 Hose (NPRM Comment #3469).
97 Consumer Action (NPRM Comment #3721); 1–800 CONTACTS (NPRM Comment #3898).
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.
prescriptions without having to ask for them. According to the surveys, when consumers who did not receive prescriptions asked for them, prescribers typically complied. 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. 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 received a prescription, 28% received one after asking for it, and 36% did not receive one at all.

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?”

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

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.

The AOA also asserted that consumer surveys may be unreliable because they are based on patient-reported data and—since 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. To rebut these surveys be reluctant to admit that they are unaware of their rights under the law. NPRM, 81 FR at 88531–32. Data was based on a SSI online survey of 500 contact lens wearers in 2015. NPRM, 81 FR at 88532. 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”).

American Academy of Ophthalmology (WS Comment #2971) (“It is our opinion that evidence should not include industry-sponsored surveys, seeking a specific result, to prop up a narrative for their benefit.”). American Optometric Association (WS Comment #3303) (“We question the legitimacy of the information on alleged non-compliance that 1–800 CONTACTS has provided to the Commission.”).

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 infra; see also American Optometric Association—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 prescriptions for non-compliant 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.”).

American Optometric Association (WS Comment #3303).

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 prescription is finalized); NPRM, 81 FR at 88530–31 (noting that consumers are not always aware of when they are entitled to their prescriptions).
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 doubts 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 phrased 111 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. 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 feel more inclined to say they follow the 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 shop-comparison 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 signed acknowledgment is needed 115 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 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 a 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 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

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

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 is 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 customers “report that optimists 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.

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 #2856); 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 Optometry (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 #647); Bausback (WS Comment #708); Lo (WS Comment #856); Hanian (WS Comment #1196); Carkner (WS Comment #1287); Myers (WS Comment #1322).

118 See, e.g., Moore (WS Comment #544); Heiby (WS Comment #604); Larson (WS Comment #716); Kriszianas (WS Comment #1085); Pebley (WS Comment #1261); Horibe (WS Comment #3242).

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).

120 E.g., 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 #3070); Cervantes (WS Comment #3125); Klong (WS Comment #3435); See also, e.g., (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 #1046); Woodward (NPRM Comment #273); McLoughlin (NPRM #1365); Blankenship (NPRM Comment #2117); Armed Forces Optometric Society (NPRM Comment #2894); Sondheim (NPRM Comment #3783); Stern (NPRM Comment #3892).

123 See, e.g., Moore (WS Comment #544); Heiby (WS Comment #604); Larson (WS Comment #716); Kriszianas (WS Comment #1085); Pebley (WS Comment #1261); Horibe (WS Comment #3242).

124 See, e.g., Moore (WS Comment #544); Heiby (WS Comment #604); Larson (WS Comment #716); Kriszianas (WS Comment #1085); Pebley (WS Comment #1261); Horibe (WS Comment #3242); Mitsougou (NPRM Comment #480); Friedman (NPRM Comment #2589); Cooper (NPRM Comment #2673).

125 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 Comment #4199); Oklahoma Academy of Ophthalmology (NPRM Comment #4204); Pennsylvania Academy of Ophthalmology (NPRM Comment #4209).
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. In 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. 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. 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.

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 percentage of third-party contact lens sales conducted via verification 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—a very 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. 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.

Other commenters, such as 1–800 CONTACTS, 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 are entitled to a copy of the prescription, (2) may not know to whom to complain, and (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.

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 insufficient to support a finding of lack of prescription release.

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 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—one 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.

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 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 rewrites the FCLCA requirement that prescribers release prescriptions automatically, and amends it to release them “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 consumer complaints as extreme.


138 See supra note 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 to the government.

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, “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 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, prescriptions 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


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 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”).

144 NPRM, 81 FR at 88532.

145 See, e.g., Information Technology and Innovation Foundation (NPRM Comment #2948); 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

Continued
commenters, the Commission needs an auditable process in order to enforce the Rule and the FCLCA. 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 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. 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. 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. 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.

Several prescribers also suggested that the signed-acknowledgment requirement itself would be difficult to enforce or that it was unlikely that prescribers who do not currently comply with prescription release would comply with the signed-acknowledgment requirement. Similarly, some prescribers doubted whether consumers would read the signed-acknowledgment document and thus questioned its use for education purposes.

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. 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. Others said they already make the prescription available electronically via patient portals, so this would just generate unnecessary paper waste.

A number of commenters predicted that the burden would force prescribers to raise patient fees to cover increased administrative costs. 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. 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. 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. Many of these commenters

See, e.g., Wright (WS Comment #743); Wesly (WS Comment #835); Norman (WS Comment #1285); Paulsen (WS Comment #1135); Dice (WS Comment #1156); Loomis (WS Comment #3300); California Optometric Association (NPRM Comment #3845).

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

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

158 See, e.g., Mitchell (WS Comment #238); Andrews (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 #2720); Joe (WS Comment #340); Webster (WS Comment #2515); Ritter (WS Comment #2888); American Optometric Association (NPRM Comment #3830).

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

160 See, e.g., Koch (WS Comment #853); Williams (WS Comment #658); Helsley (WS Comment #1028); American Optometric Association (NPRM Comment #3830); Teed (NPRM Comment #4322).

161 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

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suggested that the Commission re-
approach the Rule review with patient
safety as the number one priority.**

A few commenters also said the new
requirement would add a burden to
consumers, since they would not want
to sign another form 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
e-mail) after the patient takes home trial
lenses for a few days.**

Other commenters contested this as-
seessment, 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.**

The issue of burden, the AOA
submitted a third-party survey and
analysis conducted by Avalon Health
Economics (the “Avalon Report”),
which 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).**

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.**

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.”**

In other words, the bulk of the burden
would be derived not from the new signed-
acknowledgment proposal, but rather
from adhering to rules and regulations in
general, including existing rules and
regulations.**

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
participated.

**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 will
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.”**

**Id.**

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 Steven
(Representatives, supra note 131; Letter from Fifty-
Four Representatives, supra note 131; Boozman
Representatives, supra note 131; Letter from Fifty-Eight
Representatives, supra note 131.)

166 Kampa (NPRM Comment #3042); Mecham (NPRM
Comment #3419); Dang (NPRM Comment #3508); Warner (NPRM Comment #3533). Details are in
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168 Id.

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manageable, and will enable more effective enforcement of the rule 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 One 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 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 verification 185 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 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 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, whereas 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. As noted, this uses the assumption from the Commission’s PRA Assessment that prescribers handle all of the verification calls, the overall cost of verification burden substantially depending upon whether staff time spent verifying prescriptions but not responding to sellers is included in the calculation.

The Commission undertook a similar analysis using Dr. Baker’s assumption regarding the percentage of consumers who would present prescriptions to sellers, but using 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 some prescribers, this language makes it appear that doctors who sell contact lenses have been misleading their patients routinely accept that explanation and sign the form without too much thought or discussion”).

183 1–800 CONTACTS (WS Comment #3207); CLR Panel V Tr., supra note 50, at 7 (statement of Linda Sherry) (noting that explanation and sign the form without too much thought or discussion”).

184 E.g., National Association of Optometrists and Opticians (WS Comment #1208) (“Increased access
patients and overcharging them, and actively encourages consumers to buy their lenses elsewhere.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{196}

6. Alternative Proposals to the Signed-Acknowledgment Proposal

Some commenters suggested that instead of a signed acknowledgment, the Commission should provide better guidance and increased education.\textsuperscript{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.\textsuperscript{198} According to the AOA, signage is a common tool used to educate patients and consumers in a variety of settings.\textsuperscript{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.\textsuperscript{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.\textsuperscript{201}

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.\textsuperscript{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 a sign, while only 5% said they were more likely to pay attention to a posted sign.\textsuperscript{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.\textsuperscript{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 Commission to perform numerous spot checks across the country.\textsuperscript{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,\textsuperscript{206} although another panelist noted that when his organization looked at eye-care office compliance, the offices “passed the test.”\textsuperscript{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.\textsuperscript{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,\textsuperscript{209} even though the signage requirement has been in effect in California since 1994.\textsuperscript{210}

\textsuperscript{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 #763) (“What other industry is required in their 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 making the choice for them?”); 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 implication in the public of making Eye Care Professionals look guilty of non-release”); Frazier (NPRM Comment #2655); Kentucky Optometric Association (NPRM Comment #3174).

\textsuperscript{194} Wisconsin Academy of Ophthalmology (NPRM Comment #1152).

\textsuperscript{195} Consumers Union (NPRM Comment #3969).

\textsuperscript{196} 1–800 CONTACTS (NPRM Comment #3898).

\textsuperscript{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 #3810).

\textsuperscript{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); Gilthed (WS Comment #2205); Health Care Alliance for Patient Safety (WS Comment #3206); American Optometric Association (NPRM Comment #3810); Gridley (NPRM Comment #4150); Letter from Twenty-Four Representatitives, supra note 131; Letter from Seven Representatitives, supra note 131; Letter from Fifty-Four Representatives, supra note 131; Letter from Fifty-Eight Representatives, supra note 131.

\textsuperscript{199} American Optometric Association (WS Comment #3303).

\textsuperscript{200} Id.; Lo (WS Comment #865).

\textsuperscript{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 requirement either “helps” or “definitely helps” with prescribers and has been in effect since 1994. A panelist noted that when his organization looked at eye-care office compliance, the offices “passed the test.”\textsuperscript{207} As none of these “spot checks” can be considered scientific or thorough investigations, the Commission will not accord any of them any weight.

\textsuperscript{202} CLR Panel V Tr., supra note 50, at 14–15; id at 13 (statements of Linda Sherry).

\textsuperscript{203} Id.

\textsuperscript{204} Id. at 13 (statements of Joseph Neville).

\textsuperscript{205} 1–800 CONTACTS (WS Comment #3207, Ex. A).

\textsuperscript{206} 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 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.

\textsuperscript{207} 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-after comparison. 1–800 CONTACTS (WS Comment #3207). The Commission does not have survey evidence of California prescription-release practices from before
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. 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. According to the NAOO, allowing any of several forms of proof would provide a degree of flexibility—thus reducing prescriber burden—while still providing the Commission with more effective enforcement and verification ability than it has today.

The NAOO suggested that a prescriber who could not produce credible evidence of prescription release would face a rebuttable presumption of noncompliance.

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.

According to the NAOO, these choices would allow prescribers to tailor the acknowledgment to their practices, reduce unnecessary paper and storage issues, and yet still provide the Commission with an enforcement mechanism to ensure that prescribers are complying.

The NAOO also suggested an exemption for prescribers who do not sell contact lenses, since they lack a financial incentive to withhold a prescription. 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.

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.

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.

One 1994 signage requirement, and such data would be unhelpful in any event since the Contact Lens Rule did not exist at that point.

The 2014 Academy of Ophthalmology (NPRM Comment #4152).

The 2016 National Association of Optometrists and Opticians (WS Comment #3208), See also CLR Panel V Tr., supra note 50, at 13–14, 22, 25 (statements of Joseph Neville).

The 2017 CLR Panel V Tr., supra note 50, at 25–26 (statements of Joseph Neville).

The 2018 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 an advantage in something else.”); id. at 26 (statements of Linda Sherry that it would be simpler to have one law for everyone).

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%—are not receiving their contact lens prescriptions automatically as required by law, and millions of consumers are not receiving them at all. 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 non-compliance includes the persistently high verification numbers and consumer 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.

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

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214 See supra Section IV.B(2)(a).

215 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).
AOA prescriber survey and their own comments—that they personally always provide patients with prescriptions, and that 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. 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, that consumers 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.

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.

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 consumer against that of the prescriber. 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 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, 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, the Commission believes that enough 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. 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

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 being inconsequential, or de minimis, amount of record space. 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. 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.

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

224 See supra Section IV B(2)(a).
225 Contact Lens Rule, 69 FR 5440 (Feb. 4, 2004); Eyeglass I, 43 FR at 24002.
227 NPRM, 81 FR at 88532–34.  
228 See supra Section IV B(3).
229 See supra note 167 and accompanying text.
231 NPRM, 81 FR at 88557.
232 Id. at 88534.
233 See supra Section IV B(4).
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’ 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.\(^{234}\)

The HIPAA acknowledgment requirement more closely resembles the proposal by the National Association of Optometrists and Opticians in that it provides the prescriber with greater flexibility to adapt the acknowledgment to best suit his or her practice.\(^{235}\) 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.\(^{236}\)

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.\(^{237}\) 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 answer... What if the patient doesn’t read the notice?”\(^{238}\) Moreover, since a sign would not require a prescriber, or prescriber’s staff, to interact with each patient about the prescription, it would serve 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.\(^{239}\)

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 prescription.

\(^{232}\) See 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 Searrles, NPRM Comment #3304) (stating that from his experience as a pharmaceutical doctor, he finds it difficult to understand how some eye doctors would find it difficult to maintain ([l]eaflets 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)).
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.\textsuperscript{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.\textsuperscript{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 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.\textsuperscript{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 prescription or sales receipt\textsuperscript{249}—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.\textsuperscript{250} The Commission does not believe that such an exemption is unworkable from the standpoint of determining whether a financial interest exists,\textsuperscript{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 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.\textsuperscript{252} This interpretation is consistent with the language and intent of the Act—improving prescription portability while protecting consumer health.\textsuperscript{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 prescriptions 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.\textsuperscript{254} An increase in the

\textsuperscript{246} See also Eye specular I, 43 FR at 23998; Eyeglass II, 54 FR at 10286–87.

\textsuperscript{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).

\textsuperscript{248} Some commenters expressed concern that allowing 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 #3696) (stating that an electronic copy of a prescription should supplement but not substitute for providing a patient with a paper copy).

\textsuperscript{249} A prescriber whoelects 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.

\textsuperscript{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.

\textsuperscript{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.

\textsuperscript{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.

\textsuperscript{253} NPRM, 81 FR at 88536.

\textsuperscript{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 (NPRM Comment #3969); Contact Lens Association...
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. 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), and five business days. 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. A time limitation for prescribers to respond to such requests would promote quicker responses and, in turn, allow patients to purchase contacts sooner. However, because patients should have already received an initial copy of their prescriptions under § 315.5, the Commission believes that a longer response period, such as the forty business hours recommended by the American Academy of Ophthalmology, is more appropriate. 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 verification process, 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

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. Among other concerns with the verification process, 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. 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. 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. 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.

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, 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. Commenters also expressed concerns that: (1) The Rule does not specify how an automated telephone verification request must be communicated or structured, (2) a prescriber who receives an automated message may not have an opportunity to seek clarification, and (3) automated telephone messages do not provide sufficient records for monitoring compliance. 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. Clearly leaving a voice message on the telephone answering machine of the intended recipient setting forth all of the required information.

135 NPRM, 81 FR at 88541.
136 1–800 CONTACTS (WS Comment #3207); National Association of Optometrists and Opticians (WS Comment #3208); Consumers Union (NPRM Comment #1969).
137 See, e.g., Fuller (WS Comment #351); Whedon (WS #648); Wright (WS #743); Jolly (WS #790); Swanson (WS Comment #868); McKee (WS Comment #1290); Fandry (WS #1458); Hill (WS Comment #1755); Gibson (WS Comment #1889); Hemler (WS Comment #2212); Doyle (WS Comment #2657); Tan (WS Comment #1106); 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 6, 15.
138 American Society of Cataract and Refractive Surgery (WS #1342); Consumers Union (NPRM Comment #3969).
139 Contact Lens Institute (WS Comment #3296).
140 Id.; Health Care Alliance for Patient Safety (WS Comment #3206); CooperVision, Inc. (NPRM Comment #3841).
141 National Association of Optometrists and Opticians (WS Comment #3208).
Prescribers have an important role in safeguarding the health of their patients, and improper use of contact lenses could be harmful.282 An effective 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 quickly, and provide the Commission with a way to monitor

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.

285 Section 315.2 would be modified to add subsection (e) that states that "only in accordance with a contact lens prescription" and prohibits sellers from altering contact lens prescriptions.286

286 The Commission also proposes modifying § 315.5 to require that sellers maintain these records for a period of three years.

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.

287 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 no alternative. 288 15 U.S.C. 7603.

289 Contact Lens Rule, 69 FR at 40503.

289 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").

Allegation 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.

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-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.\textsuperscript{293} For reasons detailed in the NPRM, the Commission could not rely on that survey.\textsuperscript{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.\textsuperscript{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, 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 that products manufactured, marketed, sold, offered for sale, prescribed, and filled are not interchangeable,\textsuperscript{296} are not equivalent, and should not be treated as commodities.\textsuperscript{297} The comments were also emphasizing the need for a contact lens fitting performed by an eye-care professional.\textsuperscript{298} resulting in a prescription listing the manufacturer or brand of the selected lens.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{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.\textsuperscript{302}

With some noting that this occurred frequently,\textsuperscript{303} prescribing expressing concern that some patients were wearing different lenses than those they had prescribed, which they had not evaluated on their patients’ eyes.\textsuperscript{304} Many prescribers detailed harm that resulted from wearing unprescribed lenses, including headaches, corneal neovascularization, corneal ulcers, and other irreversible vision threatening diagnoses.\textsuperscript{305} Others commented on the general risks that may result from wearing lenses that have not been fit by prescribers.\textsuperscript{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.”\textsuperscript{307} A number of state ophthalmology associations commented that “poorly fit lenses can cause corneal ulcers and infections resulting in permanent vision loss.”\textsuperscript{308} One

\textsuperscript{293} NPRM, 61 FR at 88551–52.

\textsuperscript{294} Id.

\textsuperscript{295} Id.

\textsuperscript{296} Health Care Alliance for Patient Safety (WS Comment #2816); 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.].

\textsuperscript{297} Leung (WS Comment #1600); Ng (WS Comment #1753); Jones (WS Comment #3012); Johnson & Johnson Vision Care, Inc. (WS Comment #2131); Contact Lens Institute (WS Comment #3296); Ellenbecker (WS Comment #3357); Anderson (NPRM Comment #127); Boyer (NPRM Comment #2681); Henahan (NPRM Comment #3365).

\textsuperscript{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 V: Looking Ahead Tr. at 5 [statements of Peter Menzioso 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_v_looking_ahead.pdf [hereinafter CLR Panel V Tr.].

\textsuperscript{299} Id.

\textsuperscript{300} Contact Lens Institute (WS Comment #3296).

\textsuperscript{301} CLR Panel II Tr., supra note 296, at 13.

\textsuperscript{302} See CLR Panel II Tr., supra note 296, at 8. Dr. Eydelman also noted that the research is needed to support clinical equivalence 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 commoditization, and from which a seller can determine the manufacturer).

\textsuperscript{303} McBridge (WS Comment #659) (online retailers constantly switch lenses); A. McKee (WS Comment #730) (not uncommon); E. McKee (WS Comment #1290) (one time); 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); Johnson & Johnson Vision Care, Inc. (WS Comment #2935) (“so many patients”); Ballard (WS Comment #3027) (constant);

\textsuperscript{304} Sheila (WS Comment #483); Foutz (WS Comment #512); Mckvicker (WS Comment #517); Pulliez (WS Comment #526); and/or Lentz (WS Comment #536); Bernard (WS Comment #588); Sun (WS Comment #692); Larson (WS Comment #716); Henbane (WS Comment #730); Gitchell (WS Comment #759); Dillehay (WS Comment #822); Nowakowski (WS Comment #827); Yoder (WS Comment #830); Molamphy (WS Comment #853); McGee (WS Comment #1290); Banduy Jr. (WS Comment #1593); Leung (WS Comment #1600); Mintchell (WS Comment #1705); Kendrick (WS Comment #1725); Ng (WS Comment #1753); Seyller (WS Comment #1977); McMahon (WS Comment #1986); Bowers (WS Comment #2320); Bearden (WS Comment #2685); McGahen (WS Comment #2935); Olson (WS Comment #2970); Ballard (WS Comment #3027); Raymond (WS Comment #3090); Richmon (WS Comment #3525); Glazier (NPRM Comment #265); Lui (NPRM Comment #2051); Boyer (NPRM Comment #2681); see also American Optometric Association (WS Comment #3300, App. F) (including prescriber reports of sellers engaging in illegal alteration).

\textsuperscript{305} See, e.g., Gitchell (WS Comment #759) (discomfort and red eyes to potentially serious 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 neovascularization); Bearden (WS Comment #2685) (irreversible and vision threatening); Heinke (WS Comment #2744) (many patients with sight threatening corneal ulcers); Raymond (WS Comment #3090) (red, dry eyes and blurring vision); Wi (White (WS Comment #2320) (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 #3300, App. F) (including prescriber reports of harm from, inter alia, illegal alteration).

\textsuperscript{306} See, e.g., Johnson & Johnson Vision Care, Inc. (WS Comment #555); McLeon (WS Comment #1270); Easton (WS Comment #1333); Dice (WS Comment #1585); Staub (Comment #1597); Roth (WS Comment #1806); Rodick (WS Comment #1907); Olson (WS Comment #2970); Ballard (WS Comment #3027); Plasner (WS Comment #3085).

\textsuperscript{307} CLR Panel II Tr., supra note 296, at 9.

\textsuperscript{308} Indiana Academy of Ophthalmology (NPRM Comment #2433). See also Pennsylvania Academy
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. Prescribers blamed third-party sellers, those who sell their own brand of lenses direct-to-consumer, and online sellers more generally, as the primary sources of prescription alteration. Some asserted that certain sellers are only interested in their financial benefit and not in their customers’ eye health. Specifically, many prescribers complained that a number of sellers is not complying with—or are even abusing—the prescription verification process to unlawfully alter prescriptions and sell lenses that are not prescribed or identical to those prescribed. 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.” In addition to these comments, other prescribers stated that they have never fit, and thus never would have prescribed, certain brands of lenses, 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 FCLCA and in the NPRM in 2016. What is new, however, is the 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,310 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. 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. 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. Sellers may then contact the 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. 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. In such circumstances, the

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309 See, e.g., Wolfe (WS Comment #780); Whitsker (WS Comment #644); Pariser (WS Comment #1021); Pam Satjavatkarthapong (WS Comment #1030); Marler (WS Comment #1181); Brandenburg (WS Comment #1176); Fruchman (WS Comment #1192); Bui (WS Comment #1562); Taibiner (WS Comment #1594); Mitzche (WS Comment #1705); Engle (WS Comment #1721); Spivack (WS Comment #1778); Thau (WS Comment #1909); Yamamoto (WS Comment #2053); Bloodgood (WS Comment #2200); Persson (WS Comment #2418); Hannan (WS Comment #2537); Sugianto (WS Comment #2545); Zudel (WS Comment #2559); Horn (WS Comment #2653).

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

311 Brenden (WS Comment #600); Jones (WS Comment #644); Athlaphad (WS Comment #677); Sandberg (WS Comment #693); Cox (WS Comment #797); Marrotte (WS Comment #866); Young (WS Comment #812); Dillehay (WS Comment #1238); Derryberry (WS Comment #1333); Alwes (WS Comment #998); Dugger (WS Comment #1238); Olswang (WS Comment #2686); see also Dillehay (WS Comment #822) (stating one online supplier explained how it set up a business to use passive verification to switch lenses to their own brand). What is new, however, is the 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, 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. 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. 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. Sellers may then contact the 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. 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. In such circumstances, the

312 See, e.g., McMahon (WS Comment #1889). (stating one seller only sells one lens with one material, one base curve, one diameter, and one replacement schedule). 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.ffe.gov/sites/default/files/files/field_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).

313 See, e.g., McVicker (WS Comment #517) (stating that online supplier explained how it set up a business to use passive verification to switch lenses to their own brand). What is new, however, is the 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, 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. 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. 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. Sellers may then contact the 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. 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. In such circumstances, the

314 See, e.g., Sandberg (WS Comment #693); Swanson (WS Comment #688); Alves (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 Contact Lens Institute (WS Comment #1296); Yu-Davis (WS Comment #3410); Scullaw (WS Comment #3492); see also Rose (WS Comment #2841) (optician); Tan (WS Comment #3108) (staff optometrist office). Silverman (WS Comment #805); Marrotte (WS Comment #806); Young (WS Comment #812); Koch (WS Comment #835); Alves (WS Comment #998); Dugger (WS Comment #1238); Olswang (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). Vo (WS Comment #301); Yu-Davis (WS Comment #1301) (stating a seller on Facebook).

315 Silverman (WS Comment #805); Marrotte (WS Comment #806); Young (WS Comment #812); Koch (WS Comment #835); Alves (WS Comment #998); Dugger (WS Comment #1238); Olswang (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). Vo (WS Comment #301); Yu-Davis (WS Comment #1301) (stating a seller on Facebook).
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 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 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).


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 291, at 10 (representatives 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 from 25% to 66% 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 she also noted inaccurate prescriptions. Id. Although informative anecdotally, the Commission cannot rely on such a small informal sample as empirical evidence of the prevalence of illegal alteration. The Commission is growing 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 without a prescription without making changes to the verification framework itself. Aside from the modifications related to calls that use automated messages in Section VI in the 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 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

329 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.

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

331 Consumers Union (NPRM Comment #3969).

332 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).
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 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, 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

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 July 29, 2019. 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 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

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).
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 contact lens less 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 notified 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 actually approve the lens ordered, which is not necessary. 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 262, at 21 (stating 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. at 21 (statements of J. Pat Cummings, American Optometric Association) (“And the problem with passive verification is that people will get contact lenses without a prescription.”).
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.
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 July 29, 2019. 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?

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

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 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 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?

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 its 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. 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.

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 allot 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. Thus, 85,417 hours, cumulatively (75% × 41 million prescriptions yearly × 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 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% × 41 million prescriptions yearly × 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 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

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.

347 The prescribers previously accounted for and retains active OMB clearing as their 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 33198, 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; lower due to a reduction in years); Fla. Admin. Code r. 64B13–3.0016 (requiring optometrists to maintain patient records for at least five years).

349 PRA Assessment, supra note 185, at 62601–02; OMB Control No. 3084–0127

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 maintained. If consumers are able to choose from among competing providers; the savings consumers might achieve by purchasing lower-priced lenses; the improvements in health and safety; and the decrease 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.
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 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. (Requests 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. Applying a mean hourly wage of $57.26 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,353 to the above-noted estimate of 512,500 hours, cumulative labor costs for those tasks would total $8,333,750. 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, 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, DC 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")354 requires the Commission to conduct an analysis of the anticipated economic impact of the proposed amendments on small entities.355 The purpose of a regulatory flexibility analysis is to ensure the agency 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 RFA356 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


354 BLS Table 1.
understandable volume, and make the required information repeatable at 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 underlying revenue information) 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.

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

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.
period of not less than three years. Evidence that the prescriptions were sent, received, or made accessible, downloadable and printable.

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 make 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 maintaining an automated telephone verification systems that comply with the proposal that all complaints be at a reasonable volume and understandable. 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 the calls and the capacity for storage, and the costs associated with recording the calls and maintaining the recordings for no less than three years. 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 website or email, or text message with a digital copy of the prescription. Because a seller almost certainly has an existing account that accepts text, fax, or email, 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

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264 See supra note 285.
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 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 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.

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:


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) 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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