

FEDERAL TRADE COMMISSION**16 CFR Part 315**

RIN 3084-AB36

Contact Lens Rule

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

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: As part of its regulatory review of the Contact Lens Rule (“Rule”), and consistent with the requirements of the Fairness to Contact Lens Consumers Act (the “Act”), the Federal Trade Commission proposes to amend the Rule to require that prescribers obtain a signed acknowledgment after releasing a contact lens prescription to a patient, and maintain each such acknowledgment for a period of not less than three years. The Commission seeks comment on this proposal and several other issues.

DATES: Written comments must be received on or before January 30, 2017.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Contact Lens Rule, 16 CFR part 315, Project No. R511995” on your comment, and file your comment online at <https://ftcpublishcomment.com/ftc/contactlensrule> by following the instructions on the web-based form. If you prefer to 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 C), 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 C), Washington, DC 20024.

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

SUPPLEMENTARY INFORMATION:**Table of Contents**

I. Background

A. Overview of the Contact Lens Rule

- B. Regulatory History
- C. The Evolving Contact Lens Marketplace
- II. Contact Lens Rule Review
- III. Availability of Contact Lens Prescriptions to Patients
 - A. Section 315.3(a)(1)—Automatic Prescription Release
 - 1. Compliance With the Automatic Prescription Release Requirement
 - 2. Commenter Suggestions for Improving Automatic Prescription Release Compliance
 - 3. Analysis of Proposals for Improving Automatic Prescription Release Compliance and Commission Proposal
 - (a) Proposal To Increase Enforcement
 - (b) Proposal To Require an Eye Care Patients’ Bill of Rights or Notice-Upon-Check-In
 - (c) Proposal To Require a Signed Acknowledgment Form
 - (d) Proposal To Require Signage
 - (e) The Commission’s Proposal To Require a Signed Acknowledgment
 - 4. Additional Mechanisms for Improving Prescription Portability
 - B. Section 315.3(a)(1)—Additional Copies of Prescriptions
 - C. Section 315.3(a)(2)—Provide or Verify the Contact Lens Prescription
 - 1. Sellers Designated To Act on Behalf of Patients
- IV. Prescriber Verification
 - A. Section 315.5(a)—Prescription Requirement
 - 1. Presentation of Prescriptions “Directly or By Facsimile”
 - 2. “Verified by Direct Communication”
 - 3. Automated Telephone Calls as a Method of Direct Communication
 - B. Section 315.5(b)—Information for Verification
 - 1. Vendor Contact Information
 - 2. Prescribers’ Selection of Communication Mechanism
 - C. Section 315.5(c)—Verification Events
 - 1. Passive Verification
 - 2. Issues Regarding the Eight-Business-Hour-Window
- V. Contact Lens Prescriptions
 - A. Section 315.6—Expiration of Contact Lens Prescriptions
 - 1. Length of Contact Lens Prescriptions
 - 2. Expired Contact Lens Prescriptions
 - 3. Quantities of Contact Lenses Obtained by Patients
 - B. Private Label Lenses and Contact Lens Substitution
 - 1. Private Label Lenses
 - 2. Alteration of Contact Lens Prescriptions by Sellers
 - C. HIPAA Issues
 - D. Enforcement Efforts
 - E. Recommendations Regarding the Commission’s Complaint Reporting System
- VI. Request for Comment
- VII. Communications by Outside Parties to the Commissioners or Their Advisors
- VIII. Paperwork Reduction Act
 - A. Estimated Additional Hours Burden
 - B. Estimated Total Labor Cost Burden
- IX. Regulatory Flexibility Act
 - A. Description of the Reasons the Agency Is Taking Action
 - B. Statement of the Objectives of, and Legal Basis for, the Proposed Amendments

- C. Small Entities to Which the Proposed Amendments Will Apply
- D. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed To Comply
- X. Proposed Rule Language

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 provide the patient with a portable copy of her prescription. The Rule also requires that the prescriber verify or provide such prescriptions to authorized third parties. At the same time, the Rule requires that contact lens vendors only sell contact lenses in accordance with valid prescriptions written by licensed prescribers.

The Rule specifies that a prescriber may not require: (1) The purchase of contact lenses as a condition of providing the prescription or verification; (2) payment in addition to, or as a part of, the fee for an eye examination, fitting, and evaluation as a condition of providing the prescription or verification; or (3) the patient to sign a waiver or release as a condition of releasing or verifying the prescription.³ The prescriber is also prohibited from requiring immediate payment before the release of a prescription, unless the prescriber requires immediate payment when an exam reveals that the consumer does not need ophthalmic goods.⁴

The Rule also places certain requirements on sellers. It mandates that sellers dispense contact lenses only in accordance with a valid prescription that is either presented to the seller or verified by direct communication with the prescriber.⁵ The Rule sets out the information that must be included in a seller’s verification request, and directs that a prescription is only verified under the Rule if: (1) A prescriber confirms the prescription is accurate; (2) a prescriber informs the seller that the prescription is inaccurate and provides an accurate

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

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

³ 16 CFR 315.3(b).

⁴ 16 CFR 315.4.

⁵ 16 CFR 315.5(a).

prescription in its stead; or (3) the prescriber fails to communicate with the seller within eight business hours after receiving a compliant verification request.⁶ The Rule states that if the prescriber informs the seller within eight hours of receiving the verification request that the prescription is inaccurate, expired, or invalid, the seller shall not fill the prescription. The Rule requires that the prescriber specify the basis for the inaccuracy or invalidity of the prescription, and if the prescription is inaccurate, the prescriber must correct it.⁷

Sellers may not alter a prescription, but for private label contact lenses, may substitute identical contact lenses that the same company manufactures and sells under a different name.⁸ Sellers and others involved in the manufacture, assembly, processing, and distribution of contact lenses are prohibited from representing that contact lenses may be obtained without a prescription.⁹

The Contact Lens Rule sets a minimum expiration date of one year after the issue date of a prescription with an exception based on a patient's ocular health.¹⁰ The Rule also incorporates the Act's preemption 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.¹¹

B. Regulatory History

The FTC has more than three decades of regulatory and research experience regarding the optical goods industry. In addition to the Contact Lens Rule, the Commission enforces the Ophthalmic Practice Rules (hereinafter "Eyeglass Rule"), initially promulgated in 1978.¹² Prior to the Eyeglass Rule, many prescribers either refused to release prescriptions to their patients or charged an additional fee to do so.¹³ Prices for glasses varied widely, but

without their prescriptions, or without paying a fee to obtain their prescriptions, consumers could not comparison shop among prescribers and other vendors and purchase from sellers that best met their needs for price, service, and convenience.¹⁴ Moreover, competition did not lead the industry to offer what consumers could not choose: 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. To address this problem, the Eyeglass Rule requires prescribers—generally, optometrists and ophthalmologists—to provide each of their patients, immediately after completion of an eye examination, a free copy of the patient's eyeglass prescription.¹⁵

Consumers, sellers, and state officials complained that contact lens consumers faced similar hurdles when trying to comparison shop for contact lenses.¹⁶ To achieve freedom of choice and the benefits of competition for contact lens consumers, in 2003, Congress passed the Fairness to Contact Lens Consumers Act,¹⁷ and as the Act required, in 2004,

¹⁴ Fed. Tr. Comm'n, "The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study," 45-46 (2005), <http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf> [hereinafter 2005 Contact Lens Report].

¹⁵ 16 CFR 456.2 (separation of examination and dispensing). The FTC also has studied the effects of state-imposed restrictions in the optical goods industry. See Fed. Tr. Comm'n, Bureau of Economics Staff Paper, "The Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry" (1980), <https://www.ftc.gov/sites/default/files/documents/reports/effects-restrictions-advertising-and-commercial-practice-professions-case-optometry/198009optometry.pdf>.

¹⁶ For example, in *In re Disposable Contact Lens Antitrust Litigation*, the Attorneys General of 31 states and a certified class alleged that eye care professionals engaged in an organized effort to prevent or hinder consumers from obtaining their contact lens prescriptions. *In re Disposable Contact Lens Antitrust Litigation*, No. 94-MDL 1030-J-20A (M.D. Fla.). The complaints alleged two conspiracies: (1) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers, and (2) that manufacturers, practitioners, and trade associations, including the American Optometric Association, conspired to eliminate sales of contact lenses by pharmacies, mail order, and other alternative sellers. *Id.* According to the complaints, 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, defendant manufacturers agreed to sell contact lenses to alternative distribution channels.

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

the Commission issued the Contact Lens Rule,¹⁸ 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 issues,¹⁹ the Act requires that contact lenses be sold only to patients with valid prescriptions, which they receive after contact lens fittings. As noted above, the Act and the Contact Lens Rule only allow sales of contact lenses when the seller has a copy of the patient's prescription or has verified that prescription with the prescriber.²⁰ Sellers also are prohibited from altering a contact lens prescription.²¹ The U.S. Food and Drug Administration ("FDA") has strict labeling requirements for contact lenses, and it has the authority to take action against the sales of such lenses, which are medical devices, without a valid prescription.²²

Because of concerns that many prescribers had impeded consumers' ability to comparison shop for contact lenses—even following appropriate diagnosis and fitting by the prescribers—the Act and the Rule also impose obligations on the prescribers themselves. As noted above, prescribers are required to release a copy of the prescription to the consumer, promptly upon completion of the contact lens fitting, "[w]hether or not requested by the patient."²³ That copy must be complete and portable to enable comparison shopping; it must contain "sufficient information for the complete and accurate filling of a prescription."²⁴ Prescribers also are prohibited from requiring the purchase of contact lenses as a condition of either prescription release or verification, from requiring a separate payment for prescription release or verification, and from requiring that the patient sign a waiver as a condition of prescription release or verification.²⁵

Prescribers also are required to provide or verify a contact lens

¹⁸ Contact Lens Rule, 69 FR 40482 (July 2, 2004) (codified at 16 CFR 315). Pursuant to its congressional mandate, the FTC also issued a study of competition in the contact lens industry in 2005. See 2005 Contact Lens Report, *supra* note 14.

¹⁹ See, e.g., Fed. Tr. Comm'n, "Possible Barriers to E-Commerce: Contact Lenses, A Report from the Staff of the Federal Trade Commission," 8-9 (Mar. 2004), <http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf> [hereinafter 2004 Possible Barriers to E-Commerce Report].

²⁰ 16 CFR 315.5(a).

²¹ 16 CFR 315.5(e).

²² See 21 U.S.C. 331(a), 333, 352(f), and 353(b)(1).

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

²⁴ 15 U.S.C. 7610(3); 16 CFR 315.2.

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

⁶ 16 CFR 315.5(b)-(c).

⁷ 16 CFR 315.5(d).

⁸ 16 CFR 315.5(e).

⁹ 16 CFR 315.7.

¹⁰ 16 CFR 315.6.

¹¹ 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).

¹² Advertising of Ophthalmic Goods and Services, 43 FR 23992 (June 2, 1978). The Rule was revised in 1992, with the revisions codified at 16 CFR 456. Ophthalmic Practice Rules, 57 FR 18822 (May 1, 1992).

¹³ 43 FR at 23998. The Commission found, for example, that in nearly every survey of practicing optometrists considered in the rulemaking record, more than 50% of optometrists imposed a restriction on the availability of eyeglass prescriptions to patients. See *id.*

prescription when “directed by any person designated to act on behalf of the patient.”²⁶ Sales of contact lenses require a valid prescription that is verified by a prescriber. Such verification takes place: (1) When the prescriber confirms that the prescription is accurate, by phone, facsimile, or electronic mail; (2) when the prescriber informs the seller that the prescription is inaccurate and provides the correct prescription; or (3) when the seller seeks verification of a given prescription from a prescriber, and the prescriber does not communicate with the seller within eight business hours of the seller’s request for information.²⁷ This eight-hour, default “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—simply by refusing to respond to verification requests.

C. The Evolving Contact Lens Marketplace

When contact lenses were first introduced, they were made of rigid material that required a prescriber to custom fit each pair. Beginning in the late 1980s, manufacturers began to sell disposable lenses, designed to be replaced on a daily, weekly, or monthly basis. In addition, technological advances resolved most lens-standardization issues, eliminating the need for a prescriber to fit each pair to the individual once the initial prescription had been finalized. Today, the vast majority of replacement lenses bought pursuant to an individual’s prescription will be identical, regardless of whether the patient purchases them from the prescriber or a third-party seller.²⁸ This enables the sale of lenses to be unbundled from the fitting exam, and makes it feasible for non-prescribers to sell contact lenses.

These technological advances have increased the comfort and convenience of contact lenses, leading to growth in the number of contact lens wearers, and changes in the type and variety of lenses worn. According to the U.S. Centers for

Disease Control and Prevention (“CDC”), there are now approximately 40.9 million contact lens wearers in the United States age 18 and older, representing more than 16% of the population.²⁹

Overall, the U.S. market for contact lenses currently is estimated to be between \$4 billion and \$5 billion annually.³⁰ Of that, approximately 40% of sales are made by independent eye care professionals (optometrists and ophthalmologists), 19% by conventional retail chains (such as LensCrafters, etc.), 25% from mass merchants and wholesale clubs (such as Costco, Sam’s Club, etc.), and 18% by online sellers (16% of sales are by “pure play” online sellers, such as 1–800 CONTACTS, that do not have a physical retail presence).³¹ By contrast, in 2006, the total U.S. market for contact lenses was approximately \$3.3 billion, with estimated online sales representing less than 13% of the market.³²

There also are significantly more types of lenses in the U.S. now than there were 10 to 15 years ago.³³ At the same time, use of daily disposable lenses increased from just 7.5% in 2005 to 28% in 2015, while use of conventional one-year lenses declined sharply, from 19% to 1%.³⁴

II. Contact Lens Rule Review

On September 3, 2015, the Commission solicited comments on the Contact Lens Rule as part of its periodic review of its rules and guides.³⁵ The

²⁹ Jennifer R. Cope et al., “Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections—United States, 2014,” *Morb. Mortal. Wkly. Rep.* 64(32):865–70, 866 (Aug. 21, 2015). See also Vision Council, “Consumer Barometer,” Sept. 2015 (estimating that 16.2% of American adults wear contact lenses).

³⁰ See Vision Council, “Consumer Barometer,” Mar. 2014 (valuing the U.S. contact lens market at \$4.2 billion); Vision Council, “Consumer Barometer,” Sept. 2015 (valuing the U.S. contact lens market at \$4.6 billion).

³¹ Vision Council, “U.S. Optical Industry Report Card,” Dec. 2015.

³² See Vision Council, *supra* note 30.

³³ These include, among others, soft spherical (common soft lenses), soft toric (lenses for astigmatic patients), soft multifocal (lenses for presbyopic patients), spherical corneal GP (rigid lenses for presbyopic and astigmatic patients), and scleral (lenses for patients with corneal irregularities). Furthermore, according to Johnson & Johnson Vision Care, Inc., more than 160 different brands of contact lenses are available. Comment #582. See also Jason J. Nichols, “2015 Annual Report,” *Contact Lens Spectrum*, Jan. 1, 2016, <http://www.clspectrum.com/articleviewer.aspx?articleID=113689>.

³⁴ Carla J. Mack, “Annual Report, Contact Lenses 2007,” *Contact Lens Spectrum*, Jan. 1, 2008, <http://www.clspectrum.com/articleviewer.aspx?articleID=101240>; Nichols, *supra* note 33.

³⁵ Contact Lens Rule, Request for Comment, 80 FR 53272 (Sept. 3, 2015).

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

This Notice of Proposed Rulemaking (“NPRM”) summarizes the comments received and explains the Commission’s decision to retain the Contact Lens Rule. It also explains why the Commission proposes certain amendments and why it declines to propose others.

Additionally, it seeks comment on certain questions. Finally, the NPRM sets forth the Commission’s regulatory analyses under the Regulatory Flexibility and Paperwork Reduction Acts, as well as the text of the proposed amendments.

The Commission received 660 comments from individuals and entities representing a wide range of viewpoints, including prescribing eye care practitioners (ophthalmologists and optometrists), opticians and other eye-wear industry members, sellers of contact lenses (both online and brick-and-mortar), contact lens manufacturers, and consumer and competition advocates.³⁶ Virtually all commenters agreed that there is a continuing need for the Rule and that it benefits consumers and competition. The majority of commenters recommended some modifications to the Rule in order to maximize the benefits to consumers and competition, decrease the burden on businesses, protect consumers’ eye health, or improve overall compliance with the Rule’s existing requirements. Many commenters—including prescribers, sellers, manufacturers, legislators, and consumer advocates—also indicated that increased enforcement efforts would be beneficial.

Some commenters—including contact lens sellers, opticians, state and federal legislators, consumer advocacy groups, and others—stated that the Act’s intent to provide a competitive marketplace is

³⁶ The comments are posted at: <https://www.ftc.gov/policy/public-comments/initiative-621>. The Commission has assigned each comment a number appearing after the name of the commenter and the date of submission. This notice cites comments using the last name of the individual submitter or the name of the organization, followed by the number assigned by the Commission.

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

²⁷ 15 U.S.C. 7603(d)(1)–(3); 16 CFR 315.5.

²⁸ However, contact lens prescriptions are brand specific, and as a general matter, one brand cannot be substituted for another, even if the other technical parameters (power, base curve, diameter, cylinder, and axis) are identical. As noted previously, sellers may substitute identical contact lenses that the same company manufactures and sells under a different name.

not being fully realized because prescribers are not complying with one of the major underpinnings of the Rule: the automatic release of prescriptions to patients.³⁷ Some commenters also asserted that some prescribers are interfering with the prescription verification process and thereby impeding consumers' ability to comparison shop.³⁸

Many commenters discussed the fact that the use of contact lenses presents certain eye health risks. Prescribers pointed out that merely by wearing contact lenses, patients will experience an increased risk for microbial keratitis (also referred to as infectious or bacterial keratitis).³⁹ Indeed, contact lens wear has been identified as the largest single risk factor for microbial keratitis.⁴⁰ Furthermore, this risk increases if a patient wears the lenses too long, wears the lenses overnight, or fails to comply with the recommended replacement schedule.⁴¹ Other commenters noted that additional risk factors for ocular complications include improper care of the lenses or poor hygiene practices.⁴² Other commenters pointed out that improperly fitting contact lenses may result in corneal ulcers and other health issues.⁴³

³⁷ See, e.g., Utah Retail Merchants Association (Comment #28); Information Technology & Innovation Foundation (Comment #40); Rhode Island State Representative Kennedy (Comment #536); Arizona State Representative Carter (Comment #545); Utah State Senator Bramble (Comment #576); Lens.com (Comment #614); Consumers Union (Comment #677).

³⁸ See, e.g., LD Vision Group (Comment #544); National Association of Optometrists and Opticians (Comment #549); 1-800 CONTACTS (Comment #568); Warby Parker (Comment #593).

³⁹ See, e.g., Whipple (Comment #15); Nelson (Comment #130). See also CLAO (Comment #572) (commenting that "[t]he CDC points out that the largest single risk factor for microbial keratitis is contact lens wear"); Lupinski (Comment #499) ("[s]tudies over the years have shown that wearing contact lenses increases the risk for ocular health complications").

⁴⁰ Cope, *supra* note 29, at 866.

⁴¹ See *id.* at 867 ("sleeping in any type of contact lens increases risk for eye infection"); Fiona Stapleton, et al., "The Incidence of Contact Lens-Related Microbial Keratitis in Australia," *Ophthalmology* 2008; 115:1655, 1659 ("Overnight use of [contact lenses], irrespective of material type, continues to be the main risk factor for corneal infection."). See also Whipple (Comment #15); Butthod (Comment #81); Morgan (Comment #144); Lupinski (Comment #499); Bearden (Comment #554).

⁴² See, e.g., Shlosman (Comment #290); Israel (Comment #429); Bearden (Comment #554); Barnett (Comment #668). See also CLAO (Comment #572) (citing to a recent CDC report that found outbreaks of serious eye infections among contact lens wearers continue and "are associated with failure to wear, clean, disinfect and store their lenses as directed").

⁴³ See, e.g., Raykovicz (Comment #35); Morgan (Comment #144); Pusz (Comment #646); see also American Academy of Ophthalmology (Comment #611) ("[w]earing improper lenses can further

In light of the risks associated with the use of contact lenses, many commenters—including individual prescribers, optometric and ophthalmologic associations, and contact lens manufacturers—stressed the important need to adequately protect eye health and safety and argued that the current Rule framework is not sufficient to do so.⁴⁴ For example, the Contact Lens Association of Ophthalmologists, Inc. ("CLAO") asserted that the Rule's passive verification framework "creates a mechanism for renewal of expired prescriptions" and "eliminates a critical opportunity to improve the public health of contact lens consumers by addressing risky wear and care practices."⁴⁵ As support, the CLAO comment cited to an article in the CDC's weekly report recommending vigorous health promotion activities to encourage contact lens wearers to improve their hygiene behaviors.⁴⁶ However, the comment did not include any empirical evidence showing that the passive verification mechanism has actually resulted in the renewal of expired prescriptions. Furthermore, the CLAO did not present any data showing that patients are not visiting their eye care practitioners as a result of the passive verification mechanism (or any other Rule provision).

Other examples of patient harm identified by commenters were either hypothetical or anecdotal (such as case reports about the experiences of individual patients).⁴⁷ The comments

complicate existing vision issues, including leading to infection in the eye").

⁴⁴ Commenters provided illustrations of how they believe the current operation of the Rule is jeopardizing consumer health. For example, some commenters posited that loopholes in the Rule allow patients to obtain lenses with expired, or otherwise invalid, prescriptions. According to this line of argument, patients are obtaining lenses without annual eye examinations, or without the proper medical oversight to monitor their use of contact lenses, and this could result in delayed or missed diagnosis of contact lens-related eye issues, other eye health issues, or other health conditions that otherwise would be detected during an annual eye examination. Commenters also expressed concerns that if patients do not visit eye care prescribers regularly, they will not receive proper training on the care and use of contact lenses.

⁴⁵ Comment #572. See also American Optometric Association (Comment #644) ("[a]llowing repurchases based on long-expired prescriptions may be, at the time, convenient for the patient and profitable for the seller, but increases the risk of patient harm").

⁴⁶ Cope, *supra* note 29.

⁴⁷ See, e.g., Combs (Comment #90) (patient with corneal ulcer had not been to doctor in eight years); Simmons (Comment #104) (patient ordered contacts using spectacle prescription with on online retailer; never given proper hygiene training); Mansito (Comment #122) (sister ordered lenses online with expired prescription; they did not fit and she needed corneal transplant); Ahn (Comment #215)

did not include data indicating the number or percentage of patients who obtain lenses without a valid prescription, or empirical evidence that patients are seeing their eye care practitioners less frequently than they did prior to the Rule's adoption. In addition, while some commenters stated that patients are obtaining lenses without proper medical supervision, industry data indicates that approximately 40% of contact lenses are still obtained directly from independent prescribers, and only roughly 16% of contact lenses are obtained from online-only sellers, the retail venue most frequently mentioned by commenters.⁴⁸ Most importantly, these commenters did not point to any evidence that the implementation of the Rule has increased the incidence of contact lens complications.

Other commenters argued that contact lens sales through alternative supply channels put patients at higher risk for ocular complications. The American Academy of Optometry, for example, asserted that "careful peer reviewed research over the past ten years" shows that "the development of alternative supply chains for the sale of contact lenses—and the use of those alternative supply chains by contact lens patients—has itself become an identifiable risk factor for ocular morbidity in contact lens patients."⁴⁹ To support this contention, this commenter cited several studies that it believes show that internet purchasers of contact lenses are more likely to engage in harmful eye care practices,⁵⁰ to have a significant difference in aftercare awareness,⁵¹ and to have a higher risk of developing microbial keratitis.⁵² The Commission examined each of these studies and concludes that they are not sufficient to reliably demonstrate that purchasing lenses online is a risk factor, or that online purchasers are at a higher risk of developing microbial keratitis or any other ocular complication.⁵³

(patient sleeping in lenses for a week at a time, using outdated prescription).

⁴⁸ Vision Council, "U.S. Optical Industry Report Card," Dec. 2015.

⁴⁹ Comment #623.

⁵⁰ Joshua Fogel & Chaya Zidile, "Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices," *Optometry*, 79.1 (2008) 23–35.

⁵¹ Yvonne Wu et al., "Contact lens user profile, attitudes and level of compliance to lens care," *Cont. Lens Anterior Eye* 33 (2010) 183–188.

⁵² Stapleton, *supra* note 41.

⁵³ The Fogel and Wu studies have relatively small samples of consumers who purchased contact lenses over the Internet and the sample recruiting methodologies call into question whether the results are generalizable to the national population. In addition, the results of these studies link

Some commenters merely asserted that patient eye health is being compromised because online retailers do not comply with the Rule,⁵⁴ online retailer practices have convinced consumers that contact lenses are a commodity rather than a medical device,⁵⁵ and online retailers do not provide patients with proper care instructions.⁵⁶ Other prescribers alleged that patients who purchase contact lenses online or through mail order companies are noncompliant with follow-up eye care and the safe use of contact lenses,⁵⁷ or purchase lenses with expired prescriptions and then experience complications.⁵⁸ A few commenters asserted that online purchasing in particular allows patients to obtain lenses without a valid, unexpired prescription and provided anecdotal examples of patients who avoided regular eye examinations by purchasing lenses online.⁵⁹

The Commission does not find the evidence proffered in this Rule review sufficient to support a conclusion that the Rule inadequately protects consumer eye health. Commenters did not provide sufficient reliable empirical evidence that the current Rule leads to the increased acquisition of contact lenses without a valid prescription or increased incidence of contact lens-related eye disease or adverse eye conditions. Furthermore, despite commenters' concerns about online or mail order sales of contact lenses, the Commission has not seen reliable empirical evidence to support a finding that such sales are contributing to an

purchase locations to consumer behaviors such as having a doctor check the contact lens fitting after purchase or awareness of recommended follow-up visit, rather than actual adverse eye health outcomes. The Stapleton study identified Internet/mail order purchases as a potential risk factor for microbial keratitis in a large sample from Australia. However, when the authors of the Stapleton study limit their sample to cases of moderate to severe keratitis, Internet/mail order purchases are not found to be a risk factor. *See* Fiona Stapleton et al., "Risk factors for moderate and severe microbial keratitis in daily wear contact lens users," *Ophthalmology* 2012; 119:1516–1521.

⁵⁴ *See, e.g.*, Weissman (Comment #50); Copeland (Comment #73); Anderson (Comment #96); Woodland (Comment #98); Wheeden (Comment #214); Holliday (Comment #249); Arthur (Comment #371); Blankenship (Comment #395).

⁵⁵ Sancho (Comment #226).

⁵⁶ Miyabe (Comment #481).

⁵⁷ *See, e.g.*, Alford (Comment #18) (stating that they have a much higher rate of adverse effects such as vision threatening eye infections and inflammatory conditions, as they usually over wear their lenses and avoid seeking eye care when they have a complication).

⁵⁸ *See, e.g.*, Owen (Comment #72); Stephens (Comment #210); Ahn (Comment #215); Born (Comment #570); King (Comment #655).

⁵⁹ Gronquist (Comment #75); Butold (Comment #81); Morgan (Comment #144); Sadeghian (Comment #242).

increased incidence, or increased risk, of contact lens-related eye problems.⁶⁰ In addition, the particular risks associated with contact lens use (or overuse) were previously considered by Congress and the Commission during the passage of the Act and the implementation of the Rule.⁶¹ The current rulemaking record does not provide any basis to disrupt this original analysis.

III. Availability of Contact Lens Prescriptions to Patients

Section 315.3 of the Rule provides the framework under which prescribers are required to release contact lens prescriptions to patients and other authorized third parties. Section 315.3 also imposes limitations on the conditions prescribers may require of patients before releasing their prescription.

A. Section 315.3(a)(1)—Automatic Prescription Release

Section 315.3(a)(1) of the Rule requires a prescriber to provide a copy of the contact lens prescription to the patient after completing a contact lens fitting, regardless of whether it was requested by the patient. Section 315.3(a)(1) of the Rule tracks the language of the Act verbatim.⁶²

This provision, referred to as automatic prescription release, was intended to empower consumers to comparison shop for contact lenses.⁶³ Automatic prescription release has been in effect for 12 years and is now widely supported by commenters, including both prescribers⁶⁴ and third-party

⁶⁰ Several commenters referenced the article published in the CDC weekly report (Cope, *supra* note 29) for the proposition that the sale of contact lenses requires stricter oversight because of this article's finding that, "[a]pproximately 99% of wearers reported at least one contact lens hygiene risk behavior." The Commission notes two important caveats. First, the authors reached this number by including any wearer that indicated that they had "ever" engaged in a risk behavior. Hence, the 99% figure includes every wearer, who at any time, had engaged in a risk behavior even once. Second, the survey instrument asked users where they purchased their lenses, and in a separate article, the authors did not conclude that there was any difference in either habits or health risks based on whether the lenses were purchased from a provider, retail store without an exam, or over the internet. *See* Robin Chalmers et al., "Is Purchasing Lenses from the Prescriber Associated with Better Habits Among Soft Contact Lens Wearers?," *Cont. Lens Anterior Eye* 2016 Aug 12 (Epub ahead of print) PMID: 27527924.

⁶¹ *See, e.g.*, 2004 Possible Barriers to E-Commerce Report, *supra* note 19, at 8–12.

⁶² 15 U.S.C. 7601(a)(1).

⁶³ Contact Lens Rule, Notice of Proposed Rulemaking, 69 FR 5440 (Feb. 4, 2004).

⁶⁴ *See, e.g.*, American Academy of Ophthalmology (Comment #611) ("we believe [the Rule] empowers consumers to comparison shop for contact lenses"); Coalition for Patient Vision Care

sellers,⁶⁵ with several recognizing it as the "cornerstone,"⁶⁶ or "pillar,"⁶⁷ of the Act and the Rule. Of the 660 comments received by the Commission, none explicitly opposed the automatic release provision of the Rule although some prescribers asserted that from a safety perspective, it is in patients' best interests to purchase contact lenses from their prescribers rather than from third-party sellers.⁶⁸ More common, however, were comments supporting automatic prescription release, but suggesting that the provision was not sufficiently complied with or enforced.⁶⁹ Other commenters suggested that the automatic prescription release provision should take into account advances in technology.

1. Compliance With the Automatic Prescription Release Requirement

Several commenters stated that prescribers routinely fail to comply with the automatic prescription release requirement: Some do not—or do not always—provide a prescription unless a consumer explicitly requests it; some do not provide complete prescriptions, as required by the Rule; and some do not provide prescriptions at all.⁷⁰ These comments are, in general, concordant with complaints the Commission has received from numerous consumers apart from this rule review process.⁷¹ Some consumer complaints, however, may be based on a misunderstanding of the Rule, as there can be confusion

Safety (Comment #621) ("Since enactment, and the FTC's subsequent implementation, the market for contact lenses has become extremely competitive . . . This competition has led to increased investment in research and development, and a proliferation of innovation that served to benefit the nearly 44 million Americans who use contact lenses every day."). *See also* Carroll (Comment #5); Voigt (Comment #551); Alianello (Comment #253).

⁶⁵ *See, e.g.*, 1–800 CONTACTS (Comment #568); Lens.com (Comment #614).

⁶⁶ Warby Parker (Comment #593).

⁶⁷ Rhode Island State Representative Kennedy (Comment #536); 1–800 CONTACTS (Comment #568); *see also* Utah State Senator Bramble (Comment #576); National Association of Optometrists and Opticians (Comment #549); Utah Retail Merchants Association (Comment #28).

⁶⁸ *See, e.g.*, Woo (Comment #56).

⁶⁹ *See, e.g.*, 1–800 CONTACTS (Comment #568); Lens.com (Comment #614); Utah State Senator Bramble (Comment #576).

⁷⁰ *See, e.g.*, Consumers Union (Comment #677); Rhode Island State Representative Kennedy (Comment #536); Lens.com (Comment #614).

⁷¹ They are also consistent with longstanding practices of eye care professionals prior to enactment of the Fairness to Contact Lens Consumers Act, even in states where prescribers were required, by state statute, to release prescriptions to consumers. *See* "Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce," 108th Cong. 1 (Sept. 12, 2003) (Testimony of Ami Gadhia, Consumers Union).

about when or under what conditions patients should receive their prescriptions. For example, the Rule requires that a prescription be provided after the completion of the contact lens fitting, not necessarily at the conclusion of the initial visit with the prescriber. Because a fitting may not be complete until a follow-up visit, a patient might incorrectly believe that she should have been provided with her prescription at the conclusion of the first visit.

A number of prescribers commented, to the contrary, that they always provide contact lens prescriptions to their patients, and believe that others in their profession do so as well.⁷² Prescribers, for their part, may be aware in a general way of their obligation to release prescriptions and yet be unaware of all of the conditions of prescription release required by the Rule. Hence, they might be mistaken in assessing, and reporting on, their own compliance.

Many reports of compliance and noncompliance are anecdotal, and robust empirical data are sparse. Although the Commission would prefer better empirical evidence about compliance and noncompliance with the Rule, and about the effects of the Rule, some survey evidence has been submitted by sellers, prescribers, and manufacturers. The Commission considers these submissions to be suggestive and, to an extent, informative, but none can be regarded as definitive. It is important to note, at the outset, that all of these surveys are subject to particular methodological limitations, as well as limits commonly associated with survey evidence. For example, patients may sometimes misremember the details of any particular prior encounter with a prescriber; prescribers, for their part, may be mistaken about the particulars of a given clinical encounter, about the frequency with which they do or do not release prescriptions, or about the frequency or severity of problems they may encounter in verifying prescriptions. For the most part, the surveys do not include independent, objective tests of patient or prescriber recollections. In addition, survey responses may be sensitive to the ways in which survey questions are framed.

As part of its comment, 1-800 CONTACTS, the country's largest online seller of contact lenses, submitted a survey conducted on its behalf by a third-party research firm, Survey Sampling International. That survey found that only 35% of contact lens wearers reported receiving a copy of

their prescription without having to ask for it.⁷³ Another 28% reported receiving their prescription upon request (either at the office or afterwards), while 36% said they never received it at all.⁷⁴ Additional, and similarly-designed surveys, conducted on behalf of 1-800 CONTACTS in November 2014 and May 2015 found that 45% and 48% of contact lens wearers, respectively, reported that they were automatically given a hard copy of their prescription at their last eye exam.⁷⁵

Some commenters also cited a 2008 report in a contact lens industry publication which found that just half of surveyed optometrists replied, "yes, to every patient," when asked if they routinely release contact lens prescriptions.⁷⁶

Other commenters stated that even when consumers receive a copy of their prescription, the prescription information is not always complete or correct. One online seller of replacement lenses contended that some prescribers deliberately render prescriptions incomplete by omitting information, in order to make it more

⁷³ 1-800 CONTACTS (Comment #568), Exhibit B. According to 1-800 CONTACTS, the data derives from an online survey of 500 contact lens wearers ages 18-49 years old by Survey Sampling International between Oct. 1 and Oct. 6, 2015. The respondents were not informed of the identity of the survey sponsor. The Commission has concerns about the methodology utilized for this survey, particularly about the lack of an "I don't know" option for various questions, but believes the information may still be suggestive, particularly when viewed in conjunction with information from other sources and the absence of contradictory data.

⁷⁴ *Id.* at 3.

⁷⁵ 1-800 CONTACTS (Comment #568), Exhibit C. According to 1-800 CONTACTS, these data are based on two surveys of 2000 contact lens wearers, randomly selected and conducted in November 2014 and May 2015. These surveys were sponsored by 1-800 CONTACTS and conducted by an independent market research company. As with the 2015 survey cited above, the Commission has concerns about the methodology utilized for these surveys but believes the information may still be suggestive, particularly when viewed in conjunction with information from other sources and the absence of contradictory data.

⁷⁶ 1-800 CONTACTS (Comment #568), Information Technology & Innovation Foundation (Comment #40), Utah Retail Merchants Association (Comment #28) citing Mack, *supra* note 34. Analogously, an October 2015 SurveyMonkey survey of 1,329 respondents, sponsored by online eyewear seller Warby Parker, reported that 47% of consumers who saw optometrists were not automatically provided with an eyeglass prescription at the end of the exam. Warby Parker (Comment #813 on the Ophthalmic Practice Rules), <https://www.ftc.gov/policy/public-comments/initiative-624>. The patients surveyed by SurveyMonkey were primarily consumers who purchased eyeglasses, not contact lenses, but the prescription-release requirement for eyeglass prescriptions is similar to that for contact lenses and both eyeglasses and contact lenses are prescribed by the same categories of eye care professionals. See Ophthalmic Practice Rules, 16 CFR 456.2.

difficult for consumers to buy lenses from third-party sellers.⁷⁷ According to an internal review of prescriptions on file with 1-800 CONTACTS, 23% were missing one or more parameters required to fill an order, and 43% lacked complete contact information for the prescriber.⁷⁸

Such omissions, when they occur, may be intentional, may reflect clerical or communication errors, or may reflect an imperfect understanding of the Rule's complete requirements for prescription release. All such errors could reflect failures to comply fully with the requirements of the Rule.

The sheer number of verifications conducted by third-party sellers also may suggest that many consumers are not automatically receiving their prescriptions from prescribers, or are not receiving complete prescriptions. Under Section 315.5, verifications are only necessary if a consumer fails to provide a third-party seller with a complete prescription. According to discussions with industry, roughly three-quarters of third-party contact lens sales require prescription verification, meaning that the consumer did not present a complete prescription at the time of the attempted purchase.

Seemingly contrary to this data is a survey, conducted on behalf of Johnson & Johnson Vision Care, Inc., a large contact lens manufacturer, according to which 61% of consumer respondents said that they provided the retailer with their prescription the last time they purchased lenses online or by telephone.⁷⁹ The Commission does not have enough data or insight to determine if either of these surveys accurately reflects industry practice. It is possible that some of these consumers received incomplete or otherwise problematic prescriptions. If so, those consumers might accurately report that they provided something that they believed to be a prescription at the time of purchase when, in fact, the document they provided was not complete or fillable, and hence (a) required verification and (b) was not a "prescription" as defined by the Rule. Alternatively, some consumers could have received their prescriptions from

⁷⁷ LD Vision Group (Comment #544).

⁷⁸ 1-800 CONTACTS (Comment #568) (based on a "sample of 803 prescriptions on file with 1-800 CONTACTS."). The Commission was not provided with the data for this sample, and so cannot judge whether the data are generalizable. Apart from this internal survey, the Commission has not received other empirical evidence demonstrating that prescribers—deliberately or otherwise—failed to provide patients with complete prescriptions.

⁷⁹ Johnson & Johnson Vision Care, Inc. (Comment #582) (August 2015 telephone survey by APCO Insight for J&J).

⁷² Howe (Comment #53). See also, e.g., Galdamez (Comment #167); Ahn (Comment #215).

prescribers but misplaced them, forgot them, or simply thought it easier to obtain the refraction information from their contact lens boxes. Whatever the frequency with which each of these possibilities occurs, it is evident that third-party sellers are presently verifying a significant percentage of contact lens prescriptions with prescribers. It is also evident, based on the comments submitted, that many prescribers feel there are too many verification requests, and that it would be helpful if more patients provided a copy of their prescription to sellers rather than rely on the verification process.⁸⁰

Another concern raised by commenters is whether consumers are even fully aware of their right to their prescriptions.⁸¹ According to the aforementioned October 2015 survey conducted on behalf of 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 2004.⁸² The manner in which this particular question was phrased in the 1–800 survey,⁸³ however, raises Commission concerns about the validity of, or the weight that should be accorded to, the results for this question. In particular, the question is leading, it lacks an “I don’t know” option, it uses a term—“hard copy”—which some patients may not understand, and it is phrased in such a way that it could give rise to social desirability bias,⁸⁴ since respondents might be reluctant to admit that they are unaware of their rights under federal law. That being said, a response error resulting from social desirability bias in this instance would more likely lead to undercounting, or underestimation, of the number of patients who are unaware they have a right to their prescription. In other words, the way the question

⁸⁰ See, e.g., Carroll (Comment #5) (“[Verification] is costly to my business. the patient should have a written copy of their Rx to provide to the vendor of their choice.”); Walton (Comment #543) (“It should be the consumer’s responsibility to provide the seller a full, unexpired contact lens prescription and the doctor prescribing should not have to be involved in this process. It puts undue stress on small local businesses to have to respond to faxes”); Baur (Comment #170) (“If I am already handing patients a copy of their prescription, why do I have to verify the Rx at all?”).

⁸¹ Warby Parker (Comment #593); 1–800 CONTACTS (Comment #568).

⁸² 1–800 CONTACTS (Comment #568), Exhibit B.

⁸³ The question was phrased as follows: “Are you aware that it is your right under federal law, as a patient to receive a hard copy of your contact lens prescription from your eye exam provider?,” with the only possible answers being Yes or No.

⁸⁴ Social desirability bias is the tendency of survey respondents to answer questions in a manner that will be viewed favorably by others.

was phrased could make it seem that more patients are aware of their right than is actually the case, and it is thus possible that *more than* 46% of contact lens wearers are unaware that they have a right to automatically receive their prescription at the end of their contact lens fitting.

2. Commenter Suggestions for Improving Automatic Prescription Release Compliance

Some commenters asked the Commission to take specific actions to increase compliance with the automatic prescription release requirement.⁸⁵ Some commenters recommended that the Commission increase the number of enforcement actions it takes against prescribers who fail to comply with automatic prescription release in order to “send a message to complacent prescribers.”⁸⁶ Another suggestion, put forth by 1–800 CONTACTS and other third-party sellers, is to amend the Rule to require that, immediately upon completing a contact lens fitting, prescribers provide patients with an eye care patients’ “Bill of Rights,” informing them of their right to their prescription, that the prescription will be provided without request, and that they have a right to purchase lenses from the seller of their choice.⁸⁷ Another commenter, Consumers Union, the policy and advocacy division of Consumer Reports, suggested that prescribers inform consumers at the beginning of their visit—as part of the initial paperwork—that they will provide a prescription at the end of the examination at no additional cost.⁸⁸

Other commenters suggested requiring patients to sign an “Acknowledgment of Release” document, confirming that they received their prescriptions.⁸⁹ Prescribers would be required to retain the signed acknowledgments, which then could be inspected by the Commission to verify compliance.⁹⁰ One commenter, an Arizona state representative, said she was considering introducing state legislation that would

⁸⁵ See, e.g., 1–800 CONTACTS (Comment #568); Utah Retail Merchants Association (Comment #28); Utah State Senator Bramble (Comment #576); Information Technology & Information Foundation (Comment #40); Lens.com (Comment #614); Warby Parker (Comment #593).

⁸⁶ 1–800 CONTACTS (Comment #568). See also Utah State Senator Bramble (Comment #576); Utah Retail Merchants Association (Comment #28).

⁸⁷ 1–800 CONTACTS (Comment #568). See also Warby Parker (Comment #593); Lens.com (Comment #614).

⁸⁸ Consumers Union (Comment #677).

⁸⁹ Lens.com (Comment #614); 1–800 CONTACTS (Comment #568). See also Arizona State Representative Carter (Comment #545).

⁹⁰ *Id.*

mandate such signed acknowledgments for prescribers in her state.⁹¹

3. Analysis of Proposals for Improving Automatic Prescription Release Compliance and Commission Proposal

Having considered the various comments and suggestions, the Commission believes that improving compliance with automatic prescription release would further the goals of the Act. While none of the five surveys⁹² cited by commenters are definitive on the question of automatic release compliance, the Commission believes that the overall weight of evidence in the rulemaking record—including the surveys, the high number of verifications, the ongoing pattern of consumer complaints and anecdotal reports, and the industry’s long history of failing to provide prescriptions to patients even when obligated by state law—indicates that compliance with the automatic prescription release provision could be substantially improved. Furthermore, the potential benefits of increasing the number of patients who receive their prescriptions are substantial: Increased patient flexibility and choice in shopping for contact lenses; a reduced number of verification requests, which some prescribers find burdensome; a reduced likelihood of errors associated with incomplete prescriptions; and a reduction in the number and complications of failed attempts at verification. Increasing compliance also is likely to spur more competition and innovation among contact lens sellers and manufacturers. It should also reduce the number of attempts by sellers to verify expired or inaccurate prescriptions, as well as attempts to verify prescriptions with the wrong prescriber, practices that many prescribers complained about in their comments.⁹³ The cumulative effect of increased compliance would likely be lower costs and improved convenience and flexibility for patients, sellers, and prescribers as well as increased accuracy of prescriptions presented to sellers, thereby reducing potential consumer harm from inaccurate, expired, or otherwise invalid prescriptions.⁹⁴

Having determined that it would be beneficial to increase compliance with

⁹¹ Arizona State Representative Carter (Comment #545).

⁹² See *supra* notes 73–76, citing surveys by Survey Sampling International, Contact Lens Spectrum, and SurveyMonkey.

⁹³ See *infra* Section IV.

⁹⁴ See, e.g., Lens.com (Comment #614) (predicting that improving automatic prescription release compliance could lead to lower contact lens prices, since it would reduce verification costs for both sellers and prescribers).

the automatic prescription release provision, the Commission now evaluates various proposals put forth by commenters for how to best achieve this goal.

(a) Proposal To Increase Enforcement

Several commenters suggested that one way to better ensure automatic prescription release compliance is for the Commission to become more aggressive about enforcement.⁹⁵ According to 1-800 CONTACTS, “Prescribers today clearly believe they can disregard their legal obligations without consequence.”⁹⁶ 1-800 CONTACTS urged the Commission to regularly investigate prescriber practices and issue warning letters or take enforcement actions against prescribers that do not comply with the automatic prescription release provision.⁹⁷ According to 1-800 CONTACTS, this would not only change the behavior of the targeted prescribers, but would send a signal to other prescribers that they need to comply with the Rule.

The Commission recognizes the need for increased enforcement of the automatic prescription release provision and already has taken some recent steps to achieve better compliance. For example, in April 2016, the Commission sent warning letters to 45 contact lens prescribers after receiving consumer complaints alleging that the prescribers had violated the Rule, often by failing to provide patients with their prescriptions automatically.⁹⁸ The Commission acknowledges, however, that the absence of documentation makes it difficult to determine whether a prescriber did or did not provide a patient with a prescription as required, in any particular case. The absence of documentation also makes it difficult to determine how many times, or how frequently, a noncompliant party has violated the Rule. Instead, allegations and denials of Rule violations might often become a matter of the patient’s word against that of the prescriber, making accurate enforcement decisions, as well as enforcement actions predicated on those decisions (as opposed to warning letters) more challenging. The Commission thus believes that enforcement could improve through a mechanism to

increase its ability to assess and verify compliance with the Rule’s automatic prescription release requirements.

(b) Proposal To Require an Eye Care Patients’ Bill of Rights or Notice-Upon-Check-In

A number of commenters recommended that the Commission amend the Rule to require that prescribers provide patients with written notices informing them of their right to their prescription. One suggestion, proposed by three online sellers of eye wear, is that, immediately upon completion of a contact lens fitting, prescribers provide patients with a “Bill of Rights”; that is, a written notice informing patients of their rights under the Rule, including: (1) The right to receive their prescriptions; (a) provided promptly and automatically without their having to request them; (b) at no additional charge; and (2) the right to purchase their lenses from the seller of their choice.⁹⁹ Another suggestion, put forth by a consumers’ rights organization, is that the Rule require that, “the eye doctor inform the consumer at the beginning of the visit, as part of the initial paperwork, that the prescription will be provided at the conclusion of the visit at no additional cost.”¹⁰⁰

Either of these proposals, if implemented and complied with, would notify consumers of their rights and, presumably, would increase the percentage of patients who receive prescriptions from their prescribers. Providing the required document would remind prescribers and their staffs to provide patients with their prescriptions, and it would remind patients to ask for their prescriptions in the event that the prescriber might fail to provide them initially and without a request, as the Rule and the Act already require.

Since the Commission could draft the specific language for either the “Bill of Rights” or check-in notice, it could ensure that the notice conveys an accurate explanation of the Rule’s automatic prescription release requirements, something prescribers sometimes fail to do.¹⁰¹ The

requirement should also impose a relatively small burden upon prescribers, since prescribers would only need to provide a brief, standard form for each patient.

On the other hand, patients already receive forms and other paperwork when they visit a prescriber, increasing the possibility that patients might not read or attend to the information in the “Bill of Rights” or check-in notice.

Moreover, the Rule already requires that prescribers provide patients with copies of their prescriptions, yet diverse complaints have alleged that many prescribers do not do so. It is at least possible that many prescribers who now fail to comply with the Rule’s prescription release requirements would also fail to comply with a requirement to provide a patients’ “Bill of Rights” or check-in notice form. Without some mechanism to ensure compliance, a notice by itself might not provide substantial benefits. The notices recommended by these proposals would not require the type of prescriber record-keeping needed to assist the Commission in better Rule enforcement, either in its current form or as it might be amended. It is thus possible that adding this requirement would impose an increased burden on prescribers without providing many tangible, countervailing benefits to consumers. In light of these considerations, the Commission has determined not to propose to amend the Rule to require either a Bill of Rights or notice-upon-check-in.

(c) Proposal To Require a Signed Acknowledgment Form

Another amendment recommended by some commenters is to require that prescribers present, and patients sign, an “acknowledgment of release,” confirming that they received their prescription at the end of their contact lens fitting.¹⁰² Such an acknowledgment would be a separate, stand-alone document, and prescribers would be required to retain the signed acknowledgments.¹⁰³

An acknowledgment of release would notify consumers of their prescription portability rights and, in all likelihood, increase the percentage of patients who receive their prescription from the prescriber. Providing the required form would also serve as a reminder to

it. This, in turn, may put patients in an awkward position since they may feel they are going behind the prescriber’s back by shopping for contacts elsewhere.

¹⁰² Lens.com (Comment #614); 1-800 CONTACTS (Comment #568). See also Arizona State Representative Carter (Comment #545).

¹⁰³ *Id.*

⁹⁵ 1-800 CONTACTS (Comment #568). See also Utah State Senator Bramble (Comment #576); Utah Retail Merchants Association (Comment #28).

⁹⁶ 1-800 CONTACTS (Comment #568).

⁹⁷ *Id.* at 25–26.

⁹⁸ Press Release, Fed.Tr. Comm’n, FTC Issues Warning Letters Regarding the Agency’s Contact Lens Rule (Apr. 7, 2016), <https://www.ftc.gov/news-events/press-releases/2016/04/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule>.

⁹⁹ 1-800 CONTACTS (Comment #568). See also Warby Parker (Comment #593); Lens.com (Comment #614).

¹⁰⁰ Consumers Union (Comment #677).

¹⁰¹ Imprecise word selection by prescribers may, in some cases, lead prescribers to inadvertently violate the rule. For example, an eye care practitioner may believe he is complying by asking patients, “Do you want a copy of your prescription?” when, in fact, such a question is a violation of the automatic release provision since the prescription is not provided automatically but rather requires patients to confirm that they want

prescribers and their staffs to provide patients with their prescriptions, and serve as a reminder to patients to ask for their prescription in the event that they receive the acknowledgment form but not the prescription. Once it becomes an established practice, an acknowledgment form might also reduce confusion for patients as to when their contact lens fitting is actually complete, thus reducing the likelihood of erroneous complaints about a prescriber's perceived failure to provide a prescription after the completion of a preliminary examination but when the contact lens fitting has not yet been completed.

Additionally, since patients would have to affirmatively sign such an acknowledgment, it is less likely that such a document would go unnoticed or unread by patients than a "Bill of Rights" or notice-upon-check-in type of document. And perhaps most importantly, requiring prescribers to retain a signed acknowledgment form would improve the Commission's ability to verify whether prescribers had complied with this requirement and had met their obligation to release prescriptions to their patients. Being able to determine more accurately whether a particular prescriber had provided a prescription in a particular case would reduce the number of instances where a filed complaint simply pits the patient's word against that of the prescriber. It would also enable the Commission to evaluate the overall rate at which both individual prescribers and the population of prescribers comply with the requirement.

One potential drawback to requiring a signed acknowledgment requirement is the increased recordkeeping burden imposed on prescribers, since they would have to provide the forms and retain the signed acknowledgments for a certain period of time.¹⁰⁴ This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and input automatically into the electronic record. Furthermore, prescribers also could scan signed paper copies of the acknowledgment form and store those forms electronically to lower the costs of this recordkeeping requirement. Accordingly, the Commission believes that any recordkeeping burden would be

relatively minimal and outweighed by the benefit of having more patients in possession of their prescriptions.

(d) Proposal To Require Signage

Another possible Rule revision is to require that prescribers' offices post conspicuous signage informing consumers of their right to their prescription. Although this was not specifically suggested by commenters,¹⁰⁵ it is currently required by law in California, and the practice could be expanded via the Rule to apply nationwide.

In California, the Business and Professional Code provides that each prescriber office must post, in a conspicuous place, a notice informing patients that eye doctors are required to provide patients with a copy of their ophthalmic lens prescriptions. The notice also explains that spectacle prescriptions are released upon the completion of the exam, and contact lens prescriptions are released upon the completion of the exam or upon the completion of the fitting process.¹⁰⁶

Such a requirement, if adopted in the Rule, could provide some of the same benefits of the Bill of Rights, notice-upon-check-in, and signed acknowledgment proposals in that it would, in theory, notify consumers of their rights and, presumably, increase the percentage of patients who receive their prescription from the prescriber. A sign could also serve as a reminder to patients to ask for their prescription in the event the prescriber does not provide it. Furthermore, a sign would impose less of a burden on prescribers than the other proposals, since it would only have to be posted once, as opposed to individual copies for each and every patient. Lastly, enforcing such a provision would be relatively straightforward, since the Commission could perform spot checks on prescribers' offices to ensure they have posted the required signage.

On the other hand, the Commission lacks good evidence about the effects of California's particular version of this requirement, and it is unclear how many patients actually read posted notices at doctors' offices, particularly in locations where there are already numerous ads or other postings about

various rights, requirements, and obligations. It is likely that far fewer patients would learn of their rights from a single sign—competing for attention with ads and other signage—than from being handed or shown a document, particularly a document consumers are required to sign. Moreover, since a sign would not require a prescriber to interact with each patient, it would serve as less of a reminder to prescribers and their staff to provide patients with their prescriptions. And, although it would be relatively straightforward for the Commission to verify and enforce the signage requirement, such a requirement would do little to assist the Commission in verifying or enforcing compliance with the automatic prescription release provision itself. Furthermore, Commission staff would have to physically visit prescribers' offices located throughout the country to verify the signage, resulting in the expenditure of more Commission resources to monitor compliance.

(e) The Commission's Proposal To Require a Signed Acknowledgment

After consideration of the comments and proposals, the Commission proposes to add a signed acknowledgment requirement. The Commission believes such a provision will help inform patients of their right to their prescriptions, increase the number of patients who receive their prescriptions and, consequently, increase the number of purchases made with initial presentations of complete and valid prescriptions, thus reducing the number of verifications by third-party sellers. The addition of a signed acknowledgment requirement accomplishes the desired objectives with little increased burden on prescribers. The Commission believes that implementation of signed acknowledgments would best serve several important objectives: Reminding prescribers to release prescriptions, informing patients of their rights, reducing misunderstandings, and improving the Commission's verification and enforcement ability.

The requirement that the prescriber request the patient acknowledge receipt of the contact lens prescription is triggered once the prescriber has presented the prescription to the patient. The patient shall receive the prescription prior to being asked to sign the acknowledgment form, and signing the acknowledgment form is not a condition to obtain the prescription. If the patient refuses to sign or cannot sign the acknowledgment form, the prescriber must note the refusal or

¹⁰⁵ It was cited in the National Association of Optometrists and Opticians comment, but not expressly recommended. Comment #549.

¹⁰⁶ 16 CCR § 1566. California also has an additional state law, CAL Bus. & Prof. Code § 2554, which essentially requires the same signage, with the addition of a notice stating, "Patients may take their prescription to any eye doctor or registered dispensing optician to be filled," and requiring the inclusion of complaint contact information for the California Board of Optometry.

¹⁰⁴ 1-800 CONTACTS suggested that prescribers should maintain records of acknowledgments for three years or the length of the prescription, whichever is longer. 1-800 CONTACTS (Comment #568).

inability on the acknowledgment form and must maintain the form.

The acknowledgment form may be either paper or in electronic format. The acknowledgment form, whether paper or electronic, must be entitled “Patient Receipt of Contact Lens Prescription,” and must 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.” The acknowledgment form shall be in a format that allows either conventional or electronic signatures. Prescribers may maintain copies of the acknowledgment forms in paper or electronically.

The Commission, therefore, proposes to amend Section 315.3 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 shall 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 must 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 must also include the name of the patient, the patient signature, and the date the form was signed. In the event that the patient declines to sign the acknowledgment form, the prescriber shall note the patient’s refusal on the form and sign it. No other statements or information, other than the address or letterhead of the prescriber, shall be placed on the acknowledgment form.

The Commission also proposes to amend Section 315.3 to add the requirement that prescribers maintain the signed acknowledgments for a period of not less than three years, so that the signed acknowledgments are available for inspection by the Federal Trade Commission. The full text of the proposed Rule amendment is located in Section X of this notice.

4. Additional Mechanisms for Improving Prescription Portability

The increasing number of prescribers who offer patient “portals” accessible via the Internet has made it possible for prescribers to post, and patients to obtain, prescriptions online, while maintaining the security and privacy of

patients’ health information.¹⁰⁷ This, along with the patient’s ability to email prescription copies to sellers, increases prescription portability. It also could reduce the verification burden on prescribers, to the extent that patients could quickly and reliably obtain complete and accurate copies of their prescriptions,¹⁰⁸ without making specific requests to their prescribers for such copies, and to the extent that such prescriptions could be filled without the seller intervening to verify the prescriptions directly with the prescribers. In addition, patient portals do not raise the same concerns expressed by some prescribers about sharing patient prescription information with third parties, because patient portals enable the secure sharing of such information directly with the patients themselves.¹⁰⁹

Accordingly, the Commission believes that the use of patient portals to provide patients with access to electronic copies of their prescriptions can benefit prescribers, sellers, and patients. The Commission encourages prescribers, in

¹⁰⁷ Although the Commission lacks data on the use of patient portals by ophthalmologists or optometrists in particular, the Commission notes that a recent report to Congress observes that increasing numbers of physicians and other types of health care providers are sharing information electronically with their patients. For example, in 2014, four in 10 office-based physicians reported sharing information electronically with their patients, and 57% of all physicians reported sharing information directly with their patients electronically. U.S. Dep’t Health & Human Servs., Office of the National Coordinator for Health Information Technology, Report to Congress, “Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information” 28–30 (2016), https://www.healthit.gov/sites/default/files/Attachment_1_-_2-26-16_RTC_Health_IT_Progress.pdf.

¹⁰⁸ Empirical studies of the integrity of electronic transmission of prescription information chiefly focus on systems for transmitting prescription drug information and not contact lens prescriptions. Still, such studies suggest that the adoption of electronic prescribing greatly reduces the error rate associated with handwritten paper prescriptions. See, e.g., Rainu Kaushal et al., “Electronic Prescribing Improves Medication Safety in Community-Based Office Practices,” 25 J. Gen. Intern. Med. 530, 530 (2010) (finding that, “For e-prescribing adopters, error rates decreased nearly sevenfold, from 42.5 per 100 prescriptions (95% confidence interval (“CI”), 36.7–49.3) at baseline to 6.6 per 100 prescriptions (95% CI, 5.1–8.3) one year after adoption (p<0.001). For non-adopters, error rates remained high at 37.3 per 100 prescriptions.”).

¹⁰⁹ See, e.g., U.S. Dep’t Health & Human Servs., HealthIT.gov, “Do I Need to Obtain Consent From My Patients to Implement a Patient Portal?,” <https://www.healthit.gov/providers-professionals/faqs/do-i-need-obtain-consent-my-patients-implement-patient-portal> (noting that HIPAA permits the disclosure of health information to the patient without requiring the patient’s express consent and that portals are “an excellent way to afford patients access to their own information and to encourage them to be active partners in their health care.”)

addition to providing patients with a copy of their prescriptions, to make prescriptions available via patient portals in accordance with federal and state law, including HHS guidance. Uploading prescriptions to patient portals will make it easier for patients to access their prescriptions and, consequently, to transmit them to sellers when purchasing lenses. This, in turn, may substantially increase the accuracy of seller-filled orders and reduce the verification burden on prescribers.¹¹⁰ To facilitate the likelihood that patient portals will increase prescription portability, the patient portal should be configured to allow the patient to download, save, and print the prescription, as well as to allow the patient to email, or otherwise transmit, prescriptions directly to a seller.

At this time, the Commission does not have enough information to determine whether solely posting a contact lens prescription to a patient portal is sufficient to satisfy the Rule’s obligation for prescribers to provide copies of contact lens prescriptions to patients. However, the Commission seeks comment on the use and adoption of patient portals, as well as the potential ability for such technology to allow prescribers to comply with the automatic prescription release requirement of the Rule.

B. Section 315.3(a)(1)—Additional Copies of Prescriptions

Some commenters requested that the Commission amend the Rule to expressly obligate prescribers to provide duplicate prescription copies to patients upon request.¹¹¹ According to Consumers Union, such a requirement would provide “additional protection for situations in which the eye doctor neglects to provide the prescription during the visit, as well as for situations in which the prescription is misplaced by the consumer.”¹¹² Likewise, the health and safety organization Prevent Blindness asserted that duplicate copies should be available upon request since “[i]t is a basic consumer right to own one’s prescriptions.”¹¹³

During the initial rulemaking, the Commission stated that the Act neither requires prescribers to release, nor prohibits them from releasing, additional copies of the prescription.¹¹⁴ At that time, the Commission declined

¹¹⁰ See Kaushal, *supra* note 108.

¹¹¹ Prevent Blindness (Comment #13); Consumers Union (Comment #677).

¹¹² Consumers Union (Comment #677).

¹¹³ Prevent Blindness (Comment #13).

¹¹⁴ 69 FR at 40492.

to require or prohibit the release of additional copies of the prescription.¹¹⁵

Upon consideration of the comments, the rulemaking record, and a re-examination of the language of the Act itself, the Commission now clarifies that the Act and the Rule require that prescribers provide patients with additional copies of their prescriptions upon request. Accordingly, the Commission believes there is no need to amend the Rule, but seeks comment on this clarification.

This determination is supported by a number of considerations. First, as noted above, during the initial rulemaking, the Commission stated that the Act neither requires nor prohibits additional copies of the prescription. However, this statement was made in response to two commenters who recommended that the prescription release obligation be *limited* to one release per patient. Thus, the Commission did not fully consider whether additional copies should be required, only that the Act did not expressly limit patients to one copy.

Second, the Act and the Rule require that prescribers provide or verify the patient's prescription when so "directed by any person designated to act on behalf of the patient."¹¹⁶ This provision has been interpreted to mean that prescribers must provide a prescription whenever a patient authorizes an agent to request one, even if the patient previously received a prescription copy from the prescriber.¹¹⁷ The Commission's Division of Advertising Practices, which administers and enforces the Rule, arrived at this interpretation based upon the plain language of the Act and Rule, as well as upon recognition that when consumers want to order contact lenses, "some consumers have neither their prescription nor sufficient information about their prescription for [the seller] to prepare a proper verification request."¹¹⁸ Based upon this

interpretation, duly authorized patients' agents (sellers) are able to obtain a duplicate copy of the patients' prescription upon request. In addition, patients, acting as their own agents, are able to obtain a duplicate copy of their prescription upon request.¹¹⁹

Furthermore, as discussed earlier, because the Commission believes that many prescribers are not providing patients with their prescriptions upon completion of their contact lens fitting,¹²⁰ there is additional justification for ensuring that patients are able to obtain copies of their prescription when necessary. The Commission therefore believes that requiring prescribers to provide additional copies of contact lens prescriptions to patients upon request is consistent with the language and intent of the Act: Providing prescription portability while protecting consumer health. Consumers with ongoing access to their prescriptions will be able to obtain the correct contact lenses from the seller of their choosing.

C. Section 315.3(a)(2)—Provide or Verify the Contact Lens Prescription

Section 315.3(a)(2) of the Rule requires that prescribers shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.¹²¹

1. Sellers Designated To Act on Behalf of Patients

In addition to the obligation to release the prescription to the patient at the completion of a contact lens fitting, the Rule also requires prescribers to provide the contact lens prescription to third parties acting on behalf of the patient.¹²² Accordingly, some sellers, at the direction of their customers, have requested copies of prescriptions from

"the entire verification process would have been all but unnecessary." Comment #644. The Commission disagrees with this contention, however, because verification is simply an additional option for ensuring that patients have a valid prescription, one that is faster and less paper-intensive, for both the seller and prescriber, than requiring that the prescriber always provide the complete patient prescription. Moreover, the Act and the Rule state that the prescriber must provide or verify the contact lens prescription as directed by the patient's agent, thus leaving it up to the agent, if so authorized by the patient, to decide which method is preferable.

¹¹⁹ 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2). In addition, the HIPAA Privacy Rule right of access requires a covered prescriber to provide a copy of a prescription to the patient upon request or to another person she designates. See 45 CFR 164.524(c)(3). See *infra* Section V.C.

¹²⁰ See *supra* Section III.A.1.

¹²¹ 16 CFR 315.3(a)(2).

¹²² *Id.*

prescribers rather than just verifications of prescriptions.¹²³

Because this practice historically has been a source of confusion for some eye care practitioners, the staff clarified, in a 2006 letter to the American Optometric Association, that the Rule obligates a prescriber to provide the consumer's complete prescription to a third-party seller if the consumer has authorized that seller as an agent.¹²⁴ In its letter, FTC staff also made clear that the Act and the Rule do not permit the prescriber to require that sellers provide written documentation of the patient's authorization before providing the seller with a copy of the patient's prescription.¹²⁵ In response, the American Optometric Association has provided guidance to its members that they must comply with this provision of the Rule.¹²⁶

This option may be gaining popularity with at least one seller. As explained by 1-800 CONTACTS, "[d]ue in large part to poor prescriber compliance with prescription release requirements, many customers cannot provide a third-party seller with [a] copy of their contact lens prescription at the time they place their order."¹²⁷ 1-800 CONTACTS also pointed out that this option benefits consumers because with a copy of the prescription on file, it can ship orders without any delay and without having to contact the prescriber each time the consumer wishes to purchase lenses.¹²⁸

In its comment, however, the American Optometric Association argued that "[r]equests by sellers directly to physicians for copies of patient prescriptions should be disfavored."¹²⁹ The American Optometric Association asserted that sellers should use the verification system instead because verification requests consume less time than the retrieval, copying, and transmission of the actual prescription to sellers. The American Optometric Association acknowledged that it believes that the Rule's verification system needs improvement, but pointed out that it contains safeguards that requests for

¹²³ See, e.g., 1-800 CONTACTS (Comment #568).

¹²⁴ Staff Opinion Letter, *supra* note 116.

¹²⁵ The opinion letter also explains that neither the Health Insurance Portability and Accountability Act ("HIPAA") of 1996 nor its implementing regulations require such written documentation of the authorization.

¹²⁶ American Optometric Association, Summary of Advisory from AOA General Counsel Regarding FCLCA Enforcement Update, Sept. 1, 2015, http://www.aoa.org/Documents/advocacy/FTC_guidance_on_Rx_releases.pdf.

¹²⁷ Comment #568.

¹²⁸ *Id.*

¹²⁹ Comment #644.

¹¹⁵ *Id.*

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

¹¹⁷ See 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 (stating that if the seller is an agent of the consumer, "the prescriber has an obligation under the FCLCA and the Contact Lens Rule to provide the consumer's prescription" to the seller) <https://www.ftc.gov/public-statements/2006/10/requests-contact-lens-prescribers-provide-patients-contact-lens>; 1-800 CONTACTS (Comment #568), Exhibit E (same).

¹¹⁸ *Id.* The American Optometric Association takes exception to this interpretation, and argues that if Congress meant for retailers to be able to demand patients' prescription at any time, then

copies of prescriptions do not.¹³⁰ The American Optometric Association stated that sellers would only need to request a copy of a prescription directly from the prescriber when the patient does not submit the prescription and the patient is unable to provide any information about the prescription to the seller in order to permit use of the verification process.¹³¹

Few other prescribers addressed this issue directly in their comments to this Rule review.¹³² However, the Commission also has received anecdotal reports that prescribers are still confused about this provision of the Rule, and some comments appear to conflate requests for a copy of a prescription with an incomplete verification request. For example, some prescribers complained that 1-800 CONTACTS was sending them incomplete verification requests, but instead it appears that 1-800 CONTACTS was sending the prescriber a request for the patient's prescription.

The Commission declines to adopt the American Optometric Association's suggestion that requests for copies of a prescription by a duly authorized seller be discouraged. The plain language of the Act and the Rule provide for this method of acquiring a prescription and the Association provided no evidence demonstrating that providing a copy of a prescription to a seller, rather than verifying a prescription, was significantly more burdensome to prescribers. As to the contention that the verification system contains safeguards that requests for prescriptions do not, the Commission points out that a prescription provided by a prescriber directly to the seller would necessarily include all relevant information and would avoid some of the issues raised by commenters about the flaws of the verification system. In addition, the copy of the prescription provided by the prescriber to the seller would contain an expiration date, which also serves as a safeguard against the improper dispensing of contact lenses.

Despite clarifications that prescribers must provide copies of prescriptions to

sellers when authorized by the patient, 1-800 CONTACTS complained in its comment that in its experience, about half of prescribers "routinely ignore [their] requests" for a copy of a patient's prescription.¹³³ To address problems encountered by authorized agents in procuring copies of prescriptions, as well as ongoing prescriber confusion about this provision, two commenters proposed amending Section 315.3 "to require that in response to an authorized request, the prescriber send the prescription to the agent (by mail, facsimile or a digital image of the prescription that is sent via electronic mail) within eight business hours as currently defined under the [Rule]."¹³⁴

In support of its proposal, 1-800 CONTACTS stated that, "[e]vidence shows that in about half the cases, prescribers ignore and never respond to 1-800's authorized requests for a copy of a customer's prescription."¹³⁵ 1-800 CONTACTS does not specify this evidence in its comment. However, in a 2006 letter to the Commission, 1-800 CONTACTS asserted that an audit of 264 requests for a copy of a customer's prescription shows that 46% of prescribers did not respond within five business days.¹³⁶ The other commenter, Warby Parker, provided no evidence in support of its proposal.¹³⁷

The Act and the Rule currently require the prescriber to provide a copy of a prescription to an authorized third party, but is silent on the timing of the response. The proposed modification would require prescribers to provide a prescription within eight business hours, the same amount of time that prescribers are afforded to respond to a verification request. The Commission notes, however, that there is a qualitative difference between responding to a verification request as opposed to providing a copy of a prescription. First, if the verification request is correct, the prescriber need take no action.¹³⁸ Second, the proposed modification would require the prescriber to act within eight business hours, and if the prescriber did not act, or was unable to act, she would be in violation of the Rule. The eight-business-hour window for verification

does not place the prescriber in such jeopardy. If the prescriber is unable to respond to a verification request in a timely fashion—for whatever reason—the request is verified, but the prescriber is not in violation of the Rule.

At this time, the Commission has determined that the existing rulemaking record is not sufficient to support a Rule modification requiring a prescriber to respond to a request for a copy of a prescription within eight business hours. Accordingly, the Commission requests additional information from commenters on the costs and benefits of imposing a timeframe for prescribers to respond to requests from authorized third parties for a copy of a patient's prescription. The Commission also seeks comment on the appropriate amount of time for a prescriber to respond to prescription requests.¹³⁹

IV. Prescriber Verification

Section 315.5 of the Rule provides the framework under which sellers may dispense contact lenses to consumers and requires sellers, before selling contact lenses, to either obtain a copy of the patient's prescription or verify the prescription. Section 315.5 also sets forth the procedures for obtaining such verification as well as seller recordkeeping obligations.

A. Section 315.5(a)—Prescription Requirement

Section 315.5(a) of the Rule provides that a seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is presented to the seller by the patient or prescriber directly or by facsimile; or verified by direct communication. This provision was taken verbatim from the Act.¹⁴⁰

1. Presentation of Prescriptions "Directly or by Facsimile"

In the initial rulemaking, the Commission determined that the "directly or by facsimile" language of section 4(a)(1) of the Act allowed the

¹³⁰ Although the American Optometric Association comment did not specifically mention the safeguards, it is likely that the comment is referring to fact that if a prescription verification request lists a quantity of lenses that is excessive, the prescriber can deem such a request "inaccurate."

¹³¹ Comment #644.

¹³² Diener (Comment #6) (the "rule should be restricted to use only upon recent patient request, not used in perpetuity to obtain records for marketing purposes"); Vidulich (Comment #612) (silent on the issue, but attaching request for a copy of the prescription).

¹³³ Comment #568.

¹³⁴ *Id.*; see also Warby Parker (Comment #593).

¹³⁵ Comment #568.

¹³⁶ See 1-800 CONTACTS (Comment #568), Exhibit E.

¹³⁷ Warby Parker (Comment #593). Warby Parker also proposed that the prescriber be required to maintain a log recording the date and time a patient's prescription was requested and released to the authorized agent.

¹³⁸ Based on discussions with industry, it appears that the vast majority of verification requests are passively verified, with no prescriber action taken.

¹³⁹ Another commenter, Opternative, a telehealth provider, proposed that the Commission "consider expanding the verification requirements so that prescribers' obligations also apply to any other third party, including other prescribers, that is authorized by the patient." Comment #648. Section 315.3 explicitly states that the prescriber shall provide or verify the contact lens prescription, "as directed by any person designated to act on behalf of the patient." Nothing in the Act or Rule precludes the construction of "any person" from including other prescribers. Furthermore, the HIPAA Privacy Rule permits a "covered entity" to use or disclose protected health information without patient authorization "for treatment, payment, or health care operations." 45 CFR 164.506. The Commission does not believe that the Rule needs any modification on this issue.

¹⁴⁰ 69 FR at 40495; see also 5 U.S.C. 7603(a).

patient or prescriber to present a prescription by mail, by facsimile, or through a digital image of the prescription that is sent via electronic mail.¹⁴¹ The Commission also decided at that time not to include “substantially equivalent future technologies” within the scope of acceptable direct presentation mechanisms.¹⁴² In doing so, the Commission noted that section 4(a)(1) of the Act did not expressly reference or contemplate future technologies and the Commission was not aware of other technologies that met the statutory standard. The Commission declined at that time to include future technologies that “do not involve an exact copy of the prescription within the scope of acceptable direct presentation mechanisms.”¹⁴³

Since implementation of the Rule in 2004, technological advances—including many spurred by federal and state health information technology initiatives¹⁴⁴—have fostered the proliferation of patient portals, through which health care providers can securely share medical information, such as prescription information, directly with patients and certain third parties. The use of patient portals for presentation of contact lens

¹⁴¹ 69 FR at 40495. The Commission also concluded that presentation of the prescription information from the consumer to the seller by telephone or by email (other than an email containing a digital image of the prescription) did not meet the “directly or by facsimile” standard imposed by the Act.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Numerous federal and state programs have been designed to foster the development of health information technology and the electronic processing, storage, and transmission of patients’ health information. For example, under the HITECH Act of 2009—Title XIII and Title IV of Division B of the American Recovery and Reinvestment Act of 2009—Congress directed the Medicare and Medicaid programs to make direct payments to eligible healthcare professionals, hospitals, and certain other healthcare providers specifically to incentivize the adoption and meaningful use of electronic health records systems (EHRs). American Recovery and Reinvestment Act of 2009 (Recovery Act), Public Law 111–5, § 4101(a), 4101(b), and 4202 (2009) (Medicare incentives for eligible professionals, Medicare incentives for hospitals, and Medicaid provider payments, respectively). According to a recent report by the U.S. Department of Health & Human Services, more than \$30 billion in such incentive payments were made between 2011 and 2015. U.S. Dep’t Health & Human Servs., Office of the National Coordinator for Health Information Technology, Report to Congress, “Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information” 18 (2016), https://www.healthit.gov/sites/default/files/Attachment_1_-_2-26-16_RTC_Health_IT_Progress.pdf. Regarding patient portals in particular, *see, e.g.*, U.S. Dep’t Health & Human Servs., Office of the National Coordinator for Health Information Technology, “ONC Patient Engagement Playbook,” <https://www.healthit.gov/playbook/pe/introduction/>.

prescriptions to sellers may provide many benefits to consumers and competition. When using a portal, the patient or prescriber will have direct access to a current, exact copy of the contact lens prescription, reducing the chance that an inaccurate or expired prescription might be presented to the seller. The use of patient portals may also reduce costs for prescribers, patients, and sellers by making it easier and more efficient for patients to share and present contact lens prescriptions, and by reducing the number of verification requests placed on prescribers.

Because of these potential benefits, the Commission has made an initial determination that the provision “directly or by facsimile” includes the use of online patient portals by patients and prescribers to present contact lens prescriptions to sellers. In doing so, the Commission notes that the use of a patient portal necessarily involves “an exact copy of the prescription within the scope of acceptable direct presentation mechanisms.”¹⁴⁵ The Commission seeks comment on this clarification and requests that commenters provide information about whether the Commission should consider any other issues related to the presentation of prescriptions to sellers.

2. “Verified by Direct Communication”

Some individual commenters recommended that the Commission revise the Rule to remove verification by direct communication, and argued that the sale of contact lenses should be conditioned upon presentation of a written prescription by the consumer to the seller. These commenters noted that consumers are already being provided with a written prescription as required by the Rule, and that requiring prescribers to verify prescriptions with the seller as well was redundant, time-consuming and burdensome.¹⁴⁶ Other commenters noted that with electronic means such as email and phone cameras readily available, the consumer should be responsible for presenting the prescription to the seller rather than having the prescriber verify the prescription.¹⁴⁷ Other commenters argued that contact lens prescriptions

¹⁴⁵ 69 FR at 40495.

¹⁴⁶ Carroll (Comment #5), Driscoll (Comment #67); Kirk (Comment #131); Kalman (Comment #150); Baur (Comment #170); Bricker (Comment #195); Ahn (Comment #215); Comer (Comment #221); Kubo (Comment #234); Sanders (Comment #235); Williston (Comment #252); Campbell (Comment #348); Falcon (Comment #505); Walton (Comment #543).

¹⁴⁷ Kiener (Comment #74); Kubo (Comment #234); McWilliams (Comment #362); Falcon (Comment #505); Pham (Comment #641).

should be treated the same way as prescriptions for medications, and that consumers should only be able to obtain contact lenses by presenting a written prescription.¹⁴⁸ Some commenters also stated that relying on a written prescription to dispense lenses, rather than prescriber verification, would close loopholes in the verification framework that may allow consumers to obtain lenses without a valid, unexpired prescription.¹⁴⁹

The language of Section 315.5(a)(2) was taken verbatim from the Act.¹⁵⁰ Because Congress decided to structure the prescription verification framework to allow for either the direct presentation of a prescription to a seller or, alternatively, the verification of a prescription by direct communication, elimination of verification by direct communication is beyond the scope of this rule review.

3. Automated Telephone Calls as a Method of Direct Communication

The Commission received numerous comments objecting to contact lens sellers’ use of automated telephone calls as a method to communicate verification requests.¹⁵¹ These commenters, who often refer to these automated telephone calls as robocalls, are largely prescribers, students of optometry, and associations whose members are prescribers.

Commenters described problems arising from the use of automated telephone calls,¹⁵² and some

¹⁴⁸ Driscoll (Comment #67); Moody (Comment #92); Filandro (Comment #129); Kirk (Comment #131); Kalman (Comment #150); Boyer (Comment #246); Bolenbaker (Comment #357).

¹⁴⁹ Driscoll (Comment #67); Dieckow (Comment #151); Ahn (Comment #215); Sanders (Comment #235); Smith (Comment #319).

¹⁵⁰ 69 FR at 40495; *see also* 5 U.S.C. 7603(a).

¹⁵¹ The American Optometric Association pointed to the public’s general disfavor of robocalls, noting that they are commonly understood to be an abuse of telephone communication, one for which companies have been fined millions of dollars. Comment #644. The FTC disagrees with this characterization of automated seller verification calls. Contact lens seller verification calls are not sales calls covered by the Telemarketing Sales Rule (“TSR”), 16 CFR 310, which prohibits certain robocalls. In addition, the TSR does not apply to most business-to-business communications. 16 CFR 310.6(b)(7).

¹⁵² *E.g.*, Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Borsky (Comment #26); Matthews (Comment #25); Maanum (Comment #23); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Virginia Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Howe (Comment #53); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); Mirkin (Comment #111); California Optometric Association (Comment #119); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Pentacost (Comment #268); Easton (Comment #432); Koch (Comment #539);

commenters called for an outright ban of the use of such calls.¹⁵³ A number of commenters indicate that the automated verification calls are difficult to understand or confusing¹⁵⁴ or do not provide all of the information required to be a valid request.¹⁵⁵ Some

Connecticut Association of Optometrists (Comment #560); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); American Optometric Association (Comment #644); Rubow (Comment #649); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

¹⁵³ *E.g.*, Virginia Optometric Association (Comment #16); Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Easton (Comment #432); New Mexico Optometric Association (Comment #211); Koch (Comment #539); Connecticut Association of Optometrists (Comment #560); Tennessee Association of Optometric Physicians (#575); Colorado Association of Optometrists (Comment #584); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); American Optometric Association (Comment #644); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

¹⁵⁴ *E.g.*, Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Borsky (Comment #26); Matthews (Comment #25); Maanum (Comment #23); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Virginia Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Howe (Comment #53); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); Mirkin (Comment #111); California Optometric Association (Comment #119); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Easton (Comment #432); Koch (Comment #539); Connecticut Association of Optometrists (Comment #560); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); American Optometric Association (Comment #644) (stating they have often received complaints over the last ten years from optometrists that robocalls from 1–800 CONTACTS were difficult to understand); Rubow (Comment #649) (stating that if the entire recorded message is not completed within the allotted time on the answering machine, they then receive a message from an actual live person where the person speaks so fast that it requires playing back the message four or five times in order to get all the information); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

¹⁵⁵ Virginia Optometric Association (#46); Iowa Optometric Association (Comment #79) (stating robocalls too often provide incomplete information); Hicks (Comment #256); Pentacost (Comment #268) (stating automated messages start playing well before the voicemail begins recording so that the office does not catch the name of the patient or which company left the message); Connecticut Association of Optometrists (Comment #560) (stating robocalls too often provide incomplete information); Coalition for Patient

optometrists or state optometric associations, many of which consist of or represent small businesses,¹⁵⁶ complain that these calls are too long and time consuming,¹⁵⁷ disturb their practices, take time away from providing care and attention to their patients, and make the phone lines unavailable for their patients.¹⁵⁸ Commenters explained that part of the reason the automated calls are so disruptive is that the caller continuously redials until a message is fully communicated.¹⁵⁹ In response to the recurring disruption, one prescriber stated that his office simply ignores the robocalls.¹⁶⁰

Other commenters mentioned that sellers provide the patient name several sentences into, or at the very end of, the verification request, making it difficult for prescribers' offices to respond efficiently and to verify the prescription in real time.¹⁶¹ Some commenters also complained that the automated calls come during business hours when they

Vision Care Safety (Comment #621) (stating robocallers leave voice messages without contact information and may be cut off before conveying in entirety the patient's information); American Optometric Association (Comment #644) (stating they have often received complaints over the last ten years from optometrists that robocalls from 1–800 CONTACTS did not include all of the necessary information to confirm a prescription).

¹⁵⁶ *E.g.*, Pennsylvania Optometric Association (Comment #46); Iowa Optometric Association (Comment #79); Connecticut Association of Optometrists (Comment #560); Tennessee Association of Optometric Physicians (Comment #575); Rubow (Comment #649).

¹⁵⁷ *E.g.*, Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Iowa Optometric Association (Comment #79); Lai (Comment #620); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Plumb (Comment #219); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Easton (Comment #432); Koch (Comment #539); Tennessee Association of Optometric Physicians (#575); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); American Optometric Association (Comment #644); Vo (Comment #673).

¹⁵⁸ Easton (Comment #432); Louie (Comment #657). *See also* Iowa Optometric Association (Comment #79) (explaining the need to protect small businesses from disruptive calls that interfere with treating patients and tie up phones); Pham (Comment #232); Tennessee Association of Optometric Physicians (Comment #575); Michigan Optometric Association (Comment #86).

¹⁵⁹ *See, e.g.*, Wisconsin Optometric Association (Comment #30); Pennsylvania Optometric Association (Comment #46); New Mexico Optometric Association (Comment #211); Tennessee Association of Optometric Physicians (Comment #575).

¹⁶⁰ Scolin (Comment #369).

¹⁶¹ Brauer (Comment #68); Kalman (Comment #150); Egger (Comment #163); Plumb (Comment #219); Rosemore (Comment #468).

are busy with patients.¹⁶² Meanwhile, other commenters complain that the calls come in during non-business hours, and express concern that as a result, sellers may release the contact lenses to patients without the prescriber having time to confirm the prescription.¹⁶³

Due to the aforementioned problems with automated telephonic verification requests, the Coalition for Patient Vision Care Safety asserted that prescribers are often unable to provide the proper verification of the patient's prescription information within eight business hours, triggering the passive verification. As a result, patients may receive contact lenses based on outdated or incorrect prescription information.¹⁶⁴ The Coalition stated that "the fact that patients are receiving contact lenses based on incorrect, outdated, or unverified prescription information runs counter to the FDA's medical device safety standards, and can also lead to serious vision issues."¹⁶⁵

On the other hand, 1–800 CONTACTS requested the Commission retain the use of automated phone systems as an acceptable form of direct communication for verification purposes. It argued that changing the status quo would be "unjustified, contrary to congressional intent and not in the interest of consumers."¹⁶⁶ According to 1–800 CONTACTS, it has experimented with other forms of direct communication and concluded that "a well-functioning automated system that incorporates the latest technology is the most efficient means of handling the large volume of verification requests that are required today."¹⁶⁷ 1–800 CONTACTS indicated it has invested significant resources into the development of a system that is less subject to human error, allows accurate information to be given consistently to every prescriber, and provides assurance that it is compliant with the Rule. The company claimed that its system has an automated voice that is clear and easy to understand, and contains user-friendly options, such as the opportunity to pause the verification script or to request the system call back at a later time. 1–800 CONTACTS'

¹⁶² *See, e.g.*, Chang (Comment #126); Scolin (Comment #369); Tennessee Association of Optometric Physicians (#575).

¹⁶³ Connecticut Association of Optometrists (Comment #560); Colorado Optometric Association (Comment #584).

¹⁶⁴ Comment #621. *See also* Iowa Optometric Association (Comment #79); Chakuroff (Comment #189); Bricker (Comment #195); Spaeth (Comment #486).

¹⁶⁵ Comment #621.

¹⁶⁶ Comment #568.

¹⁶⁷ *Id.*

comment also noted that, while its messages are automated, calls are initiated by live agents to guarantee that all calls are placed to the intended prescribers.¹⁶⁸ 1-800 CONTACTS also asserted that when a message is left on an answering machine, the live agent remains on the line during the entire automated message to ensure that the complete message is conveyed to the prescriber.¹⁶⁹

According to 1-800 CONTACTS, each week it places approximately 100,000 calls to prescribers to verify prescriptions. The complete phone script for an automated verification call from 1-800 CONTACTS is 2 minutes, 29 seconds (149 seconds) in length, and prescribers familiar with the system have the option to skip the first 48 seconds of the message to reduce the total time of the message to 1 minute, 41 seconds (101 seconds). 1-800 CONTACTS indicated that the average prescriber receives only one verification request per week from the company,¹⁷⁰ and the highest volume office in its records received, on average, six verification requests per week in 2014.¹⁷¹ The company explained that it places verification calls as it receives orders, and that it receives orders 24 hours a day, seven days a week, with many orders coming in on weekends or during evening hours. The company further explained that it leaves verification messages shortly after its receipt of orders because a continuous call process is “logistically efficient and prevents a shipping bottleneck at a single hour each day.”¹⁷²

Regardless of when it places the verification call to the prescriber, however, 1-800-CONTACTS stated that it never ships an order under the passive verification system before passage of eight business hours. The company added that in almost 30% of verification requests, prescribers hang up on verification calls.¹⁷³

The Commission did not receive other comments from contact lens sellers about their use of automated verification systems to verify prescriptions.¹⁷⁴ Consumers Union, the policy and

advocacy division of Consumer Reports, also commented in support of automated calling systems, stating that such systems, of which eye doctors should now be aware, are a reasonable means for a retailer to efficiently handle a large volume of prescription requests. Consumers Union also stated that most eye doctors’ offices have automated answering systems and it believed they could set up an efficient means for recording the verification request information without significant burden.¹⁷⁵

The Act expressly authorizes sellers to send prescription verification requests by direct communication¹⁷⁶ and defines “direct communication” to include communication by telephone, facsimile, or electronic mail.¹⁷⁷ In previously considering this issue, the Commission noted that telephone is commonly understood to include automated telephone systems. The Commission therefore concluded in the initial rulemaking that “it would thus seem to be contrary to Congressional intent to prohibit the use of this technology.”¹⁷⁸ Nevertheless, then and now, the Commission emphasizes that automated telephone systems must fully comply with all applicable Rule requirements in order to transmit valid verification requests.

For example, any automated verification request must provide complete verification request information as required under section 315.5(b),¹⁷⁹ and this information must be either received by a person on the telephone or otherwise received in full (e.g., all of the requisite information is left on a telephone answering machine). A request delivered by an automated telephone system does not comply with the Rule if it is not delivered in a volume and cadence that a reasonable person can understand, or if it contains incomplete verification information. The seller must also allow eight business hours for the prescriber to respond. During the initial rulemaking in 2004, the Commission indicated that it would “continue to monitor whether

full, valid requests for verification of a prescription are being made through the use of automated telephone systems” and may revisit the issue “[i]f evidence demonstrates that sellers are not making valid verification requests but are providing consumers with contact lenses despite deficient requests.”¹⁸⁰

The comments submitted in this Rule review by optometrists, students of optometry, and their trade associations provide the Commission with some evidence that some prescribers are receiving incomplete or otherwise inadequate verification requests. In addition, the Coalition for Patient Vision Care Safety asserted there is substantial evidence that verification requests are deficient and the American Optometric Association claimed that problems with 1-800 CONTACTS’ automated verification systems are often reported by its members.¹⁸¹ However, commenters did not provide any empirical data regarding the frequency of these various practices, average or aggregate costs associated with automated calls in particular, or the number of illegal or otherwise deficient contact lens sales that result from such calls. Furthermore, the Commission lacks evidence indicating whether these problems occur with automated calls generally or are chiefly associated with only one or a small group of sellers. If the reported problems chiefly are associated with the practices or systems of a limited number of sellers, the Commission would consider education of, or enforcement against, such sellers, rather than an amendment to the Rule at this time.¹⁸²

Incomplete or incoherent verification requests are not valid verification requests.¹⁸³ However, a seller may not always realize that it has made an invalid request and, hence, might dispense lenses under an assumption of

¹⁸⁰ 69 FR at 40489.

¹⁸¹ Coalition for Patient Vision Care Safety (Comment #621); American Optometric Association (Comment #644).

¹⁸² In fact, a number of state optometric associations note that the costs prescribers’ offices expend related to the Rule are most often due to incomplete or otherwise inadequate verification requests. Michigan Optometric Association (Comment #86); Wisconsin Optometric Association (Comment #30); Pennsylvania Optometric Association (Comment #46); Iowa Optometric Association (Comment #79); New Mexico Optometric Association (Comment #211). Thus, education and enforcement efforts to improve sellers’ compliance with the verification aspects of the Rule may have a large benefit for prescribers, without the need to prohibit automated verification calls.

¹⁸³ 69 FR at 40496 (“The Commission emphasizes that the sale of contact lenses based on a verification request which does not contain all of the required information constitutes a Rule violation.”).

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ However, if the call is not completed, 1-800 CONTACTS will call the prescriber again. Therefore, one verification request may result in more than one call.

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ Comment #187. See also Consumers Union (Comment #677) (calling prescriber hang-ups a reported problem).

¹⁷⁴ Warby Parker, an online seller of eyeglasses, commented on its support of the use of automated phone systems as a form of direct communication for verification purposes. Comment #593.

¹⁷⁵ Comment #677.

¹⁷⁶ 15 U.S.C. 7603(a)(2).

¹⁷⁷ 15 U.S.C. 7603(g).

¹⁷⁸ 69 FR at 40489.

¹⁷⁹ When seeking verification of a prescription, the seller must provide the prescriber with: The patient’s full name and address; the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; the quantity of lenses ordered; the date of patient request; the date and time of verification request; the name of a contact person at the seller’s company, including facsimile and telephone numbers; and, if the seller is counting the prescriber’s regular Saturday hours as “business hours,” a clear statement of the prescriber’s regular Saturday business hours. 16 CFR 315.5(b).

passive verification if the prescriber does not contact the seller within eight business hours of the invalid request. Accordingly, to prevent the improper dispensing of lenses, the Commission encourages prescribers to contact the seller in these circumstances to inform them that the request is invalid and state the basis for the invalidity. Once the prescriber communicates that the request is invalid and states the basis for the invalidity, the seller shall not fill the order. Alternatively, for incomplete requests, the Commission encourages prescribers, to the extent they are able, to complete the missing information in order to facilitate the dispensing of the contact lenses.

The Commission is sensitive to the business concerns of the prescribers who complain about the burden and inconvenience they experience from the sellers' use of automated telephone systems. However, the Commission has not seen convincing evidence that the volume of automated verification calls they receive each day presents a burden that is not outweighed by the competitive benefits of the Rule, or that these practices frequently result in illegal sales of contact lenses. If the Commission receives evidence of a compelling widespread problem, it may revisit its position on the use of automated verification requests.¹⁸⁴ At this point, however, the Commission declines to prohibit the use of automated verification calls.

Nevertheless, the Commission encourages sellers, to the extent possible, to consider whether they could alleviate some of the commenters' concerns by modifying their automated telephonic verification procedures or, alternatively, by increasing the use of other permissible communication methods. The Commission also seeks additional information on possible modifications to the Rule that, short of prohibiting automated verifications calls, could address the issues raised by commenters relating to these calls.

The Commission declines to restrict when sellers may place automated phone verification calls. As long as sellers are placing valid and complete verification requests, and are not shipping orders prior to active verification, or the passage of eight business hours, automated telephone

verification requests placed outside of a prescriber's business hours comply with the Rule. Moreover, a review of the comments reveals that some prescribers object to calls during office hours, while others object to calls during evening and weekend hours. The Commission therefore does not propose, at this time, to limit the time period when sellers may place automated calls.

B. Section 315.5(b)—Information for Verification

Section 315.5(b) delineates the information required for a prescription verification request: (1) Patient's full name and address; (2) the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; (3) the quantity of lenses ordered; (4) the date of patient request; (5) the date and time of verification request; (6) the name of a contact person at the seller's company, including facsimile and telephone numbers; and (7) if the seller opts to include the prescriber's regular business hours on Saturday as "business hours" for purposes of computing the eight business hour calculation, a clear statement of the prescriber's regular Saturday business hours.

1. Vendor Contact Information

A few individual prescribers stated that they were unable to contact vendors in order to get additional information when the verification request was incomplete.¹⁸⁵ The American Optometric Association also voiced concerns about the difficulty that prescribers have in reaching an individual at 1-800 CONTACTS to discuss prescription concerns.¹⁸⁶ Several state optometric associations asserted that physician small businesses may spend significant time on hold or attempting to use various phone numbers or automated prompts to reach a live person. These commenters recommended that the Commission require larger contact lens retailers to make available more than one individual at a company to act as the contact person for physician questions and concerns.¹⁸⁷ Commenters did not

explain the nature of the incomplete verification requests such that a live person was necessary to address the inadequacy of the request, nor did they elaborate upon the reasons why prescribers need to reach live persons at contact lens retailers to answer "questions and concerns."

The Commission declines to propose this Rule modification. The Rule requires that the seller provide the name of a contact person at the seller's company, including facsimile and telephone numbers.¹⁸⁸ In requiring a facsimile number as well as a telephone number, it is clear that the Act and the Rule intended to provide for direct communication, but not necessarily contemporaneous, live communication. The language of the Act and the Rule anticipates that some sellers will communicate with prescribers via live agents, but does not require it. Instead, the Act and the Rule allow sellers also to communicate with prescribers about verification requests via facsimile as well as voicemail.

Furthermore, the Commission does not believe it is necessary to require large contact lens retailers to have more than one individual available for prescriber questions and concerns, as long as a contact person is "reasonably accessible to the prescriber."¹⁸⁹ As discussed in the initial rulemaking, the vendor contact provision is intended to ensure that the prescriber is able to reach a responsible person at the seller's company.¹⁹⁰ No evidence was presented showing how often prescribers experience difficulty in obtaining reasonable access to a contact person at the seller's company.¹⁹¹ Without such

(Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

¹⁸⁸ 16 CFR 315.5(b)(6).

¹⁸⁹ 69 FR at 40497.

¹⁹⁰ *Id.* The Rule also requires that during the eight-business-hour window, "the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request." 16 CFR 315.5(c)(3). In the initial rulemaking, the Commission declined to articulate with specificity the equipment or personnel that sellers must have to handle verification requests, in order to give sellers the flexibility to determine the most effective and efficient means of providing the opportunity to communicate. Rather, the Commission promulgated the final Rule to require that sellers provide prescribers a "reasonable opportunity" for the prescriber to communicate with the seller. 69 FR 40499.

¹⁹¹ Likewise, the Commission did not receive evidence sufficient to show that the methods for communication offered by sellers do not provide prescribers with a reasonable opportunity to

Continued

¹⁸⁵ Truong (Comment #55); Cervantes (Comment #479).

¹⁸⁶ Comment #644.

¹⁸⁷ Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association

¹⁸⁴ The Commission notes that since Congress expressly permitted telephone as a form of direct communication for verification, if the Commission were to prohibit automated telephone calls, more live communications might result. Such communications would not necessarily alleviate all of the concerns expressed by commenters and might cause more problems for sellers with a large volume of orders and/or a small amount of staff.

evidence, the Commission cannot determine whether a modification of the Rule is necessary.

Moreover, as discussed earlier,¹⁹² if a verification request is incomplete, the request is invalid. If the prescriber communicates to the seller within the Rule-specified deadline that the verification request or the prescription is invalid,¹⁹³ the seller may not fill the prescription.¹⁹⁴ It is not necessary to reach a live person to perform this function. Once alerted that a verification request is invalid and the reason for the invalidity, the burden falls on the seller to resolve the invalidity, if possible. In addition, in routine cases it would not be necessary to reach a live person in order to correct a prescription. Accordingly, the rulemaking record contains insufficient evidence to show that mandating a mechanism for contemporaneous live communications is necessary to carry out the Act.

The American Optometric Association also urged the Commission to amend the Rule to require sellers to respond to prescriber questions within an eight-business-hour window, or cancel the sale without verification. The Association's comment did not explain the types of concerns that prescribers need to discuss with live agents at contact lens retailers. This proposal would require that once a prescriber contacted a seller with concerns, the seller could not assume the prescription was verified. Instead, the seller would be required to personally contact the prescriber and discuss the concerns

communicate with the seller about the verification request.

¹⁹² See *supra* Section IV.A.3.

¹⁹³ If a prescriber deems a prescription invalid, the Rule requires that the prescriber specify the basis for the invalidity. 16 CFR 315.5(d).

¹⁹⁴ In addition, Warby Parker proposed that the Commission include stronger language in the Rule to make clear that it is a violation for prescribers to respond to a verification request by stating that prescription information is incorrect when, in fact, it is not; or to respond to a verification request by stating that prescription information is inaccurate or invalid without providing the basis for the inaccuracy or invalidity of the prescription. Comment #593. The Rule already provides that if a prescriber indicates that a prescription is inaccurate or invalid, the prescriber shall specify the basis for doing so. A failure to do so violates the Rule. See 16 CFR 315.5(d). Further, falsely indicating that a prescription was inaccurate would essentially equal a failure to "correct" a prescription, as mandated by the Rule and therefore, also would be a violation. See *id.* The Commission does not believe it needs to clarify these prescriber obligations further. Warby Parker also proposed that the Commission clarify that it is a violation of the Rule for a prescriber to interfere, in any way, with a seller's effort to verify a prescription. This proposal is not described in detail nor is the frequency of this problem supported with empirical evidence. The Commission therefore declines to propose this Rule modification.

within eight business hours, or cancel the sale.¹⁹⁵

The Commission declines to propose this modification as well. As discussed above, neither the Act nor the Rule requires contemporaneous, live communication between prescribers and sellers. Furthermore, the Commission believes that such a requirement would undercut the Act's passive verification framework. Such a mechanism could conceivably allow any prescriber to lodge a concern or question and thereby halt the passive verification mechanism. As discussed above, if the prescription verification request is incomplete or inaccurate, or if the prescription is expired or otherwise invalid, the prescriber may alert the seller. The seller cannot fill a prescription if the prescriber has indicated that the prescription is expired or otherwise invalid.

2. Prescribers' Selection of Communication Mechanism

A few commenters suggested that the prescriber should have the ability to choose the method of communication sellers use to communicate verification requests with their offices.¹⁹⁶ One commenter stated that she requested a seller make all future verification requests through facsimile, but the seller, who sometimes made requests via facsimile, refused her request.¹⁹⁷ A number of prescribers expressed a preference for sellers to use another type of communication to verify contact lens prescriptions, including facsimile or email.¹⁹⁸ A few prescribers requested that sellers use live telephone calls to communicate with their offices.¹⁹⁹ The concept of having prescribers select the communication method that the seller would use to verify a prescription (*i.e.* by telephone, fax, or online) was previously raised with the Commission

¹⁹⁵ Comment #644.

¹⁹⁶ Filandro (Comment #129); Chakuroff (Comment #189); Stuart (Comment #635).

¹⁹⁷ Chakuroff (Comment #189).

¹⁹⁸ Mirkin (Comment #111) (stating that fax or email verifications are quick and easy to answer); Chang (Comment # 126) (requesting fax or email verification system); Filandro (Comment #129) (requesting sellers offer all offices fax option for verification requests); Koch (requesting use of fax); Rubow (Comment #649) (seeking a requirement that online retailers verify through a route that is intelligible, including fax or a live person). *But see* Hicks (Comment #256) (stating automated fax systems are difficult for their offices as the fax machine is in an area of the business that is not frequently used); Ambler (Comment #524) (complaining of receipt of poor quality faxes when the office is closed).

¹⁹⁹ Mirkin (Comment #111); Hicks (Comment #256) (stating a simple, quick phone call is much easier and would result in faster turnaround times for the patients); Rubow (Comment #649).

during the initial rulemaking.²⁰⁰ As the Commission then determined, because the Act defines "direct communication" to include three different communication mechanisms that sellers may use—telephone, facsimile or electronic mail—the Act does not permit prescribers to limit the communication mechanisms sellers may use to submit verification requests.²⁰¹ Nevertheless, nothing prevents a seller from honoring a prescriber's request for a certain type of communication and the Commission suggests that sellers evaluate whether honoring such requests would increase the speed and efficiency of the verification process.

C. Section 315.5(c)—Verification Events

Section 315.5(c) sets forth the three circumstances under which a seller can consider a prescription "verified by direct communication" and proceed to sell contact lenses to its customer: (1) The prescriber confirms the prescription is accurate by direct communication with the seller; (2) the prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; and (3) the prescriber fails to communicate with the seller within eight business hours after receiving a proper verification request from the seller.²⁰²

1. Passive Verification

A number of commenters expressed the view that because contact lenses are restricted medical devices, they should not be dispensed unless the prescriber actively verifies the prescription.²⁰³ The Contact Lens Association of Ophthalmologists, for example, in arguing for the elimination of passive verification, stated that it "puts the health of consumers at risk and is inconsistent with regulatory practices for confirmation of the validity and accuracy of prescriptions for drugs and for other Class II and Class III medical devices."²⁰⁴

Other commenters expressed the concern that the passive verification framework can be manipulated and, therefore, does not adequately ensure that patients receive contact lenses in accordance with proper medical

²⁰⁰ 69 FR at 40497.

²⁰¹ See 15 U.S.C. 7603(g).

²⁰² 16 CFR 315.5(c).

²⁰³ California Optometric Association (Comment #119) ("Contact lenses are medical devices. Therefore, it is reasonable to replace passive verification with active verification for contact lenses."); Weissman (Comment #50) (same); Bainbridge (Comment #152) ("Start treating contact lenses like the medical devices they are and start respecting the clinical judgment of doctors.").

²⁰⁴ Comment #572.

oversight. For example, some commenters asserted that passive verification is problematic because patients, in some circumstances, may be able to obtain lenses by providing fictional or incorrect information to sellers.²⁰⁵ A common scenario relayed by commenters is that if the patient provides the seller with the name of a fictional prescriber and a fictional fax number, the prescription will be passively verified when there is no response within eight hours.²⁰⁶

Some prescribers reported instances where some patients were never seen by a prescriber, and apparently the consumer just pulled the prescriber information from a Web site in an attempt to get a prescription verified via passive verification.²⁰⁷ A few commenters reported that patients said they were instructed—by sellers—to use any optometrist name, or any facsimile number, in order to facilitate the order.²⁰⁸ A few commenters also complained that after they have flagged a verification request as invalid, some sellers try to game the system and trigger a passive verification by then repeatedly faxing the same verification request to the prescriber in the hopes that the prescriber will not have the opportunity to deny the verification

²⁰⁵ Wang (Comment #94) (discussing “deliberate attempts to evade verification with the knowledge that a lack of verification is equivalent to a prescription being verified”); Anklin (Comment #107) (describing the use of incorrect or even falsified information); Filandro (Comment #129) (noting that patients can fax the request to their own home or email); Stewart (Comment #136) (patients are able to use any fax number); McCutchan (Comment #624) (describing use of fax numbers for practices that are no longer active).

²⁰⁶ Caughell (Comment #7); Truong (Comment #55); Navarro (Comment #117); Zierlein (Comment #123); Ammon (Comment #128); Ciszek (Comment #134); Lee (Comment #158); Ambrose (Comment #196); Ahmed (Comment #209); Dell (Comment #227); Williston (Comment #252); Pentecost (Comment #268); Smith (Comment #319); Makler (Comment #356); Bolenbaker (Comment #357); McWilliams (Comment #362); Diaz (Comment #380); Liebig (Comment #478); Balitski (Comment #485); Garcia (Comment #511); Loerzel (Comment #550); Pham (Comment #641); Lisenby (Comment #662).

²⁰⁷ Driesen (Comment #47); Howe (Comment #53); Cherian (Comment #89); Hosaka (Comment #240); Chavez (Comment #334); Ling (Comment #390); Redder (Comment #454); Nakasone (Comment #469); Ball (Comment #590); Heuer (Comment #467); Ostrom (Comment #489); Hartman (Comment #522); Milsky (Comment #559).

²⁰⁸ Sadeghian (Comment #242) (“A number of patients tell me that it is common practice by these online contact lens companies to tell the consumer to leave [the consumer’s] fax number as the doctor’s fax so nobody would respond to their requests.”); Alianiello (Comment #253) (“I asked where he’s been buying contact lenses and he told me the online avenue he uses asked him for his doctor’s name, and when he told them he couldn’t spell my last name they told him to look in the phone book and give them a name of an optometrist and they’d take care of it.”).

request again, and it will end up passively verified.²⁰⁹

In light of these concerns, some commenters concluded that the passive verification system is not working as intended to protect patient eye health and instead, recommended that all contact lens prescriptions be actively verified.²¹⁰ One commenter recommended that the Rule be modified to prevent the shipping of contact lenses without active verification.²¹¹ Another commenter said that if the retailer has not received an image of the actual prescription, the seller should at least obtain some confirmation that the customer is genuinely a patient of the prescriber that is being contacted for verification.²¹²

The Commission declines to propose these Rule modifications. Issues identical to these were raised during the initial rulemaking process in 2004, when commenters either opposed or expressed significant concern about the passive verification system imposed by the Act and the Rule.²¹³ At that time, some commenters were concerned about the use of a passive verification system for prescription medical devices such as contact lenses. Other commenters, during the initial rulemaking, expressed concern that verification requests could be sent to the wrong prescriber and might be improperly filled via passive verification because the prescriber neglected to respond to it.²¹⁴

The Commission responded to concerns about passive verification by finding that “[b]ecause Congress has decided to impose a passive verification system through the Act, whether to adopt a passive verification system is not at issue in this rulemaking proceeding.”²¹⁵ The same holds true today, and this rule review does not revisit the decision to include a passive verification system.

With respect to concerns that patients are manipulating the passive verification system by deliberately providing inaccurate prescriber information, the Commission notes that

²⁰⁹ See, e.g., Christensen (Comment #149).

²¹⁰ Driscoll (Comment #67); Diaz (Comment #380); Whittington (Comment #443).

²¹¹ Palmer (Comment #484).

²¹² Milsky (Comment #559). This commenter also proposed that in order to allow eye doctors and the Commission to be able to track in detail what happens to online orders after the verification request is sent, the seller should be required to inform the prescriber whether the transaction was cancelled or completed, and if so, what exactly was shipped and when. This mechanism would document whether lenses were shipped before any verification took place.

²¹³ 69 FR at 40497 and note 206.

²¹⁴ 69 FR at 40497 and note 198.

²¹⁵ 69 FR at 40497.

if prescribers receive verification requests for individuals who are not their patients, prescribers have the ability and incentive to respond that such requests are “invalid” under section 315.5(d) of the Rule,²¹⁶ thus preventing an improper passive verification.

With regard to concerns that patients are deliberately providing fictional prescriber information and fictional contact information, commenters produced only anecdotal evidence of such actions, and did not provide empirical data regarding the frequency of these activities. Although it is possible that such activities could allow some patients to obtain contact lenses without a valid prescription, the Commission notes that in doing so, such individuals are intentionally circumventing the Rule. As discussed above, the passive verification framework has been mandated by Congress in an effort to balance the interests of consumer health and prescription portability. At the time the Act was under consideration, Congress was aware—after being informed by the Commission and the American Optometric Association, among others—that passive verification was not a foolproof method for preventing the verification of invalid prescriptions.²¹⁷ The Commission will consider consumer education efforts designed to encourage consumers to act responsibly,

²¹⁶ *Id.*

²¹⁷ See, e.g., “Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce,” 108th Cong. 1 (Sept. 12, 2003) (Testimony of J. Pat Cummings, American Optometric Association) (testifying that “the problem with passive verification” is that some people will be able to get contact lenses without a prescription); *id.* (Testimony of Howard J. Beales, Federal Trade Commission) (noting that passive verification contains a risk that some contact lenses will be provided based on out-of-date prescriptions). Congress opted for passive verification after hearing repeated reports of the difficulties consumers confronted having prescriptions verified in states with active verification systems. See H.R. Report No. 108–318, at 5 (2003) (stating the Fairness to Contact Lens Consumers Act “adopts a passive verification system in order to best serve the consumer,” after hearing testimony from consumers and businesses of the “unusually high number of consumer complaints in states that rely on active verification schemes.”). See also “Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce,” 108th Cong. 1 (Sept. 12, 2003) (Testimony of Peggy Venable, Texas Citizens for a Sound Economy) (testifying that under an active verification system in Texas, there was a “widespread practice [by optometrists] of failing to verify the prescription”); *id.* (Testimony of Jonathan C. Coon, 1–800 CONTACTS) (testifying that under active verification, 1–800 CONTACTS had to cancel half of all orders in Texas due to prescribers’ failure to respond to verification requests).

within the confines of the Rule. In addition, to the extent that the Commission receives evidence that sellers are encouraging consumers to provide inaccurate or fictional prescriber information, the Commission will investigate such allegations, as appropriate.

#2. Issues Regarding the Eight-Business-Hour Window

Some commenters stated that the current eight-business-hour window is a reasonable length of time for prescribers to respond to verification requests.²¹⁸ 1–800 CONTACTS, for example, asserted that the “eight business-hour time frame for passive verification gives prescribers sufficient time to confirm important health information and correct any inaccurate orders without imposing a needless delay on consumers who place a premium on quick delivery.”²¹⁹ As support, 1–800 CONTACTS stated that last year it cancelled orders worth approximately \$40 million in response to communications from prescribers, and that the “number of deleted orders and the value of sales cancelled demonstrate that prescribers have more than adequate time to respond when necessary.”²²⁰

Other commenters, however, argued that the eight-business-hour time frame for passive verification does not allow enough time for doctors to notify sellers that a prescription is expired, inaccurate, or nonexistent. The American Academy of Ophthalmology, for example, stated that the eight-business-hour requirement “is far too short and ultimately imposes significant burdens on providers and in many instances eliminates a necessary patient safety check.”²²¹ Some prescribers noted that their offices are very busy and that eight business hours was not enough time to verify prescriptions.²²² The CLAO suggested that eight business hours was insufficient because

²¹⁸ 1–800 CONTACTS (Comment #568). See also Warby Parker (Comment #593) (“Passive verification provides prescribers with a reasonable opportunity to verify, address or correct an inaccurate, invalid or expired prescription without imposing an undue burden on the prescriber. Furthermore, it gives the seller a reasonable end-point at which to proceed with the sale. This ensures that prescribers do not thwart patient choice of where to purchase contact lenses by failing to verify a prescription and relegating the patient back to the prescriber for the ultimate purchase. We also believe that eight business hours is a reasonable length of time for passive verification.”).

²¹⁹ Comment #568.

²²⁰ *Id.*

²²¹ Comment #611.

²²² Tran (Comment #260); Bierwerth (Comment #308); Loerzel (Comment #550); Fink-Freeman (Comment #609).

“validation requests arrive with incomplete or erroneous patient information complicating the process by which clinical records are retrieved.”²²³ These comments, however, did not quantify how the eight-business-hour time frame imposed “significant burdens” on providers, nor establish that a significant number of prescribers were unable to respond to verification requests within eight business hours. Commenters similarly failed to provide specific information quantifying the frequency of incomplete or incorrect validation requests.

Many commenters did not propose a specific extension of time to respond to a verification request,²²⁴ and merely stated that eight business hours was not enough. Some commenters did put forth specific proposals, such as changing the language to “eight (8) business hours or twenty-four (24) clock hours, whichever is later,”²²⁵ doubling the length of time to 16 hours,²²⁶ or extending the verification window to at least two business days.²²⁷ Others suggested providing at least 48 to 72 hours,²²⁸ or two to three business days,²²⁹ to confirm the validity of a prescription. A few commenters suggested that increasing the window to 72 hours would alleviate issues that arise when verifications are received on Friday, Saturday or Sunday.²³⁰

Having considered these comments, the Commission declines to propose a Rule modification lengthening the eight-business-hour timeframe during which a prescriber must respond to a verification

²²³ CLAO (Comment #572).

²²⁴ Whittington (Comment #443) (“more than eight hours to confirm the RX request”); Heuer (Comment #467) (“reasonable amount of time to respond”).

²²⁵ Milsky (Comment #559) (“That change would still not prevent the situation where, for example, a verification request comes in on a holiday weekend and the prescriber’s office is closed for an extra day off, or when a practice is not open on Wednesdays, but at least it would mean that the prescriber would have a little more of an opportunity (especially at the beginning or end of the workday) to correct any errors in the verification request, before the order is shipped and it’s too late.”).

²²⁶ Kiener (Comment #74); Perala (Comment #315); Diaz (Comment #380).

²²⁷ CLAO (Comment #572); Koury (Comment #573); Fink-Freeman (Comment #609); American Academy of Ophthalmology (Comment #611). See also Hua (Comment #45) (recommending an increase to 24 to 48 hours); Bhadra (Comment #105) (same).

²²⁸ Gooderman (Comment #10); Galdamez (Comment #167) (at least 72 hours); Lin-Dilorinzo (Comment #476); Espy (Comment #587).

²²⁹ Voight (Comment #551); Figazolo (Comment #24) (three days); Truong (Comment #55) (three days).

²³⁰ Yaklich (Comment #364); Raff (Comment #373). See also Coalition for Patient Vision Safety (Comment #621).

request. Despite comments that the timeframe is too short, the Commission believes that the current eight-business-hour time frame is adequate for the vast majority of prescribers. Commenters put forth no empirical evidence that prescriptions are being improperly verified via passive verification due to prescribers not having enough time to respond, and cited no compelling changes in the marketplace that would justify extending the time frame beyond eight business hours. If anything, because of advances in technology, electronic communications, and record-keeping, eight business hours is as appropriate, if not more so, than when implemented in 2004. As the Commission explained in the initial rulemaking, “Congress recognized that consumers may be harmed if they face undue delays in receiving their contact lenses from a seller” and balanced that consideration against the possible harm consumers may experience if sellers provide contact lenses based on invalid prescriptions.²³¹ The Commission has found nothing thus far in the record for this rule review proceeding to disturb that determination.

In addition to concerns about the time prescribers have to respond, some commenters expressed concern about when verification calls are placed and received. Some optometrists expressed concern that some sellers are exploiting the Rule by placing verification requests after hours in order to circumvent the eight-business-hour window.²³² Other prescribers noted with frustration that sellers fax verification requests outside of normal business hours, such as in the middle of the night or on weekends, thereby making it impossible for them to respond in a timely fashion.²³³ Some commenters complained that because they only had 24 hours to respond to a

²³¹ 69 FR at 40482.

²³² Berger (Comment #200) (“[u]nder the current law, retailers are allowed to fill a prescription if verification is not received within 8 hours. This is commonly exploited by faxing or robodialing verification requests outside of normal business hours, then filling the prescription before the prescriber responds.”). See also Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Hodes (Comment #42); Dodge (Comment #44); McBride (Comment #171); Sloan (Comment #177); Kirkconnell (Comment #202); Hamilton (Comment #216); Leach (Comment #257); Chang (Comment #258); Yaklich (Comment #364); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

²³³ Plumb (Comment #219); St. Martin (Comment #292); Diaz (Comment #380); Witmeyer (Comment #418); Nakasone (Comment #469); Garcia (Comment #511); Egbert (Comment #515); Steinleitner (Comment #517).

verification request,²³⁴ such verifications would be confirmed automatically over the weekend because no one was in the office.²³⁵ Other commenters noted that they receive verification faxes outside of normal business hours and therefore have no way of verifying, denying, or correcting prescriptions.²³⁶ Many of these commenters recommended that the Rule be amended to prohibit sellers from sending prescription verifications after business hours and on weekends.²³⁷ Along the same lines, the Coalition for Patient Vision Safety recommended that the Commission modify “the eight-hours of communication when the initial communication begins prior to a holiday or on a weekend when the doctor is not conducting normal office hours.”²³⁸

At this time, the Commission does not propose to amend the Rule to prohibit sellers from sending prescription verification requests after business hours and on weekends or to otherwise extend the eight-business-hour window to account for weekends and holidays. It appears that the majority of commenters suggesting this prohibition are concerned that they do not have the opportunity to verify a prescription because they believe the eight-business-hour window for verification of a contact lens order is triggered upon receipt of a verification request, no matter when that request is received. That concern is misplaced. Section

315.2 of the Rule provides that “[f]or verification requests received by a prescriber during nonbusiness hours, the calculation of ‘eight (8) business hours’ shall begin at 9 a.m. on the next weekday that is not a Federal holiday or, if applicable, on Saturday at the beginning of the prescriber’s actual business hours.”²³⁹

Other commenters expressed frustration that verification requests were sent after regular business hours with the statement that the prescription would be filled unless the prescriber contacted the seller within 12 to 24 hours.²⁴⁰ Depending upon when these requests are sent, these sellers’ practices could result in contact lenses being shipped before or after the end of the eight-business-hour window. To the extent that sellers are dispensing contact lenses prior to the end of the eight-business-hour window, the Commission notes that this practice violates the Rule. If the Commission receives evidence that sellers are dispensing contact lenses before the end of the eight-business-hour window, the Commission will investigate such allegations, as appropriate.

A few commenters expressed concern that some prescriptions were being automatically filled without a prescriber’s oversight because the calculation of an eight-business-hour window does not take into consideration the fact that their offices may not be open or able to verify prescriptions during the Rule’s established timeframe for business hours.²⁴¹ For example, an office may be closed due to vacation, inclement weather, or regularly scheduled office closures that occur during the normal workweek.²⁴²

²³⁹ See also 69 FR at 40486.

²⁴⁰ Huang (Comment #17); Magee (Comment #95); Green (Comment #162); Shugarman (Comment #266).

²⁴¹ A small number of commenters complained that they regularly received verification requests from sellers that state that their records indicate that the prescriber has Saturday business hours. See Alianiello (Comment #253); Raff (Comment #373). These commenters said that despite correcting this misimpression, the seller continued to send verification requests that would begin the eight-business-hour window on Saturday morning. The Commission reiterates that this is a Rule violation because the seller only may count Saturday hours as business hours if the seller has actual knowledge of the prescriber’s Saturday business hours. Here, the seller has actual knowledge to the contrary. 69 FR at 40485. If the Commission receives evidence of such practices, the Commission will investigate such allegations, as appropriate.

²⁴² Robins (Comment #165); Glassband (Comment #218); Kubo (Comment #234); Whang (Comment #355); Makler (Comment #356); Falcon (Comment #505); Manuel (Comment #508); Voight (Comment #551); Koury (Comment #573); Kowaleski (Comment #578).

Similar concerns were raised by commenters in the initial rulemaking in 2004. At that time, the Commission declined to adopt an actual hours or other prescriber-specific approach to business hours, noting that “[i]t likely would be difficult and burdensome—perhaps impossible—for some sellers to determine and keep track of the actual hours of 50,000 prescribers. By contrast, a general rule using a uniform definition of business hours for all prescribers provides clarity and relative ease of compliance and enforcement.”²⁴³ In addition, the Commission recognized that there “does not appear to be any practical way to accommodate the myriad circumstances during which the offices of 50,000 individual prescribers may be closed or otherwise not able to respond to a prescription verification request.”²⁴⁴ The Commission continues to believe that such an approach would be impractical and declines to propose an actual hours or other prescriber-specific approach to calculating business hours.

V. Contact Lens Prescriptions

A. Section 315.6—Expiration of Contact Lens Prescriptions

As set forth by Section 315.6(a) of the Rule, a contact lens prescription expires on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription.²⁴⁵ If State law specifies no date or specifies a date less than one year after the issue date of the prescription, the Rule provides that the prescription shall not expire less than one year after the issue date of the prescription.²⁴⁶ A prescriber, nonetheless, can specify a shorter expiration date if that date is “based on the medical judgment of the prescriber with respect to the ocular health of the patient.”²⁴⁷ The prescriber then must document the reasons in the patient’s medical record.²⁴⁸ In other words, contact lens prescriptions cannot expire in less than one year unless, based on medical judgment, a prescriber specifies a different date and documents the

²⁴³ 69 FR at 40484.

²⁴⁴ *Id.*

²⁴⁵ 16 CFR 315.6(a)(1). The majority of states require that a contact lens prescription not expire less than one year after the issue date, except when a special medical circumstance necessitates that it expire sooner. A few states, such as Maryland and Washington, require that contact lens prescriptions not expire less than two years after the issue date except for special medical circumstances. See, e.g., Maryland Code § 11–404.4; Wash. Admin. Code § 246–852–010 (1)(f).

²⁴⁶ 16 CFR 315.6(a)(2).

²⁴⁷ 16 CFR 315.6(a)(3).

²⁴⁸ 16 CFR 315.6(b)(1).

²³⁴ Whipple (Comment #15); Huang (Comment #17); Wilson (Comment #76); Green (Comment #162); Frederick (Comment #207); Zair (Comment #512).

²³⁵ Magee (Comment #95); Mueller (Comment #513); Born (Comment #570); Shugarman (Comment #266).

²³⁶ Glavine (Comment #62); Tolchin (Comment #194); Bricker (Comment #195); Ahn (Comment #215); Lester (Comment #231); Kegarise (Comment #447).

²³⁷ California Optometric Association (Comment #119); Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Loydall (Comment #225); Leach (Comment #257); Chang (Comment #258); Liebig (Comment #478); Harris (Comment #490); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

²³⁸ Comment #621. Similarly, some commenters suggested increasing the eight-business-hour window because, based on their apparent misunderstanding of how the eight business hours are calculated, they believed that they did not have enough time to respond to verification requests received after business hours and on weekends. See Mirkin (Comment #111); Kalman (Comment #150); Bender (Comment #164); Hans (Comment #168); Baur (Comment #170); Yaklich (Comment #364); Raff (Comment #373); Diaz (Comment #380); Kegarise (Comment #447); Heuer (Comment #467); Zair (Comment #512); Gandhi (Comment #588).

reasoning. The language of these Rule provisions closely tracks that of the Act.²⁴⁹

1. Length of Contact Lens Prescriptions

The Commission received several comments about the length of contact lens prescriptions. Some commenters expressed the view that the prescription length should be longer. For example, Consumers Union requested that the Commission “consider whether a longer minimum period is warranted in the best interests of the consumer.”²⁵⁰ One consumer commented that contact lens prescriptions should be at least two years in length.²⁵¹

The Professional Opticians of Florida recommended that the Commission modify the Rule to prohibit the use of expiration dates on prescriptions for adult patients with low risk factors,²⁵² while an optometrist argued that, “[c]ompetition for the sales of contact lenses is so great that placing any regulations on the length of the prescription is unnecessary and should be at the sole discretion of the prescriber.”²⁵³ LD Vision Group, a contact lens retailer, declared that while it generally makes sense for patients to undergo a comprehensive eye examination to ensure good eye health, patients should not have to undergo a follow-up contact lens fitting after receiving a trial pair of contact lenses from a prescriber.²⁵⁴ Furthermore, according to that commenter, patients should be able to waive the requirement that their contact lens prescriptions be verified—and yet still be able to obtain contact lenses—by acknowledging that they are aware of the risks of not obtaining an annual eye examination.²⁵⁵

However, many commenters, primarily prescribers, urged the Commission not to “deregulate” prescription length²⁵⁶ or otherwise extend the length of contact lens prescriptions.²⁵⁷ Other prescribers

encouraged the Commission to retain the one-year prescription length, citing the importance of annual eye examinations for preventing complications related to contact lens use, diagnosing other conditions by examining the eyes, and providing patient education about contact lens use.²⁵⁸ A few commenters expressed satisfaction with the two-year prescription length imposed by some States’ laws.²⁵⁹

The Commission declines to propose any changes—either removing or lengthening—the Rule’s prescription length provisions. As indicated above, the Rule’s language closely tracks that of the Act, which set a minimum expiration date “to prevent prescribers from selecting a short expiration date for a prescription that unduly limits the ability of consumers to purchase contact lenses from other sellers, unless medical reasons justify setting such an expiration date.”²⁶⁰ Accordingly, the Commission is not at liberty to remove the prescription expiration provision. In addition, the Commission declines to propose to lengthen the Rule’s prescription expiration provisions and believes the current framework is appropriate. As the Commission concluded in response to commenters arguing for a minimum expiration date of two years during the initial rulemaking, in drafting the Act, Congress intended to defer to applicable State law except where such law establishes an expiration period of less than one year.²⁶¹

Nguyen (Comment #412); Eng (Comment #414); Frady (Comment #440); Santhanam (Comment #444); Calhoun (Comment #446); Howard (Comment #453); Desai (Comment #462); Douglas (Comment #526); Geiger (Comment #598); Ancona (Comment #650); Webster (Comment #670).

²⁵⁸ See, e.g., Coalition for Patient Vision Care Safety (Comment #621); Williford (Comment #38); Kapoor (Comment #58); Anderson (Comment #96); Tse (Comment #146); Morrison (Comment #239); Major (Comment #263); Uy (Comment #277); Williams (Comment #261); Walker (Comment #283); Murray (Comment #287); Rice (Comment #295); Harris (Comment #305); Cluff (Comment #309); Hollister (Comment #318); Oliver (Comment #323); Gelman (Comment #326); Cox (Comment #336); Zimmerman (Comment #372); Sherman (Comment #375); Klein (Comment #377); Hafford (Comment #383); Blankenship (Comment #395); Elmore (Comment #396); Assell (Comment #397); Yaryan (Comment #401); Stefanovic (Comment #417); Enochs (Comment #423); Moore (Comment #437); Archibald (Comment #438); Lott (Comment #445); Goller (Comment #448); Eggers (Comment #473); Abbott (Comment #497); Nazario (Comment #518); Neuenfeldt (Comment #542); Maino (Comment #555); Bieter (Comment #602); Lac (Comment #631); Bandy (Comment #643); Lee (Comment #659); Alexander (Comment #666).

²⁵⁹ Hua (Comment #45); Campbell (Comment #348).

²⁶⁰ 69 FR at 40504; 69 FR at 5443.

²⁶¹ 69 FR at 40504.

2. Expired Contact Lens Prescriptions

A number of prescribers reported that some of their patients are obtaining contact lenses through online vendors even though their contact lens prescriptions have expired.²⁶²

According to Johnson & Johnson Vision Care, Inc., “roughly one-in-three online contact lens purchasers” surveyed in a 2015 APCO Insight online survey “admit[ted] to ordering lenses using an already expired prescription.”²⁶³ In response to these concerns, some commenters recommended that the Commission amend the Rule specifically to prohibit the sale of contact lenses to patients with expired prescriptions.²⁶⁴

After reviewing the comments, the Commission has determined that no amendment is necessary because the current regulatory framework sufficiently prohibits the use of expired prescriptions. As a threshold matter, Section 4(e) of the Act and Section 315.5(d) of the Rule clearly identify three categories of invalid prescriptions (inaccurate, expired, and otherwise invalid).²⁶⁵ Accordingly, the Act and the Rule already make explicit that an expired prescription is not a valid prescription. Under the Rule, sellers may only dispense lenses using either a prescription that has been presented to the seller, or a prescription that has been verified with the prescriber by the seller.²⁶⁶ A prescription presented to the

²⁶² See, e.g., Williford (Comment #38); Glavine (Comment #62); Jones (Comment #63); Copeland (Comment #73); Weinberg (Comment #87); Moody (Comment #92); Butthod (Comment #81); Kreda (Comment #93); Magee (Comment #95); Voreis (Comment #114); Navarro (Comment #117); Taylor (Comment #120); Dyak (Comment #124); Stewart (Comment #136); Madden (Comment #155); Robertson (Comment #180); Chakurhoff (Comment #189); Law (Comment #190); Burruss (Comment #192); Bricker (Comment #195); Stephens (Comment #210); Sadeghian (Comment #242); Pentecost (Comment #268); Shaw (Comment #339); Chea (Comment #352); Steinleitner (Comment #517); Holler (Comment #553); Song (Comment #654).

²⁶³ Comment #582 (emphasis deleted). The survey, conducted on behalf of Johnson & Johnson Vision Care, Inc. included 500 contact lens users 18 years of age or older who had purchased contacts online in the prior six months. See also Coalition for Patient Vision Care Safety (Comment #621) (referencing 2015 APCO Insight Survey).

²⁶⁴ Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Ellingson (Comment #66); Leach (Comment #257); Chang (Comment #258); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

²⁶⁵ 15 U.S.C. 7603(e); 16 CFR 315.5(d). See also 69 FR at 40502.

²⁶⁶ 16 CFR 315.5(a).

²⁴⁹ 15 U.S.C. 7604.

²⁵⁰ Comment #677.

²⁵¹ Schodowski (Comment #65).

²⁵² Comment #563.

²⁵³ Bolenbaker (Comment #357).

²⁵⁴ LD Vision Group (Comment #544).

²⁵⁵ *Id.*

²⁵⁶ Wood (Comment #37); Compton (Comment #275); Singhai (Comment #281).

²⁵⁷ See, e.g., Morgan (Comment #144); Stoliker (Comment #286); Parikh (Comment #288); Shlosman (Comment #290); Lee (Comment #293); Paulsen (Comment #296); Turano (Comment #303); Yang (Comment #307); Daniel (Comment #310); Huynh (Comment #313); Stetson (Comment #314); Theroux (Comment #317); Wong (Comment #330); Tarr (Comment #344); Peres-Maes (Comment #346); Dronka (Comment #347); Scott (Comment #354); Cantor (Comment #358); Cesar (Comment #359); Philippe (Comment #365); Geller (Comment #370); Uchida (Comment #403); Sharma (Comment #404);

seller must contain an expiration date in order to satisfy the definition of contact lens prescription.²⁶⁷ If the prescription presented to, or in possession of, the seller is expired, that prescription is invalid and the seller cannot use the expired prescription to dispense lenses to the patient. Because the seller has actual knowledge that the prescription is expired, neither may the seller use the expired prescription as the basis for a passive verification request. If, however, a seller has been presented with, or is in possession of, a prescription that does not contain an expiration date, or is otherwise relying on prescription information provided by the patient, then the seller may proceed to verify such prescription with the prescriber.²⁶⁸ In this latter instance, the seller does not have any knowledge as to whether or not the prescription is expired, and can rely on the prescriber to alert the seller if the prescription is expired.

Other commenters, recognizing that selling contact lenses on an expired prescription is not allowed by the Rule, instead urged the Commission to increase enforcement.²⁶⁹ The Commission believes that the clarification regarding expired prescriptions as set forth in this document will assist sellers in understanding their obligations under the Rule. In addition, if the Commission receives evidence that sellers are dispensing contact lenses based on expired prescriptions, the Commission will investigate such allegations, as appropriate.

Other commenters explained that because of flaws in the passive verification system sellers “can request verification of an otherwise expired prescription and can ship the lenses if the prescriber does not recognize within eight business hours that the expiration date has passed and inform the seller.”²⁷⁰ In its comment, the Contact Lens Association of Ophthalmologists argued that passive verification “creates a mechanism for renewal of expired prescriptions, which is in the seller’s interest, may be in the consumer’s immediate interest, but is not in the

interest of the consumer’s long term ocular health.”²⁷¹

In its comment, the American Optometric Association noted that “an expiration date and issue date are required elements of a prescription” and the FTC “should require the expiration date or issue date to be provided in prescription verification.”²⁷² This commenter argued that this requirement would incentivize sellers to make sure patients know their prescription expiration date when placing orders. The American Optometric Association further explained that because sellers often market to consumers to reorder in the final month or weeks that the prescription is valid, it believes that sellers already know the prescription expiration date.²⁷³ This commenter concluded that by requiring the expiration date or issue date in the verification request, sellers would be aware, and could not deny when they are using an invalid prescription.²⁷⁴

The Commission declines to propose that the Rule be modified in this way. Similar proposals were suggested and rejected during the initial rulemaking.²⁷⁵ As the Commission recognized at that time, there is “no reason to believe or evidence to suggest that a seller who is attempting to verify a prescription would necessarily have this information.”²⁷⁶ Furthermore, the Commission believes that adopting such a proposal might thwart the intent of the Act. For example, although prescribers themselves have the prescription expiration information because they issued the prescription, a seller verifying a prescription—as opposed to a seller who has a copy of a prescription with an expiration date—may not have access to this information. Because a verification request that does not contain all the required information is not a valid verification request,²⁷⁷ sellers without expiration information would be at a disadvantage in that they would not be able to verify patient

prescriptions based on Section 315.5(c)(3). Furthermore, as noted, prescribers are already in possession of the expiration date, and it is in their economic and professional interest to check the prescriptions and respond to verification requests by informing the seller whenever a prescription has expired.²⁷⁸

For the same reasons, the Commission declines to propose to amend the Rule to reflect the American Optometric Association’s proposal “to ban sellers from marketing to specific customers to reorder their lenses after the prescription has expired (more than one year after the issue date or when the customer originally ordered lenses from the seller) unless the seller has specific knowledge the customer’s prescription is valid for more than one year.”²⁷⁹ To the extent a patient does not have a valid prescription, the Rule already prohibits the sale of contact lenses. However, nothing in the Act supports the extension of this prohibition to the marketing (as opposed to the sale) of contact lenses. It may be in the patient’s best interest to receive a reminder to reorder lenses. If the patient does not have a valid prescription, the seller is prohibited from selling the lenses. However, if the patient has visited a prescriber in the interim, the patient will have a valid prescription and the sale can be made.

3. Quantities of Contact Lenses Obtained by Patients

Many commenters expressed the concern that because of inadequacies in the Rule or lack of enforcement, consumers are able to obtain more than a year’s supply of contact lenses.²⁸⁰ For example, some commenters asserted that this occurs because some contact lens retailers allow patients to purchase

²⁷⁸ See “Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce,” 108th Cong. 1 (Sept. 12, 2003) (Testimony of Howard Beales, Federal Trade Commission) (noting that passive verification is “in many respects self-enforcing”).

²⁷⁹ American Optometric Association (Comment #644).

²⁸⁰ See, e.g., Rohleder (Comment #57) (“Because of lack of enforcement, patients are able to purchase more contact lenses than they can use in a year, thus allowing them to circumvent seeing their doctor almost indefinitely.”); Filandro (Comment #129) (“A patient can order ten years’ worth of contacts and can’t be stopped by the law. A patient can order one years’ [sic] worth of contacts from ten different vendors and can’t be stopped by the law.”); Stewart (Comment #136) (“Patients are able to purchase multi-years [sic] worth of contact lenses even though the prescription clearly states expires in one year.”); Tjandera (Comment #502) (noting that the Rule can be evaded because patients can order from multiple online retailers before the prescription expires).

²⁷¹ Comment #572. See also American Optometric Association (Comment #644) (“[a]llowing repurchases based on long-expired prescriptions may be, at the time, convenient for the patient and profitable for the seller, but increases the risk of patient harm”).

²⁷² American Optometric Association (Comment #644).

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ A state optometry association requested that the Rule be amended to require the verification request to contain the prescription’s expiration date as well as the number of refills prescribed. 69 FR at 40496.

²⁷⁶ *Id.*

²⁷⁷ *Id.* (“The Commission emphasizes that the sale of contact lenses based on a verification request which does not contain all of the required information constitutes a Rule violation.”).

²⁶⁷ 16 CFR 315.2.

²⁶⁸ 16 CFR 315.5(a)(2).

²⁶⁹ See, e.g., Peterson (Comment #222); Smith (Comment #319); Heuer (Comment #467); Santarias (Comment #471); Johnson & Johnson Vision Care, Inc. (Comment #582) (“critical to ensure patients continue to see their eye care professionals for their annual check-up and prescription renewal by upholding and enforcing the one-year contact lens prescription expiration date”); Coalition for Patient Vision Care Safety (Comment #621).

²⁷⁰ American Optometric Association (Comment #644). See also Stewart (Comment #136) (stating that expired prescriptions have been filled for years because there was no reply to passive verification).

more than a year's supply of contact lenses,²⁸¹ while other prescribers reported that patients are able to refill their contact lenses prescription and obtain more lenses just prior to the prescription expiring.²⁸² Prescribers also were concerned that they were receiving verification requests from sellers for contact lenses just as the patient's prescription was expiring.²⁸³ A number of commenters complained that contact lens sellers are actively encouraging patients to refill their prescriptions right before they expire.²⁸⁴ For example, one commenter reported that sellers "send reminders to patients about a month before their contact lens prescription is expired, to buy another whole year's prescription."²⁸⁵ One contact lens manufacturer reported that an online survey that it had commissioned showed that 58% of the online consumers that were surveyed indicated that they had received an email or letter from their retailer reminding them that their prescription was expiring soon and that the majority of these consumers had ordered more lenses as a result.²⁸⁶ Other commenters noted that patients are able to obtain

²⁸¹ Young (Comment #91); Anklin (Comment #107); American Optometric Association (Comment #644).

²⁸² Day (Comment #4); Driesen (Comment #47); Schwartz (Comment #80); Magee (Comment #95); Johnson (Comment #109); Rosemore (Comment #468); Garcia (Comment #511). *See also* Milsky (Comment #559) ("Another common concern among prescribers is, for example, a prescription for a year's supply of contact lenses getting filled one month before it expires, eleven months after the exam and fitting.").

²⁸³ Shin (Comment #70); Young (Comment #91); Chakuroff (Comment #189); Koury (Comment #573).

²⁸⁴ Mathai (Comment #33) ("1800 contacts and other retailers prompt their customers to purchase an annual supply right before their prescription expires so they can save a trip to their Dr [sic] office."); Jones (Comment #83) ("Contact lens suppliers are actively targeting patients to get them to order outside the limits of the prescription and/or fishing for patient information."); Young (Comment #91) ("Some online retailers are actively marketing to consumers to purchase more contact lenses when their prescription is 'about to expire.'"); Nelson (Comment #130) ("1-800 Contacts also will not respect a number of refills on the Rx. Instead, they will email the patient before their Rx expires and tell them to order more. Patients then order another year of contacts and then cancel their yearly examination."); Hans (Comment #168) (patients prompted to save trip to doctor's office); Ellenberger (Comment #272) (same); Gandy (Comment #530) (stop sellers from aggressive and unethical practice of encouraging patients to buy another year's supply of lenses right before their prescription expires); Tass (Comment #586) (same).

²⁸⁵ Combs (Comment #90).

²⁸⁶ Johnson & Johnson Vision Care, Inc. (Comment #582) ("nearly six-in-ten online consumers say they have received an email or letter from their retailer reminding them their Rx was expiring soon (58%) and the vast majority who received this notice (86%) ordered more contacts as a result").

more than a year's supply of contact lenses by ordering from multiple sources.²⁸⁷

As explained by other commenters, if patients can obtain lenses in excess of a year's supply, expiration dates on prescriptions become meaningless²⁸⁸ and patients do not return to their eye care professional on an annual basis.²⁸⁹ Some prescribers provided anecdotal reports of patients not returning for an annual eye exam, sometimes for several years, because they had been able to purchase contact lenses online.²⁹⁰

To address these concerns, a number of commenters—optometric and ophthalmologic associations, individual prescribers, and contact lens manufacturers—proposed that the Commission amend the Rule to require contact lens prescriptions to include a maximum quantity of lenses that consumers can purchase prior to the prescription's expiration.²⁹¹ These

²⁸⁷ Jones (Comment #83); Filandro (Comment #129); Heuer (Comment #467); Endry (Comment #552); Milsky (Comment #559).

²⁸⁸ Mirkin (Comment #111); Endry (Comment #552). *See also* Harris (Comment #490) (purchasing contacts right before the prescription expires defeats the purpose of annual expiration dates and the monitoring of patient eye health).

²⁸⁹ *See, e.g.*, Rohleder (Comment #57); Butthod (Comment #81); Moody (Comment #92); Anklin (Comment #107); Nett (Comment #449); Lisenby (Comment #662).

²⁹⁰ *See, e.g.*, Weissman (Comment #50) (five years); Grace (Comment #64) (several years); Butthod (Comment #81) (3–5 years); Patel (Comment #188) (companies filling prescriptions for 10 years without successful verification); Pentecost (Comment #268); Silani (Comment #270) (returning for an exam "years" later); Chea (Comment #352); Arthur (Comment #371) (five years); Hornberger (Comment #457) (as many as five years); Pickering (Comment #475) (four to five years); Born (Comment #570) (many years); Gronquist (Comment #630) (years).

²⁹¹ American Optometric Association (Comment #644); American Academy of Optometry (Comment #623); Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595); Coalition for Patient Vision Care Safety (Comment #621); Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Kapoor (Comment #58); Comer (Comment #221); Leach (Comment #257); Chang (Comment #258); Whang (Comment #355); Knight (Comment #360); Senator Perdue (Comment #569); Reed (Comment #579); Johnson & Johnson Vision Care, Inc. (Comment

commenters asserted that including a quantity limit on prescriptions would be beneficial to patients' health and safety.²⁹² One contact lens manufacturer stated that quantity limits "impose important safeguards and also strengthen the prescriber-patient relationship," arguing that if a patient runs out of contact lenses, this would "offer[] yet another opportunity for consumers to ask questions, share health and other issues they may be encountering with their lenses, or adjust their prescription under the supervision of an eye care professional."²⁹³

In addition to including the maximum quantity on the prescription itself, several state optometric associations also recommended that the Commission "limit the number of contact lens boxes that can be purchased from a retailer at one time."²⁹⁴ Similarly, the Coalition for Patient Vision Care Safety proposed that the Commission "forbid retailers to sell in a single transaction a quantity of contact lenses that exceeds a single year's supply."²⁹⁵ As an alternative, the Coalition suggested the Commission require that sellers only provide a supply equal to the length of the underlying prescription.²⁹⁶ A few commenters stated that because passive verification might allow the consumer to obtain more lenses than medically prescribed, quantity limits should be considered.²⁹⁷

A number of commenters argued that contact lens prescriptions should be

#582); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

²⁹² *See, e.g.*, American Optometric Association (Comment #644).

²⁹³ Johnson & Johnson Vision Care, Inc. (Comment #582).

²⁹⁴ Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

²⁹⁵ Comment #621.

²⁹⁶ *Id.* *See also* Dierks (Comment #32); Ellingson (Comment #66); Moody (Comment #92); Bhadra (Comment #105); Rana (Comment #139); Patel (Comment #237); Santry (Comment #529).

²⁹⁷ Wilson (Comment #76) (passive verification allows the contact lens seller to sell the patients more lenses than are medically prescribed); Kline (Comment #161) (same); Johnson & Johnson Vision Care, Inc. (Comment #582).

treated the same way as pharmaceutical prescriptions in order to prevent the dispensing of excess quantities.²⁹⁸ As described by one commenter, this would require the quantity to be included on the prescription and the retention of the prescription by the dispenser filling it.²⁹⁹ A few commenters suggested a pro rata approach. For example, one prescriber recommended that consumers should only be able to obtain refills commensurate with the amount of time left on the prescription.³⁰⁰ Likewise, the Coalition for Patient Vision Safety proposed a similar approach, suggesting that the Commission “restrict the sale of contact lenses on a prescription that is nine months after issuance or older to up to 25 percent of the prescription’s course.”³⁰¹ One contact lens manufacturer recommended that the Commission modify the Rule to “place[] reasonable limits on the quantity of contact lenses a patient can purchase under a prescription (especially within a few months of a prescription expiring)” in order to encourage patients to go to their eye care professional for routine examinations.³⁰²

However, other commenters disagreed with the proposal to include quantity limits on contact lens prescriptions. 1–800 CONTACTS argued that imposing quantity limits would “inconvenience consumers and lead to unhealthy practices, such as wearing lenses longer than recommended.”³⁰³ This commenter asserted that patients could misplace or tear lenses, or might replace their lenses more frequently than anticipated by their prescription, and consequently concluded that “there are any number of very legitimate reasons a consumer may want to purchase what appear to be (based on simple multiplication) extra lenses and there is no valid reason to restrict that consumer’s options.”³⁰⁴

Another contact lens retailer claimed that prescribers were circumventing the minimum one-year expiration period by

“limit[ing] the quantity of replacement lenses, despite the lack of any medical reason for ever doing so” and that “a consumer’s need for additional lenses could arise for a number of reasons.”³⁰⁵ This commenter proposed that the Commission amend Section 315.6 of the Rule to include a provision stating that a “contact lens prescription shall be valid for an unlimited quantity of lenses regardless of any prescriber-imposed limitation to the contrary.”³⁰⁶

After reviewing the comments, the Commission has determined not to propose to amend the Rule to adopt any of the contact lens quantity proposals put forth by commenters. First, the Commission does not believe that there is sufficient evidence in the rulemaking record to support amending the Rule to impose the quantity limit proposals suggested by commenters. Although some commenters conducted and submitted data from online surveys for the proposition that consumers are purchasing contact lenses as their prescriptions are about to expire, this data does not show the quantity of lenses that consumers are actually purchasing. For example, even if one were to assume that the APCO online survey results were completely reliable, the survey only asked consumers whether they purchased lenses at certain points in time; it did not assess the quantity of lenses that consumers actually purchased. The fact that a consumer purchased some contact lenses just prior to a prescription expiring does not necessarily mean that the consumer has purchased an excessive amount of contact lenses, nor does it support the contention that consumers are no longer getting eye examinations. Instead, consumers could be purchasing small amounts of lenses to last until their next scheduled eye examination. When the Commission examined the contact lens industry in 2005, it found that consumers do not typically purchase a full year’s supply at one time.³⁰⁷ The Commission has not seen any evidence indicating that this has changed. Although commenters to the current Rule review provided various anecdotal and hypothetical accounts of consumers buying excessive quantities of lenses, they did not provide empirical evidence regarding the amount of lenses consumers are obtaining, nor did they submit evidence to show that consumers are not visiting

their eye care practitioners as frequently.³⁰⁸ Second, regardless of the evidence, or lack thereof, in the record to support the quantity limit proposals, the Commission believes that it would be difficult to administer the proposed limits, and that rather than increasing patient eye health and safety, such proposals could have the opposite effect. For example, if a consumer is running out of contact lenses and does not have time to see a prescriber promptly, there is a significant chance that the consumer will not adhere to the recommended contact lens replacement schedule and will instead try to “stretch out” their lenses by re-wearing them until they can visit a prescriber. The failure to replace lenses is a well-documented cause of many contact-lens-related health issues.³⁰⁹ Absent empirical evidence that a substantial number of consumers are obtaining excessive amounts of contact lenses, or are not returning to their prescribers for eye examinations, the Commission believes that the risk of not replacing lenses outweighs the harm of consumers obtaining more lenses than strictly anticipated by the length of a contact lens prescription.

Nevertheless, the Commission is concerned about anecdotal reports that sellers are contacting patients and encouraging them to stockpile contact lenses prior to the expiration of their prescriptions in order to avoid visiting their eye care professionals. The Commission cautions sellers that such practices run counter to the spirit of the Act, and the Commission will look closely at these alleged practices.

The Commission also declines to propose that the Rule be amended to provide that a “contact lens prescription shall be valid for an unlimited quantity of lenses regardless of any prescriber-imposed limitation to the contrary.”³¹⁰ The commenter suggesting this amendment produced no evidence supporting the allegation that prescribers are using quantity limits to undercut the length of a prescription.

The Commission also notes that, as recognized during the initial rulemaking, some State laws or regulations may require prescribers to include quantity information on the prescription and some prescribers in other States without such requirements

²⁹⁸ See, e.g., Filandro (Comment #129); Kalman (Comment #150); Bainbridge (Comment #152); Anderson (Comment #185); Palermo (Comment #212); Sanders (Comment #235); Sanders (Comment #236); Smith (Comment #319); Chesen (Comment #350); Perichak (Comment #415); Witmeyer (Comment #418); Palmer (Comment #484); Pierzchala (Comment #500); Haefs (Comment #525); Johnson & Johnson Vision Care, Inc. (Comment #582); Tass (Comment #586); Ball (Comment #590); Alexander (Comment #666).

²⁹⁹ Kalman (Comment #150).

³⁰⁰ See, e.g., Milsky (Comment #559).

³⁰¹ Comment #621.

³⁰² CooperVision, Inc. (Comment #591).

³⁰³ Comment #568.

³⁰⁴ *Id.*

³⁰⁵ LD Vision Group (Comment #544).

³⁰⁶ *Id.*

³⁰⁷ 2005 Contact Lens Report, *supra* note 14, at 6 note 18 (citing two studies that found that just 12–20% of consumers purchase a year’s supply at a time).

³⁰⁸ Indeed, the Coalition for Patient Vision Care Safety indicated that “87 percent of contact lens patients had an eye exam last year.” Comment #621.

³⁰⁹ Cope, *supra* note 29, at 867 (“contact lens wearers who do not follow recommended contact lens replacement schedules have more complications and eye discomfort”).

³¹⁰ LD Vision Group (Comment #544).

may choose to include such information on the prescription. At this time, the Commission reiterates that such prescribers must not use quantity limits to frustrate the prescription expiration requirements of Section 315.6, and that the quantity specified in the prescription must be sufficient to last through the prescription's expiration date.³¹¹

Finally, the Commission also believes that the Rule, as currently drafted, is sufficient to address the quantity limit concerns posited by commenters. During the initial rulemaking, the Commission examined the issue of requiring quantity limits on prescriptions.³¹² At that time, the Commission concluded that it was not necessary to include the quantity of lenses on the prescription to limit patients' ability to circumvent the expiration date because the verification process would allow prescribers to prevent patients from ordering excessive contact lenses.³¹³ In this rule review, commenters raised concerns that the verification process was not an adequate safety net because the "verification process is not triggered when a patient provides a contact lens retailer with a complete copy of prescription" and the verification process is bypassed.³¹⁴ Accordingly, it is possible that consumers could use a copy of a prescription to shop at multiple retailers, or engage in other practices, in order to obtain excessive amounts of contact lenses.³¹⁵ Although it is possible that these practices could occur, there is no empirical evidence in the record to show the frequency or extent of such practices.³¹⁶

³¹¹ 69 FR at 40488. If the prescription specifies a lesser quantity of lenses or refills, the prescriber must have a legitimate medical reason for doing so, and the requirements imposed by Section 315.6(b) on writing a prescription for less than one year must be met. *Id.*

³¹² In reaching that determination, the Commission first noted that the Act did not require the inclusion of quantity information on the prescription. The Commission then discussed its concern that if quantity information was included, prescribers might use those quantity limits to impose prescription expiration dates that are effectively shorter than the one-year period imposed under the Act. 69 FR at 40488.

³¹³ 69 FR at 40488 (explaining that Section 315.5(b) requires verification requests to contain the quantity of lenses ordered, and that the quantity ordered may be a legitimate basis for a prescriber to treat a request for verification of a prescription as "inaccurate").

³¹⁴ American Optometric Association (Comment #644). See also Coalition for Patient Vision Care Safety (Comment #621).

³¹⁵ *Id.*

³¹⁶ For the same reasons, the Commission also declines to propose to amend the Rule per the American Optometric Association's proposal that the Commission limit the quantity of contact lens boxes that retailers advertise as being able to be

Other commenters encouraged the Commission to increase enforcement efforts to prevent consumers from obtaining more contact lenses than anticipated by the length of the prescription.³¹⁷ As already noted, if the Commission receives evidence that sellers are dispensing contact lenses in violation of the Rule, the Commission will investigate such allegations, as appropriate.

B. Private Label Lenses and Contact Lens Substitution

1. Private Label Lenses

A few sellers commented on the Rule provision regarding private label lenses.³¹⁸ Section 315.2 of the Rule defines private label contact lenses as "contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers."³¹⁹ A prescription for private label contact lenses, in addition to other required information, must include the name of the manufacturer, trade name of the private label brand, and if applicable, trade name of equivalent brand name.³²⁰ The Rule's requirements for private label lens prescriptions track the language of the Act.³²¹ Although most contact lenses are sold under their national brand name, some manufacturers also distribute their lenses to prescribers and retailers under private labels. Sometimes the private label is unique to that seller and other times the private label brand may be available at multiple outlets.³²²

LD Vision Group, an online contact lens retailer, asserted that manufacturers and prescribers design anticompetitive strategies involving private label lenses to "thwart consumer freedom."³²³ Specifically, the company contended

purchased at one time. Comment #644. In its comment, the American Optometric Association contended that it is possible that consumers could purchase large amounts of contact lenses from some online retailers; however, it did not provide support for this contention.

³¹⁷ See, e.g., Day (Comment #4); Mathai (Comment #33); Nelson (Comment #130); Hans (Comment #168); Garcia (Comment #511); Gandy (Comment #530); Tass (Comment #586).

³¹⁸ LD Vision Group (Comment #544); 1-800 CONTACTS (Comment #568).

³¹⁹ 16 CFR 315.2.

³²⁰ *Id.*

³²¹ See 15 U.S.C. 7610(3).

³²² 2005 Contact Lens Report, *supra* note 14, at 14-15.

³²³ Comment #544. LD Vision Group explained that manufacturers acquiesce to prescribers because it is the prescribers who select their patients' contact lenses. *Id.*; see also 1-800 CONTACTS (Comment #568) (commenting on manufacturers' strong incentives to cater to the interests of prescribers rather than consumers because prescribers determine the brand and modality of their patients' lenses).

that to keep consumers from purchasing contacts elsewhere, some prescribers "will provide unpopular or private-label lenses without published equivalents or for which the equivalents are confusing."³²⁴ For instance, the company stated that one private label "is purportedly available with an 8.3 or 8.6 base curve, while the brand name lens—though it is the exact same lens—is purportedly available with an 8.4 or 8.7 base curve."³²⁵ Another manufacturer, according to LD Vision Group, "offers four different lenses under a private label: Standard, plus, premium, and premium plus, but the national-label equivalents do not use the same identifiers."³²⁶ Although prescribers are required by the Rule to list equivalent information on the prescription, LD Vision Group asserted that prescribers do not always comply, and absent manufacturers' identification of equivalent lenses, "the retailer must either refuse to dispense unknown equivalents or make assumptions based on intentionally misleading private-label designations and risk dispensing the wrong lenses to the potential detriment of their customers' eye health."³²⁷ LD Vision Group did not quantify the extent of this problem, or provide empirical evidence as to its scope.³²⁸

In order to remedy the aforementioned issues, LD Vision Group proposed that the Commission amend the Rule to require prescribers to annotate a private label lens prescription with the brand-name equivalent and, if a name-brand equivalent is unavailable, the private label prescription must be medically necessary for that particular patient. It also recommended requiring manufacturers of contact lenses to disclose brand equivalency information on private label and brand-label packaging, or otherwise make it available to sellers.³²⁹

The Commission declines to propose to modify the Rule to implement these recommendations. Although the Act expressly requires that, in the case of private label contact lens prescriptions, prescribers include "trade name of equivalent brand name," the Act does

³²⁴ Comment #544.

³²⁵ LD Vision Group did not identify the private label or manufacturer engaged in this practice. Comment #544.

³²⁶ *Id.*

³²⁷ As discussed in Section V.B.2, *infra*, when sellers substitute lenses that are not identical to the prescribed contact lenses, they violate the Rule.

³²⁸ The Commission understands that sales of private label lenses comprise a small part of the market, and most major manufacturers do not sell private label lenses.

³²⁹ LD Vision Group (Comment #544).

not impose a requirement of medical necessity in order for a prescriber to prescribe a private label lens for which no name-brand equivalent exists.³³⁰ Nor does the Act expressly contemplate the imposition of disclosure requirements on manufacturers. However, nothing in the Act or Rule prohibits manufacturers from making brand equivalency disclosures on their packaging, or otherwise making such information available to sellers. The Commission understands that some, if not all, manufacturers who offer private labels already make this information readily available to retailers. Additionally, the Commission notes that it is a violation of the Rule for prescribers to fail to comply with their obligation to specify a brand equivalent, should one exist, when writing a prescription. The Commission encourages sellers and consumers to submit evidence of any such violations to the agency for possible enforcement action.

2. Alteration of Contact Lens Prescriptions by Sellers

Section 315.5(e) of the Rule prohibits sellers from altering a contact lens prescription.³³¹ Notwithstanding this prohibition, a seller may substitute for private label contact lenses specified on a prescription, “identical contact lenses that the same company manufactures and sells under different labels.”³³² The language of this Rule provision is substantively the same as the language of the Act, with one exception discussed below.³³³

The Commission received a number of comments, primarily from prescribers, that complained that online contact lens sellers are selling patients lenses different from those they prescribed.³³⁴ Prescribers expressed

³³⁰ In the initial rulemaking, sellers made a recommendation to open up the market by requiring prescribers, when prescribing private label contact lenses, to identify on the prescription the name of a brand that a consumer could purchase from a retailer other than the prescribing office. 69 FR at 40503. The Act does not limit, in any way, the brand that a prescriber must select and thus, the Commission concluded that such a requirement would go beyond the Act. *Id.* LD Vision Group’s similar proposal to limit prescribers from prescribing private label brands without a brand-equivalent, except in the case of medical necessity, fails for the same reason.

³³¹ 16 CFR 315.5(e).

³³² *Id.*

³³³ See 15 U.S.C. 7603(f).

³³⁴ See, e.g., Kapoor (Comment #58); Narayan (Comment #60); Thomas (Comment #61); Weinberg (Comment #87); Anderson (Comment #96); Hopkins (Comment #102); Johnson (Comment #109); O’Brien (Comment #127); Stewart (Comment #136); Hans (Comment #168); Hamilton (Comment #216); Gibson (Comment #217); Cassis (Comment #233); Chesen (Comment #321); Silver (Comment #349); McWilliams (Comment #362); Wittmann (Comment

concern that contact lenses are being treated like commodities, rather than restricted medical devices regulated by the FDA.³³⁵ These commenters contended that contact lenses, even those with similar refractive specifications, are not interchangeable.³³⁶ One commenter, a manufacturer, opined that “each brand is unique and proprietary to each manufacturer and designed to suit a different set of corresponding patient physiology and consumer needs.”³³⁷

Several prescribers and a manufacturer also explained that prescribers work with patients to fit them with the most compatible, safe, and effective contact lens and that each patient’s eyes react differently to individual brands.³³⁸ According to these commenters, when a patient receives a contact lens that is not identical to the one prescribed, those lenses have not been fit on the patient, may not be appropriate, and can even be harmful for the patient.³³⁹ Specifically, prescribers stated that scarring, infection, allergic reactions, corneal ulcers, impaired or even lost vision can result or have resulted from patients wearing lenses that were not

#421); Nett (Comment #449); Eggers (Comment #473); Kegarise (Comment #477); Kosunick (Comment #501); Wren (Comment #520); Lai (Comment #541); Hamada (Comment #603); Coalition for Patient Vision Care Safety (Comment #621); Maceyko (Comment #642); American Optometric Association (Comment #644).

³³⁵ Kelly (Comment #78); Callihan (Comment #187); Sancho (Comment #226); West (Comment #230); Nett (Comment #449); Vu (Comment #561); Reed (Comment #579). *Cf.* LD Vision Group (Comment #544) (calling lenses a “disposable commodity”).

³³⁶ See, e.g., Johnson & Johnson Vision Care, Inc. (Comment #582) (citing studies supporting this statement). A number of commenters similarly explained that because each contact lens fits the eye differently, there is no such thing as a generic contact lens. See, e.g., Jones (Comment #63); Miyamura (Comment #77); Jones (Comment #83); Easton (Comment #432).

³³⁷ Comment #582. Johnson & Johnson Vision Care, Inc. described several parameters that make a contact lens brand unique, including oxygen transmissibility, water content, iconicity, rigidity or modulus, silicone and fluorine content, lipid deposition, wettability/wetting agent, thickness, diameter, base curve, edge design, surface characteristics/treatments, modality, UV blocking, and interaction with care solutions. Other commenters mentioned modality (daily, two week replacement, or monthly), optical clarity, lifestyle, medical conditions, and current medications as factors influencing the prescriber’s selection of the contact lens to prescribe. Morgan (Comment #144); Assell (Comment #397).

³³⁸ See Sasner (Comment #182); Williams (Comment #261); Steinleitner (Comment #517); Nielson (Comment #565) (prescriber questioning why he learned how to fit contact lenses if patients can get any lens they want without his input); Johnson & Johnson Vision Care, Inc. (Comment #582).

³³⁹ *Id.*

prescribed.³⁴⁰ A few prescribers described patients who, after wearing lenses that had not been prescribed for them, could no longer wear contact lenses or whose vision could no longer be fully corrected.³⁴¹

As to the source of the alteration problem, commenters pointed to both online sellers as well as patients. Commenters, almost exclusively prescribers, asserted that sellers want to maximize their profits and may have little to no consideration for their customers’ eye health,³⁴² and that patients switch brands to obtain cheaper lenses or seek brands they have seen in commercials.³⁴³ Some prescribers also stated or implied that these substitutions occur as a result of the passive verification system, and encouraged the Commission to adopt an active verification system.³⁴⁴

It is unclear how frequently illegal substitutions are occurring, or how many sellers are engaged in this activity. In its comment, Johnson & Johnson Vision Care, Inc. cited to a 2015 online survey conducted on its behalf that found that “one-in-four online consumers report having received a different brand of contact lenses than they had ordered without being given advanced warning they were getting another brand.”³⁴⁵ Even assuming the survey methodology is sound and the stated conclusion of the survey is accurate, it is not clear whether the positive responses reflect instances

³⁴⁰ Williford (Comment #38); Kapoor (Comment #58); Jones (Comment #63); Morgan (Comment #144); Herve (Comment #148); Sausner (Comment #182); McWilliams (Comment #362); Elmore (Comment #396); Wittmann (Comment #421); Kegarise (Comment #447); Sirotkin (Comment #464); Abbott (Comment #497); Wren (Comment #520); Evans (Comment #523); Hamada (Comment #603); Capps (Comment #610); Coalition for Patient Vision Care Safety (Comment #621); Vehab (Comment #622); Mortenson (Comment #636); Maceyko (Comment #642).

³⁴¹ Schram (Comment #184); McWilliams (Comment #362).

³⁴² Nguyen (Comment #82); Eggers (Comment #473); Lupinski (Comment #499); Nielsen (Comment #565). Other prescribers are concerned that they will be liable or at risk of losing their licenses if the substitution causes the consumer harm. See, e.g., Carroll (Comment #5); Thomas (Comment #61).

³⁴³ LaDouceur (Comment #178); Schram (Comment #184); Marler (Comment #504); Vehab (Comment #622).

³⁴⁴ Prescribers contend that after sellers convince patients to order different lenses than those prescribed, or patients give sellers the name of a lens not identical to the prescribed lens, the sellers send a verification request containing the non-prescribed lenses, and those requests are sometimes passively verified. Eggers (Comment #473); Wren (Comment #520). As previously explained, *see supra* Section IV.C.1, the Commission lacks authority to eliminate the passive verification system.

³⁴⁵ Comment #582.

when sellers made illegal alterations or, alternatively, instances when consumers ordered a brand other than the prescribed brand and the prescribers then corrected the prescriptions. Nor is it clear whether positive responses include instances where eye care professionals prescribed private label lenses and sellers appropriately substituted them with identical lenses, made by the same manufacturer and sold under a different label, as expressly permitted by Section 315.5(e). Because one cannot tell the percentage that was the result of unauthorized alterations, the survey data is not conclusive.³⁴⁶

The Commission notes that unauthorized alterations violate the Rule as currently written, and thus there is no need to amend the Rule to address this issue.³⁴⁷ In some cases, patients may request to purchase a brand of lenses not identical to the one prescribed. In those instances, the seller may include the wrong brand in the verification request. If any of the information required by Section 315.5(b)(2) to be included in the verification request is incorrect, prescribers are encouraged to provide the correct information to the seller.

Several commenters requested that the Commission better enforce the Rule against sellers that engage in illegal substitutions.³⁴⁸ If the Commission receives evidence that sellers are engaged in illegal substitutions, the Commission will investigate the allegations, as appropriate.³⁴⁹

³⁴⁶ Other seemingly relevant survey questions, one of which a commenter cited to, may be similarly flawed. For example, the Coalition for Patient Vision Care Safety pointed out that 31% of respondents answered positively when asked: "When buying contact lenses online or over the phone in the past, has the company you were ordering from ever informed you that they do not carry or do not currently have stocked, the brand of contact lenses on your prescription, and advised you to get another brand of contact lenses instead?" Comment #621. In response to a subsequent survey question, 80% of those respondents indicated that they "then order[ed] that other brand of contact lenses." The Commission notes that positive responses to these questions do not necessarily reflect a violation of the Rule. For example, a prescriber changing a prescription to a different lens in the interim would thereby render the sale proper.

³⁴⁷ Because prescription alteration violates the Rule, the Commission need not make its own assessment of Johnson & Johnson Vision Care, Inc.'s and numerous prescribers' statements concerning the non-interchangeability of lenses and the resulting eye health risks.

³⁴⁸ Thomas (Comment #61); Lai (Comment #541); Johnson & Johnson Vision Care, Inc. (Comment #582).

³⁴⁹ The Commission notes that the prescriber has the ability to block an illegal substitution by actively responding to a verification request for a non-prescribed lens and indicating its invalidity. In fact, in circumstances where a consumer selects a non-prescribed brand, the prescriber is likely the only one who can "catch" the error.

Lastly, one commenter, an optometrist, recommended that a retailer should be required to warn or educate patients about the potential consequences of changing brands or other parameters without a doctor's authorization through a "statement of education" with every order, warning patients that "contact lenses are a medical device and the wearing of or changing of a brand or prescription without a doctor's authorization is illegal and could result in damage, even blindness to the recipient."³⁵⁰ The Commission declines to modify the Rule in such a fashion. Although the Commission does not take issue with the importance of educating patients about the need to consult their prescriber before switching contact lens brands, and encourages sellers, prescribers, and manufacturers to do so, we have no evidence that the benefit of imposing such a requirement on sellers would outweigh the costs.

Through discussions with industry members, it has come to the Commission's attention that in addition to prescribers, some other sellers market and sell private label contact lenses that are identical to, and are made by the same manufacturer as, brand name contact lenses. As a result, when a patient presents a contact lens prescription for brand name contact lenses to certain sellers, those sellers may wish to sell, as a substitute, their own private label lenses to the patient. The language of the Act clearly permits substitution in cases where the same contact lenses are manufactured by the same company and sold under multiple labels to individual providers.³⁵¹ Although the Rule similarly permits a seller to substitute lenses that are identical to, and are made by the same manufacturer as, the one listed on the prescription,³⁵² the language set forth in Section 315.5(e) of the Rule could be read to limit such substitution to instances where private label lenses are listed on the prescription and the seller wishes to substitute brand name lenses.³⁵³

The Commission recognizes that the current construction of Section 315.5(e) of the Rule does not conform to the language or intent of the Act. The clear language of the Act allows sellers to substitute private label lenses for brand name lenses when the substituted lenses are "manufactured by the same

company and sold under multiple labels to individual providers."³⁵⁴ To conform the Rule to the Act, the Commission proposes to strike the words "private label" from Section 315.5(e) and seeks comment on its proposal. The definitions in the Rule of a "contact lens prescription" and of a "private label contact lens" would remain unchanged.

C. HIPAA Issues

The Commission received a few comments that identified concerns with how the Rule's verification framework interacts with the Health Insurance Portability and Accountability Act of 1996³⁵⁵ ("HIPAA") Privacy and Security Rules ("HIPAA Rules").³⁵⁶ One prescriber expressed the opinion that the Contact Lens Rule's verification system was in direct conflict with HIPAA and detailed his attempts to procure HIPAA authorizations from his patients prior to releasing the prescription to a third-party seller.³⁵⁷ Another commenter recommended that HIPAA should apply to the verification process and that any verification request should be accompanied by an authorization signed by the patient.³⁵⁸ A third commenter expressed concern that automated telephonic verification requests were in direct violation of HIPAA because the patient's personal information was relayed to the person answering the telephone, without any mechanism to ensure that it was the intended recipient.³⁵⁹ A few prescribers also complained that sellers' practices of trying to obtain prescriptions without patient authorization violated HIPAA.³⁶⁰

Other commenters stated that some prescribers were not complying with the Contact Lens Rule and were using HIPAA to avoid doing so. One seller complained that "[s]ome prescribers will still refuse to verify even with the law in place, stating (incorrectly) that HIPAA or a state privacy rule prohibits

³⁵⁴ 15 U.S.C. 7603(f). Although the Commission imagines it would be quite rare, it believes a seller should be permitted under the Rule to substitute one private label lens for another private label lens as long as the lenses are identical.

³⁵⁵ Public Law 104-191 (Aug. 21, 1996).

³⁵⁶ 45 CFR parts 160, 164.

³⁵⁷ Ciszek (Comment #134).

³⁵⁸ Pao (Comment #181).

³⁵⁹ Stuart (Comment #635) (consumers' "personal and medical information is currently being transmitted unsecured to a third party by using an automated phone verification system").

³⁶⁰ St. Martin (Comment #292) ("their phishing for prescriptions should be considered a HIPAA violation because often this is done without the patient's permission"). See also Vensand (Comment #59) (expressing concern about the acquisition and sale of patient information); Ciszek (Comment #134) (complaining that sellers are calling of their own accord, without the patient initiating the request).

³⁵⁰ Kegarise (Comment #447).

³⁵¹ 15 U.S.C. 7603(f).

³⁵² 16 CFR 315.5(e).

³⁵³ Section 315.5(e) modifies "contact lenses" with the term "private label," but the Act does not contain that modifier. Cf. 15 U.S.C. 7603(f).

release of the prescription and that only the patient can ask for it.”³⁶¹ Likewise, the National Association of Optometrists and Opticians noted that it was “aware of instances where prescribers incorrectly inform patients that HIPAA or other laws require a written authorization from the patient or face-to-face requests by the patient to the prescriber.”³⁶² This commenter recommended that the Commission make clear to prescribers, sellers, and consumers that HIPAA does not prevent compliance with the Rule’s verification process and that to claim otherwise is an unfair and deceptive practice.³⁶³

The Commission reiterates that the HIPAA Privacy Rule does not restrict prescribers’ ability to provide or verify contact lens prescriptions under the Rule.³⁶⁴ As a preliminary matter, HIPAA does not require submission of a HIPAA authorization for the prescriber to release a contact lens prescription to a patient.³⁶⁵ Furthermore, as the Commission explained in the initial rulemaking, the HIPAA Privacy Rule permits a HIPAA covered entity, such as a covered prescriber, to disclose protected health information (“PHI”) without patient authorization for “treatment” purposes or when “required by law,” as well as for other specified purposes.³⁶⁶ Providing, confirming, or correcting a prescription for contact lenses for a contact lens seller as contemplated under the Contact Lens Rule constitutes “treatment” under the HIPAA Privacy Rule.³⁶⁷ In addition, to the extent the

disclosure of PHI to provide, confirm, or verify a contact lens prescription is required under the Act and the Rule, such disclosure constitutes a disclosure “required by law” under the HIPAA Privacy Rule.³⁶⁸ For these reasons, patient authorization is not required for a prescriber to provide or verify a contact lens prescription with the contact lens seller, or to provide a contact lens prescription to the patient.³⁶⁹

In addition to the comments submitted in this rule review, the Commission has received other questions and complaints related to prescribers’ HIPAA obligations under the Rule. For example, one prescriber asked whether HIPAA precluded his office from emailing a copy of a prescription to a patient without written authorization if the email communication was not encrypted. Correspondingly, some consumers have complained that their eye care practitioners have refused to email contact lens prescriptions to them.

As a threshold matter, the Contact Lens Rule itself contemplates email communication, stating that the prescriber shall “provide or verify” the prescription “by electronic or other means.”³⁷⁰ Further, the HIPAA Rules do not preclude covered prescribers from emailing contact lens prescriptions to patients or sellers. According to guidance provided by the U.S. Department of Health & Human Services, the HIPAA Rules allow health care providers to communicate electronically with patients, provided they apply reasonable safeguards.³⁷¹ Although a covered provider must consider encryption to protect against unintentional disclosures, the provider may determine that it is not reasonable

and appropriate, and may instead apply precautions when transmitting unencrypted email, such as checking the email address for accuracy before sending, sending an email alert to the intended recipient for address confirmation prior to sending the message, and limiting the amount and type of PHI transmitted through the email.³⁷²

Regardless, where an individual requests that the covered entity transmit PHI by unencrypted email, as is their right under the HIPAA Privacy Rule right of access, a covered entity must do so.³⁷³ Before sending unencrypted email containing PHI to a patient, the entity should advise the patient of the risk that the unencrypted PHI could be intercepted and accessed by unauthorized third parties. If, after having been advised of the risks the patient still prefers to receive his or her PHI via unencrypted email, the patient has the right to receive the PHI in that manner and the covered entity is not responsible for unauthorized access to the PHI during electronic transmission, nor is the covered entity responsible for safeguarding the PHI once delivered to the patient.³⁷⁴ Conversely, a covered prescriber also must honor a patient’s reasonable request that the prescriber *not* send communications via unencrypted email, by offering other means, such as encrypted email, secure patient portal, postal mail, or telephone.³⁷⁵

D. Enforcement Efforts

In addition to proposing amendments to specific Rule provisions to further the Rule’s goals of competition and patient welfare, several commenters also urged the Commission to increase its enforcement efforts and stressed the importance of enforcing the Rule to ensure that its benefits are realized and

³⁷² Encryption of PHI must be implemented where a covered entity has determined that it is a reasonable and appropriate safeguard as part of its risk management. See U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Is the use of encryption mandatory in the Security Rule?,” <http://www.hhs.gov/hipaa/for-professionals/faq/2001/is-the-use-of-encryption-mandatory-in-the-security-rule/index.html>. A covered health care provider also must protect PHI in those emails while they are stored on servers, workstations, mobile devices, and other computer systems, through encryption and other safeguards, as appropriate. See 45 CFR 164.306(a).

³⁷³ 45 CFR 164.524(c). See also U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Individuals’ Right under HIPAA to Access their Health Information 45 CFR 164.524,” <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/>.

³⁷⁴ 78 FR 5634 (Jan. 25, 2013).

³⁷⁵ 45 CFR 164.522(b).

³⁶¹ LD Vision Group (Comment #544).

³⁶² Comment #549.

³⁶³ *Id.*

³⁶⁴ 69 FR at 40501.

³⁶⁵ See 45 CFR 164.502(a)(1); U.S. Dep’t of Health & Human Servs., Office for Civil Rights, “Summary of the HIPAA Privacy Rule” 4–5 (2003), <http://www.hhs.gov/sites/default/files/privacysummary.pdf> (“A covered entity is permitted . . . to use and disclose protected health information, without an individual’s authorization, for the following purposes or situations: (1) To the Individual (unless required for access or accounting of disclosures); (2) Treatment, Payment, and Health Care Operations; (3) Opportunity to Agree or Object; (4) Incident to an otherwise permitted use and disclosure; (5) Public Interest and Benefit Activities; and (6) Limited Data Set for the purposes of research, public health or health care operations. Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.”) (footnote omitted).

³⁶⁶ 69 FR at 40501.

³⁶⁷ *Id.* See also Standards for Privacy of Individually Identifiable Health Information, 67 FR 53182, 53219 (Aug. 14, 2002). The U.S. Department of Health & Human Services has explained further that “disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is a treatment disclosure and is permitted under the Privacy Rule at 45 CFR 164.506.” See U.S. Dep’t Health & Human Servs.,

Health Information Privacy, FAQs, “Does the HIPAA Privacy Rule permit an eye doctor to confirm a contact prescription received by a mail order contact company?,” <http://www.hhs.gov/hipaa/for-professionals/faq/270/does-hipaa-permit-an-eye-doctor-to-confirm-a-contract-prescription-from-a-mail-order-company/index.html>.

³⁶⁸ See 45 CFR 164.512(a).

³⁶⁹ In addition, the HIPAA Privacy Rule right of access requires a covered prescriber to provide to the patient upon request or to another person she designates a copy of a prescription. See 45 CFR 164.524(c)(3). See also U.S. Dep’t Health & Human Servs., Health Information Privacy, HIPAA Guidance, “Individuals’ Right under HIPAA to Access their Health Information,” <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/>.

³⁷⁰ 16 CFR 315.3(a)(2).

³⁷¹ U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Does the HIPAA Privacy Rule permit health care providers to use email to discuss health issues and treatment with their patients?,” <http://www.hhs.gov/hipaa/for-professionals/faq/570/does-hipaa-permit-health-care-providers-to-use-email-to-discuss-health-issues-with-patients/>. See also 45 CFR 164.530(c).

its risks minimized.³⁷⁶ For example, several optometric associations urged the Commission to enforce the basic patient safeguards outlined in the Act to protect patients and reduce unnecessary costs.³⁷⁷ These commenters argued that the sale of contact lenses without a valid prescription increases risks for patients and ultimately leads to higher health costs, and called for the Commission to take action against retailers selling lenses without a valid prescription.³⁷⁸ The Coalition for Patient Vision Care Safety asserted that “noncompliance with and loopholes within the law have resulted in a deceptive flow of information to contact lens patients, and have the potential to compromise seriously the vision health of patients.”³⁷⁹ Many individual prescribers also urged the Commission generally to increase enforcement of the Rule.³⁸⁰

On the other hand, online retailers such as 1-800 CONTACTS and Warby Parker recommended increased enforcement efforts against non-compliant prescribers, particularly with respect to the automatic release of prescriptions.³⁸¹ These commenters complained that despite “the widespread refusal of prescribers to release prescriptions,” Commission

action against prescribers has been limited to a handful of warning letters.³⁸² These commenters proposed that the Commission amend Section 315.9 of the Rule, the enforcement provision, to add language to clarify that any violation of the Rule—*by either sellers or prescribers*—constitutes a violation of a rule under Section 18 of the Federal Trade Commission Act, subject to the same fines and penalties as any other violation of the Act.³⁸³

With respect to commenters’ recommendations that the Commission increase its enforcement efforts, the Commission notes that the rule review process has been instrumental in identifying areas that need further investigation. Accordingly, the Commission will consider ways to leverage its enforcement, consumer education,³⁸⁴ and business guidance efforts to address the concerns identified.³⁸⁵ However, the Commission does not believe it necessary to amend Section 315.9 of the Rule to clarify that violations by either sellers or prescribers constitute a violation of the Rule under Section 18 of the Federal Trade Commission Act. The language of the Act and Rule are clear on this point.³⁸⁶

E. Recommendations Regarding the Commission’s Complaint Reporting System

The Commission received a variety of comments suggesting proposals to improve perceived shortcomings in the agency’s complaint reporting system to aid Rule enforcement efforts. Several optometric associations, for example, expressed their opinion that the

Commission’s consumer reporting process is not adequately designed to deal with contact lens complaints, and recommended that the Commission “develop a distinct complaint submission process for contact lens-related concerns.”³⁸⁷ More specifically, the American Optometric Association asserted that the online complaint assistant service is not appropriately set up to receive these types of complaints, and doctors who report issues of concern often feel their reports go unnoticed.³⁸⁸ This commenter stated that setting up a distinct Contact Lens Rule complaint system would benefit patients as well, providing them with a simple process to follow in case they have contact lens sale-related concerns.³⁸⁹ Likewise, the Coalition for Patient Vision Care Safety was troubled that the agency “routes eye contact complaints about non-compliance to its general complaint lines” and asserted that the general routing of complaints discourages the reporting of complaints and fails to provide the Commission with adequate and accessible information to enforce the Rule.³⁹⁰ The Coalition recommended that the Commission instead utilize dedicated personnel paired with a dedicated Web site or phone number within the Commission.³⁹¹

Other commenters expressed doubts that the complaint reporting system was adequate to capture specific types of complaints. For example, two State representatives, Rhode Island State Rep. Brian Patrick Kennedy and Arizona State Rep. Heather Carter, asserted that the current system favors eye care providers and their ability to file complaints against resellers of contact lenses.³⁹² These commenters recommended that the Commission consider simplifying the complaint process to make it easier for consumers

³⁷⁶ See, e.g., Barr (Comment #639).

³⁷⁷ American Optometric Association (Comment #644); Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595). See also American Academy of Ophthalmology (Comment #611) (“Wearing improper lenses can further complicate existing vision issues, including leading to infection in the eye. The sale of lenses without a prescription is a practice that continues despite the Rule, and the Academy believes that the Commission should take swift action to improve enforcement of the Rule.”).

³⁷⁸ *Id.*

³⁷⁹ Comment #621.

³⁸⁰ See, e.g., Filandro (Comment #129); Sandler (Comment #135); Jankowski (Comment #153); Hans (Comment #168); Nguyen (Comment #175); Robertson (Comment #180); Schumacher (Comment #193); Sisson (Comment #254); Frederick (Comment #269); Bolenbaker (Comment #357); Yamamoto (Comment #408); Palmer (Comment #484); Williams (Comment #494); Marler (Comment #504); Koop (Comment #506); Korth (Comment #516); Lai (Comment #541); Piersol (Comment #571). See also Senator Perdue (Comment #569).

³⁸¹ 1-800 CONTACTS (Comment #568); Warby Parker (Comment #593).

³⁸² *Id.*

³⁸³ 5 U.S.C. 57a.

³⁸⁴ The state optometric associations also encouraged the Commission to do more to “ensure that patients are aware that contact lenses are regulated medical devices, whose safe use and optimal performance depends on eye examinations and professional supervision.” Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

³⁸⁵ Furthermore, the Commission believes that the proposed Rule amendment requiring a signed acknowledgment of receipt of a contact lens prescription will also aid Rule enforcement efforts. See *supra* Section III.A.3.

³⁸⁶ See 15 U.S.C. 7608; 16 CFR 315.9.

³⁸⁷ American Optometric Association (Comment #644); Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

³⁸⁸ Comment #644.

³⁸⁹ *Id.*

³⁹⁰ Comment #621.

³⁹¹ *Id.*

³⁹² Comments #536, 545.

to file complaints against their eye care provider, as well as replacement contact lens resellers. Likewise, some online retailers recommended that to facilitate enforcement efforts the Commission should “create a user-friendly online complaint process for consumers.”³⁹³ These commenters argued that the online complaint assistant is difficult to navigate and does not ask the appropriate questions to identify a Rule violation.³⁹⁴

After careful consideration of these comments, the Commission declines to redesign its complaint reporting mechanism. The Commission has designed the FTC Complaint Assistant, the agency’s online complaint reporting system, to be responsive to consumers who wish to file complaints about more than a hundred different types of products or services, while at the same time facilitating the filing of complaints regarding the most common complaint areas. Accordingly, the home page of the complaint system contains primary links for the FTC’s seven most common complaint areas. The Commission’s goal is that the primary links on the home page be responsive to at least 80 percent of the consumer complaints the agency receives. Although highlighting the most frequent types of complaints necessarily means that many areas of concern cannot be listed as separate categories, users can easily submit their complaint under the category “Other” when there is no listed category for the complaint, as is the case with contact lenses. Once the “Other” category is selected, the subsequent Web page includes the “Health and Fitness” subcategory, which is described as including, “prescriptions, eye care.” After screening out complaints related to telemarketing phone calls and spam email, the first option on the following Web page asks whether the complaint relates to “Eyeglasses or Contact Lenses.” During this process, the person lodging the complaint is given ample room to describe the details of the complaint.

Instructions on the FTC Complaint Assistant page explain that the FTC will categorize a complaint even if it does not fit one of the listed categories. In addition, the Web page also informs users that if they are “having trouble categorizing [their] complaint,” they can chat online with FTC tech support.

³⁹³ 1–800 CONTACTS (Comment #568); Warby Parker (Comment #593). See also LD Vision Group (Comment #544) (recommending that the Commission “[c]reate an online reporting mechanism for sellers and consumers to report unfair prescriber practices”).

³⁹⁴ 1–800 CONTACTS (Comment #568); Warby Parker (Comment #593).

Accordingly, the Commission believes that the FTC Complaint Assistant is configured to capture and report all contact lens-related complaints, whether they originate from consumers, prescribers, sellers, or others. However, resources permitting, the Commission will explore whether a dedicated email address would also be beneficial to complement the Complaint Assistant.

VI. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 30, 2017. 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, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Web site. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a 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, do not include any “[t]rade secret or any commercial or financial information which is . . . privileged or confidential,” as discussed in 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). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 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.

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://ftcpublic.commentworks.com/ftc/contactlensrule> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov#!/home>, you also may file a comment through that Web site.

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 C), 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 C), Washington, DC 20024.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice 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 January 30, 2017. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <http://www.ftc.gov/ftc/privacy.htm>.

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 NPRM:

1. What benefits would a proposed change confer and on whom? The Commission in particular seeks information on any benefits a change would confer on consumers of contact lenses.

2. What costs or burdens would a proposed change impose and on whom? The Commission in particular seeks information on any burdens a change would impose on small businesses.

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

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

5. What evidence supports your answers?

B. Acknowledgment of prescription release:

1. Would the proposed amendment to require prescribers, after the completion of a contact lens fitting, to request the contact lens patient acknowledge receipt of the contact lens prescription by signing an acknowledgment form 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. Would the proposed amendment to require prescribers to maintain copies of the signed acknowledgments for a period of not less than three years increase, decrease, or have no effect on the Commission's ability to measure and enforce the Rule's automatic prescription release provision? Why?

3. Would the proposed amendment to require the acknowledgment form to inform patients that they may purchase contact lenses from the seller of their choice increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

4. Should the Commission consider other language to be included in the signed acknowledgment form? If so, what?

5. Would allowing the acknowledgment form to be in either paper or electronic format increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? What other

factors should the Commission consider to lower the cost and improve the reliability of executing, storing, and retrieving the signed acknowledgment forms?

6. Should the proposed amendment contain specific language about the use of electronic acknowledgment forms and electronic signatures? If so, what? Should the proposed amendment contain particular requirements about the type of electronic acknowledgment forms and electronic signatures to be used? If so, what types should be required?

7. Are there alternate ways to structure a patient acknowledgment requirement that would reduce the burdens of the proposed amendment while providing the same, or greater, benefits?

8. What evidence supports your answers?

C. Additional mechanisms for improving prescription portability:

1. The Commission believes that the use of patient portals to provide patients with access to electronic copies of their prescriptions would benefit prescribers, sellers, and patients. The Commission seeks comment on the benefits or burdens that the use of patient portals would confer.

2. The Commission seeks comment on the level of adoption of patient portals. Do prescribers use patient portals? Do patients use them? What are the rates of patient adoption when prescribers make them available?

3. What characteristics should patient portals have in order to best promote prescription portability?

4. Do patient portals have the potential to allow prescribers to comply with the automatic prescription release requirements of the Rule? If so, how? Do patient portals have limitations that would prevent them from being used by prescribers to comply with the automatic prescription release requirements of the Rule? If so, what are they?

5. If the Commission were to determine that patient portals could be used to comply with the automatic prescription release requirements of the Rule, how would this determination affect the requirement that prescribers obtain a signed acknowledgment form from patients? Do patient portals have characteristics that could serve as a substitute for the signed acknowledgment form?

6. What other technologies are available that could be implemented to improve prescription portability and thereby increase benefits and decrease burdens related to prescription release?

7. What evidence supports your answers?

D. Additional copies of prescriptions:

1. In this NPRM, the Commission has preliminarily determined that requiring prescribers to provide additional copies of contact lens prescriptions to a patient upon request is required by the Act. How does this determination affect, if at all, the portability of contact lens prescriptions?

2. Does this determination affect the accuracy of contact lens prescriptions presented to sellers? If so, how?

3. Does this determination affect the administrative burden of prescribers? If so, how? Would any burden caused by this determination be offset by a reduced burden related to prescription verification requests? If so, how?

4. What evidence supports your answers?

E. Sellers designated to act on behalf of patients:

1. Should the Commission impose a timeframe for prescribers, under Section 315.3(a)(2) of the Rule, to respond to requests from authorized third parties for a copy of a patient's prescription?

2. If so, what would be the appropriate amount of time for a prescriber to be required to respond to a request from an authorized third party for a copy of a patient's prescription?

3. What evidence supports your answers?

F. Presentation of prescription "directly or by facsimile" under Section 315.5(a)(1):

1. The Commission has initially determined that presenting a prescription to a seller "directly or by facsimile" includes the use of online patient portals. Does this determination further the Act's goal of prescription portability? If so, how?

2. What is the impact, including costs and benefits, of this determination?

3. What evidence supports your answers?

G. Automated telephone systems as "direct communication" under Section 315.5(a)(2):

1. What modifications to automated telephone calls, short of prohibiting the use of such calls, should the Commission consider to address the concerns raised by prescribers about the burden of such calls?

H. Section 315.5(e)—No alteration of prescription provision:

1. To conform the language of the Rule to the language of the Act, the Commission proposes to amend Section 315.5(e) to strike the words "private label." Would this proposed amendment alter the way that prescribers, sellers, or manufacturers do business, and if so, how?

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

3. What evidence supports your answers?

VII. 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).

VIII. 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 Office of Management and Budget ("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 obtain from patients, and maintain for a period of not less than three years, a signed acknowledgment form, entitled "Patient Receipt of Contact Lens Prescription," confirming that patients received their contact lens prescriptions at the completion of their contact lens fitting. The proposed recordkeeping requirement would 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. The Commission will also submit this notice of proposed rulemaking and associated Supporting Statement to OMB for review under the PRA. The proposed requirement that prescribers provide an acknowledgment form to patients, however, does not constitute an information collection under the PRA, in that the Rule specifies the language that the form must contain.³⁹⁵

A. Estimated Additional Hours Burden

Commission staff estimates the paperwork 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 maintain the signed acknowledgment

³⁹⁵ The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a "collection of information." 5 CFR 1320.3(c)(2).

forms 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.³⁹⁶ Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 41 million people would read and sign an acknowledgment form every year.³⁹⁷

Maintaining the form for a period of not less than three years does not impose a substantial new burden on individual prescribers and their office staff. The majority of states already require that optometrists maintain records of eye examinations for at least three years,³⁹⁸ and maintaining a one-page acknowledgment form per patient per year should not take more than a few seconds of time, and an inconsequential, or *de minimis*, amount of record space. Some prescribers might present the acknowledgment form electronically, and such format would allow the signed acknowledgment to be preserved without any additional burden. For other prescribers, the new recordkeeping requirement would likely require that office staff either preserve the signed acknowledgment form in paper format or electronically scan the signed acknowledgment form and save it as an electronic document. In the latter scenario, the Commission estimates this scanning and saving would take approximately one minute. The Commission does not possess any information regarding the percentage of prescribers' offices that use paper forms, electronic forms, or that scan paper files and maintain them electronically. Therefore, for purposes of this notice, staff will assume that *all* prescriber offices require a full one minute per form per year for record maintenance purposes arising from the proposed modifications.

As noted above, the number of contact lens wearers in the United States is currently estimated to be approximately

³⁹⁶ Cope, *supra* note 29, at 866.

³⁹⁷ In the past, some commentators have suggested that typical contact lens wearers obtain annual exams every 18 months or so, rather than one every year. However, because most prescriptions are valid for a minimum of one year under the Rule, and use of a longer exam cycle would lead to an estimate of a lower number of signed acknowledgment forms and a reduced burden, we continue to estimate that patients seek exams every 12 months.

³⁹⁸ See, e.g., 246 Mass. Code Regs. § 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code § 246-851-290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645-182.2(2) (requiring optometrists to maintain patient records for at least five years); Fla. Admin. Code r. 64B13-3.003(6) (requiring optometrists to maintain patient records for at least five years).

41 million. Therefore, assuming one signed acknowledgment form for each contact lens wearer per year, prescribers' offices, collectively, would have to spend approximately 41 million minutes, or 683,333 hours, per year maintaining records of eye examinations (recordkeeping requirement).

In all likelihood, the actual overall increased burden on prescribers may be less than 683,333 hours, because increasing the number of patients in possession of their prescriptions should correspondingly increase the number of consumers who provide their prescriptions to third-party sellers when purchasing contact lenses. This, in turn, should reduce the number of verification requests that third-party sellers would otherwise make to prescribers. Based on current estimates, responding to verification requests requires that prescribers spend approximately five minutes per request.³⁹⁹ The Commission, however, does not presently have enough information to devise a reliable estimate for how many more consumers are likely to present third-party sellers with a complete copy of their prescription following the proposed Rule modification. Therefore, for purposes of calculating the burden, the Commission, at this time, will not credit the expected reduction in verification burden.

B. Estimated Total Labor Cost Burden

Commission staff derives labor costs by applying appropriate hourly cost figures to the burden hours described above. The Commission assumes that office clerks will perform most of the labor when it comes to printing, disseminating, and storing the acknowledgment forms for prescribers' offices. According to Bureau of Labor Statistics, general office clerks earn an average wage of \$15.33 per hour.⁴⁰⁰ Based on this data, the estimated total additional labor cost attributable to the proposed modifications to the Rule would amount to approximately \$10,475,495.

While not insubstantial, this amount constitutes just under one-fourth of one percent of the estimated overall retail market for contact lens sales in the

³⁹⁹ See American Optometric Association, Comment in response to the Agency Information Collection Activities; Proposed Collection; Comment Request, 81 FR 31938 (May 20, 2016), <https://www.ftc.gov/policy/public-comments/initiative-665>.

⁴⁰⁰ Press Release, U.S. Dep't of Labor, Bureau of Labor Statistics, "Occupational Employment Statistics—May 2015," <http://www.bls.gov/news.release/ocwage.t01.htm>.

United States.⁴⁰¹ Furthermore, the burden is likely to be less, because many prescribers' offices will not require a full minute to store the acknowledgment form. And, as noted above, increasing the number of patients in possession of their prescriptions should correspondingly increase the number of consumers who provide their prescriptions to third-party sellers when purchasing contact lenses. This, in turn, could potentially reduce the number of verification requests made to prescribers, and the time prescribers spend responding.

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 shall have practical utility; (2) the accuracy of the FTC's burden estimates, including whether the methodology and assumptions used are valid; (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 information collection requirements subject to review under the PRA should also be submitted to Office of Management and Budget. If sent by U.S. mail, address comments 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 should be sent by facsimile to (202) 395-5167.

IX. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA")⁴⁰² requires the Commission to conduct an analysis of the anticipated economic impact of the proposed amendments on small entities.⁴⁰³ 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 RFA⁴⁰⁴ 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 they may affect a substantial number of small businesses. The proposed amendments require that prescribers obtain from patients, and maintain for a period of not less than three years, a signed acknowledgment form, entitled "Patient Receipt of Contact Lens Prescription," confirming that patients received their contact lens prescriptions at the completion of their contact lens fitting. The Commission believes the burden of complying with this requirement likely will be relatively small. As discussed in the Paperwork Reduction Act section, the majority of states already require that optometrists maintain records of eye examinations for at least three years. The proposed amendment would require one additional page to be maintained as a record, which is likely a minimal burden. 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 proposes amending the Rule to ensure that patients are receiving a copy of their contact lens prescription at the completion of a contact lens fitting.

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

The objective of the proposed amendment 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.⁴⁰⁵ The Act authorizes the Commission to implement its requirements through the issuance of rules.

C. Small Entities to Which the Proposed Amendments Will Apply

The proposed amendments apply to prescribers of contact lenses. The Commission believes that many prescribers will fall into the category of small entities (e.g., offices of optometrists less than \$7.5 million in size).⁴⁰⁶ Determining a precise estimate of the number of small entities covered by the Rule's prescription release requirements is not readily feasible because most prescribers' offices do not release the underlying revenue information necessary to make this determination.⁴⁰⁷ Based on its knowledge of the eye care industry, staff believes that a substantial number of these entities likely qualify as small businesses. The Commission seeks comment with regard to the estimated number or nature of small business entities, if any, for which the proposed amendments would have a significant impact.

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

As explained earlier in this document, the proposed amendments require that prescribers obtain from patients, and maintain for a period of not less than three years, a signed acknowledgment form, entitled "Patient Receipt of Contact Lens Prescription," confirming that patients received their contact lens prescriptions at the completion of their contact lens fitting.

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 acknowledgment form and clerical personnel to collect signatures from patients and maintain records. The Commission believes the burden imposed on small businesses by these requirements is relatively small, for the reasons described previously in Section

⁴⁰¹ According to The Vision Council, the contact lens sales market in the United States in 2015 totaled \$4,664,200,000 at the retail level. See The Vision Council, "U.S. Optical Industry Report Card," Dec. 2015. The estimated additional burden of \$10,475,495 thus amounts to approximately 0.22% of the total market.

⁴⁰² 5 U.S.C. 601-612.

⁴⁰³ The Commission also conducted an RFA analysis of prior amendments to the Rule implementing the Fairness to Contact Lens Consumers Act. 69 FR 40482, 40507 (July 2, 2004).

⁴⁰⁴ 5 U.S.C. 605.

⁴⁰⁵ 15 U.S.C. 7601-7610.

⁴⁰⁶ See U.S. Small Business Admin., "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," (eff. Feb. 26, 2016), https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

⁴⁰⁷ 5 U.S.C. 601(6).

VIII of this notice. The Commission invites comment and information on these issues, including estimates or data on specific compliance costs that small entities 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

The Commission has not proposed any specific small entity exemption or other significant alternatives, as the proposed amendments clarify and update the Rule in light of marketplace practices to ensure that patients are receiving a copy of their contact lens prescription at the completion of a contact lens fitting. Under these limited circumstances, the Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendments. 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. This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and input automatically into the electronic record. Furthermore, prescribers also could

scan signed paper copies of the acknowledgment form and store those forms electronically to lower the costs of this recordkeeping requirement. Nonetheless, the Commission seeks comment on the need, if any, for alternative compliance methods to reduce the economic impact of the Rule on small entities. If the comments filed in response to this NPRM 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.

X. 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 as discussed in the preamble, the Federal Trade Commission proposes to amend title 16 of the Code of Federal Regulations by revising part 315 as follows:

PART 315—CONTACT LENS RULE

■ 1. The authority citation for part 315 continues to read as follows:

Authority: Pub. L. 108–164, secs. 1–12; 117 Stat. 2024 (15 U.S.C. 7601–7610).

■ 2. Amend § 315.3 by adding paragraph (c) to read as follows:

§ 315.3 Availability of contact lens prescriptions to patients.

* * * * *

(c) *Acknowledgment of prescription release.* Upon completion of a contact lens fitting, and after providing a copy of the contact lens prescription to the patient, the prescriber:

(1) Shall 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” that states, “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.”

(2) The acknowledgment form shall include, in addition to the title and statement specified in paragraph (c)(1), the name of the patient, the patient signature, and the date executed. In the event that the patient declines to sign the acknowledgment form, the prescriber shall note the patient’s refusal on the form and sign it. No other statements or information, other than the address or letterhead of the prescriber, shall be placed on the acknowledgment form.

(3) The prescriber shall maintain the signed acknowledgments received under paragraph (c)(1) for a period of not less than three (3) years, and such signed acknowledgments shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

■ 3. Amend § 315.5 paragraph (e) by revising the second sentence to read as follows:

§ 315.5 Prescriber verification.

* * * * *

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

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–28471 Filed 12–6–16; 8:45 am]

BILLING CODE 6750–01–P