



[Billing Code: 6750-01P]

## **FEDERAL TRADE COMMISSION**

### **16 CFR Part 315**

### **RIN 3084-AB36**

### **Contact Lens Rule**

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

**ACTION:** Final rule.

**SUMMARY:** The FTC is publishing a final rule to implement amendments to the Contact Lens Rule. These amendments require that prescribing eye care practitioners obtain a confirmation of prescription release from patients after releasing a contact lens prescription and maintain each such acknowledgment for a period of not less than three years. The Commission is permitting prescribers to comply with automatic prescription release via electronic delivery in certain circumstances. Further, these amendments specify a time period for prescribers to respond to requests for prescriptions; clarify and institute additional requirements for automated telephone verification messages; more precisely delineate what constitutes unlawful alteration of a prescription; and require that sellers provide a method for, and notice of the method for, patient prescription presentation.

**DATES:** This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Relevant portions of the record of this proceeding, including this document, are available at <https://www.ftc.gov>.

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## **I. Background**

### **A. Overview of the Contact Lens Rule**

In 2003, Congress enacted the Fairness to Contact Lens Consumers Act (“FCLCA” or “Act”),<sup>1</sup> and pursuant to the Act, the Commission promulgated the Contact Lens Rule on July 2, 2004.<sup>2</sup> The Rule went into effect on August 2, 2004.

The Contact Lens Rule (“Rule”) promotes competition in retail sales of contact lenses by facilitating consumers’ ability to comparison shop for contact lenses. When an eye care practitioner (“prescriber”)<sup>3</sup> completes a contact lens fitting, the Rule requires that the prescriber automatically provide the patient with a portable copy of the patient’s prescription, whether or not the patient requests it.<sup>4</sup> The Rule also requires that the prescriber verify or provide such prescriptions to authorized third parties. At the same time, the Rule requires that sellers only sell contact lenses in accordance with valid prescriptions written by licensed prescribers that were either (a) presented to the seller by

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<sup>1</sup> 15 U.S.C. 7601-7610 (Pub. L. 108-164).

<sup>2</sup> Contact Lens Rule, 16 CFR part 315 (2015).

<sup>3</sup> Under the Rule, prescriber is defined as an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration. ‘Other person,’ in this context, includes dispensing opticians who are permitted under State law to issue prescriptions and who are authorized or permitted under State law to perform contact lens fitting services. 16 CFR 315.2.

<sup>4</sup> The Commission also notes that apart from requiring that the contact lens fitting be complete, the FCLCA and Rule do not include any other requirements or exceptions that would permit a prescriber to withhold a patient’s contact lens prescription following a fitting. 16 CFR 315.3(a)(1). Therefore, prescribers must automatically provide patients with copies of their prescriptions following their fitting, regardless of whether patients indicate an intention to purchase contact lenses—no matter the quantity (and even an annual supply)—from their prescribers.

the patient or a designated agent of the patient or (b) verified by direct communication with the prescriber.<sup>5</sup>

The Rule further sets out the information that must be included in a seller's verification request, and directs that a prescription is only verified under the Rule if: (1) the prescriber confirms the prescription is accurate; (2) the prescriber informs the seller that the prescription is inaccurate and provides an accurate prescription in its stead; or (3) the prescriber fails to communicate with the seller within eight business hours after receiving a compliant verification request.<sup>6</sup> The Rule states that if the prescriber informs the seller within eight business hours of receiving the verification request that the prescription is inaccurate, expired, or invalid, the seller shall not fill the prescription. The Rule requires that the prescriber specify the basis for the inaccuracy or invalidity of the prescription, and if the prescription is inaccurate, the prescriber must correct it.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup> 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

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<sup>5</sup> 16 CFR 315.5(a).

<sup>6</sup> 16 CFR 315.5(b)-(c).

<sup>7</sup> 16 CFR 315.5(d).

<sup>8</sup> 16 CFR 315.5(e).

<sup>9</sup> 16 CFR 315.6.

require active verification.<sup>10</sup>

## **B. History of the Rule**

The FTC has more than three decades of regulatory and research experience regarding the optical goods industry; this history continues to inform the basis and purpose of the Contact Lens Rule and this rule review. In addition to the Rule, the Commission enforces the Ophthalmic Practice Rules (known as the “Eyeglass Rule”), initially promulgated in 1978.<sup>11</sup> Prior to the Eyeglass Rule, surveys of optometrists found that a majority of prescribers imposed some restriction on the availability of the patient’s prescription, usually by either refusing to release prescriptions or charging an additional fee to do so.<sup>12</sup> Prescribers also used waivers and liability disclaimers to discourage comparison shopping, mislead consumers, and frighten them into purchasing ophthalmic goods from the prescriber.<sup>13</sup> The Commission determined that these actions reduced consumers’ ability to obtain the lowest prices and hindered competition in the optical

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<sup>10</sup> 16 CFR 315.11(a). The Rule also preempts any other state or local laws or regulations that are inconsistent with the Act or the relevant section of the Rule, to the extent of the inconsistency. 16 CFR 315.11(b).

<sup>11</sup> Final Trade Regulation Rule, Advertising of Ophthalmic Goods and Services, 43 FR 23992 (June 2, 1978) [hereinafter Eyeglass I]. The Rule was revised in 1992, with the revisions codified at 16 CFR part 456. Ophthalmic Practice Rules, 57 FR 18822 (May 1, 1992).

<sup>12</sup> 43 FR at 23998. *See also* FTC, “Staff Report on Advertising of Ophthalmic Goods and Services and Proposed Trade Regulation Rule” 240-48 (1977) [hereinafter 1977 Staff Report] (detailing myriad accounts of prescribers refusing to release eyeglass prescriptions to their patients), [https://www.ftc.gov/system/files/documents/reports/staff-report-advertising-ophthalmic-goods-services-proposed-trade-regulation-rule-16-cfr-part-456/r611003 - staff\\_report\\_on\\_advertising\\_of\\_ophthalmic\\_goods\\_and\\_services\\_and\\_proposed\\_trade\\_regulation.pdf](https://www.ftc.gov/system/files/documents/reports/staff-report-advertising-ophthalmic-goods-services-proposed-trade-regulation-rule-16-cfr-part-456/r611003-staff_report_on_advertising_of_ophthalmic_goods_and_services_and_proposed_trade_regulation.pdf).

<sup>13</sup> 43 FR at 23998; *Am. Optometric Ass’n v. FTC*, 626 F.2d 896, 916 (D.C. Cir. 1980) (noting considerable “evidence of abuse” by prescribers); *see also* 1977 Staff Report, *supra* note 12, at 277.

marketplace.<sup>14</sup> To address these problems, the Eyeglass Rule required prescribers—generally, optometrists and ophthalmologists—to provide each of their patients, immediately after completion of an eye examination, a free copy of the patient’s eyeglass prescription.<sup>15</sup>

The Eyeglass Rule, however, did not encompass contact lens prescriptions. While a majority of states enacted their own statutes requiring some form of contact lens prescription release,<sup>16</sup> many prescribers continued to withhold prescriptions for contact lenses.<sup>17</sup> This, and other prescriber practices (such as requiring liability waivers, refusing to verify prescriptions when consumers tried to buy lenses from third-party sellers, and encouraging manufacturers not to distribute contact lenses to third-party sellers), made it challenging for consumers to obtain lenses from anyone other than their prescribers.<sup>18</sup>

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<sup>14</sup> FTC, “The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study” 45-46 (2005), <https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf> [hereinafter 2005 Contact Lens Report].

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

<sup>16</sup> By 2003, more than two-thirds of states had laws requiring some form of contact lens prescription release. H.R. Rep. No. 108-318, 108<sup>th</sup> Cong., 1<sup>st</sup> Sess. 4 (2003), at 8 (2003).

<sup>17</sup> *See id.* at 4 (noting that “[t]he practice of optometrists withholding the prescription [for contact lenses] has limited the consumer’s ability to shop for the best price and has impacted competition”); Fairness to Contact Lens Consumers Act: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 108<sup>th</sup> Cong. 1 (2003) [hereinafter FCLCA Subcomm. Hearing] (statement of Ami Gadhia, Consumers Union) (noting that multiple surveys of consumers in Texas had found considerable numbers were unable to obtain their contact lens prescription from their prescribers).

<sup>18</sup> H.R. Rep. No. 108-318, at 4; FCLCA Subcomm. Hearing, *supra* note 17 (statements of Howard Beales, Jonathan Coon, Ami Gadhia, Robert Hubbard, Maria Martinez, Rep. W. J. Tauzin; Peggy Venable). *See also In re Disposable Contact Lens Antitrust Litig.*, No.

According to Congress, these obstacles were rooted in an “inherent conflict of interest” in that “[u]nlike medical doctors who are prohibited from selling the drugs they prescribe, eye doctors and optometrists . . . are able to fill the contact lens prescriptions they write.”<sup>19</sup> Third-party sellers are thus forced to compete for the sale of lenses with the individual who is writing the prescription.<sup>20</sup> To address this inherent conflict of interest and achieve freedom of choice and the benefits of competition for contact lens consumers, Congress passed the Fairness to Contact Lens Consumers Act in 2003,<sup>21</sup> and, in 2004, the Commission issued the Contact Lens Rule,<sup>22</sup> 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<sup>23</sup> and Congress recognized that consumers may be harmed by contact lenses

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94-MDL 1030-J-20A (M.D. Fla.), in which the Attorneys General of 31 states alleged that eye-care professionals engaged in an organized effort to prevent or hinder consumers from obtaining their contact lens prescriptions. The complaints alleged two conspiracies: (1) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers, and (2) that manufacturers, practitioners, and trade associations, including the American Optometric Association, conspired to eliminate sales of contact lenses by pharmacies, mail order, and other alternative sellers. *Id.* According to the Attorneys General, the conspiracy severely restricted the supply of contact lenses available to alternative sellers, which hampered the growth of such sellers, decreased the supply of lenses to consumers, and increased the price of lenses. *Id.* The parties reached settlements, the last of which the court approved in November 2001. As part of the settlements, manufacturers agreed to sell contact lenses to alternative distribution channels.

<sup>19</sup> H.R. Rep. No. 108-318, at 5. *See also* Letter from Senators Richard Blumenthal and Orrin G. Hatch of the United States Senate Regarding the Contact Lens Rule Rulemaking Proceeding and the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (Aug. 11, 2017) (recognizing the “inherent conflict of interest” and noting that the FCLCA was made necessary by “the unique nature of the contact lens marketplace”), [https://www.ftc.gov/system/files/filings/initiatives/677/public\\_comment\\_from\\_senators\\_blumenthal\\_and\\_hatch\\_re\\_contact\\_lens\\_rulemaking.pdf](https://www.ftc.gov/system/files/filings/initiatives/677/public_comment_from_senators_blumenthal_and_hatch_re_contact_lens_rulemaking.pdf) [hereinafter Blumenthal Letter].

<sup>20</sup> H.R. Rep. No. 108-318, at 4; FCLCA Subcomm. Hearing, *supra* note 17 (statements of Rep. W.J. Tauzin) (noting there is a “classic conflict of interest that robs the consumers

purchased with an expired, inaccurate, or otherwise invalid prescription,<sup>24</sup> the Act requires that contact lenses be sold only to patients with valid prescriptions, which they receive after contact lens fittings by a prescriber. The Act and the Rule only allow sales of contact lenses when a patient presents a seller with a copy of the prescription or the seller has verified the patient's prescription with the prescriber.<sup>25</sup> Sellers also are prohibited from altering a contact lens prescription.<sup>26</sup>

The Act and the Rule further impose obligations on prescribers. First and foremost, prescribers are required to release a copy of the prescription to the patient promptly upon completion of the contact lens fitting, “[w]hether or not requested by the patient.”<sup>27</sup> Prescribers also are prohibited from requiring: (1) the purchase of contact lenses as a condition of either prescription release or verification, (2) a separate payment for prescription release or verification, and (3) that the patient sign a waiver as a condition of prescription release or verification.<sup>28</sup>

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of the ability to shop competitively for the best price,” and stating that the FCLCA takes the “necessary steps to remedy this stranglehold on contact lens competition”).

<sup>21</sup> 15 U.S.C. 7601-7610. The FCLCA passed with a vote of 406 in favor and 12 opposed in the House, and unanimous consent in the Senate.

<sup>22</sup> Contact Lens Rule, 69 FR 40482 (July 2, 2004) (codified at 16 CFR pt. 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.

<sup>23</sup> *See, e.g.*, FTC, “Possible Barriers to E-Commerce: Contact Lenses, A Report from the Staff of the Federal Trade Commission” 8-9 (2004), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/possible-anticompetitive-barriers-e-commerce-contact-lenses-report-staff-ftc/040329clreportfinal.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/possible-anticompetitive-barriers-e-commerce-contact-lenses-report-staff-ftc/040329clreportfinal.pdf).

<sup>24</sup> Contact Lens Rule, 69 FR 40482.

<sup>25</sup> 16 CFR 315.5(a).

<sup>26</sup> 16 CFR 315.5(e).

<sup>27</sup> 15 U.S.C. 7601(a)(1); 16 CFR 315.3(a)(1).

<sup>28</sup> 15 U.S.C. 7601(b)(1)-(3); 16 CFR 315.3(b)(1)-(3).

Additionally, prescribers are required to provide or verify a contact lens prescription when “directed by any person designated to act on behalf of the patient.”<sup>29</sup> Such verification occurs when the seller provides the prescriber with a consumer’s prescription information and: (1) the prescriber confirms that the prescription is accurate, by phone, facsimile, or electronic mail; (2) the prescriber informs the seller that the prescription is inaccurate and provides the correct prescription; or (3) the prescriber does not communicate with the seller within eight business hours of the seller’s request for verification (“passive verification”).<sup>30</sup> The eight-business-hour passive verification lessens the demands on prescribers in the event a seller forwards a query about an accurate and complete prescription from a properly identified patient. It also prevents prescribers from blocking verification—and impeding consumer access to contact lenses that may be lower-priced, or sold by sellers who offer other benefits or convenience—simply by refusing to respond to verification requests.

One outcome of passive verification, however, is that, if a prescriber does not respond to a verification request containing inaccurate information or for an invalid prescription within eight business hours, the prescription is deemed verified; thus, passive verification allows for the possibility that patients can be sold lenses for which they do not have a valid prescription. Congress, when considering the FCLCA, was aware that a passive-verification regime could, in some instances, allow sellers to sell and ship contact lenses based on an invalid or inaccurate prescription, and that this could potentially lead

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<sup>29</sup> 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2).

<sup>30</sup> 15 U.S.C. 7603(d)(1)-(3); 16 CFR 315.5.

to health risks.<sup>31</sup> Congress opted for a passive-verification regime despite this concern in order “to ensure that consumers are not caught in the competitive tug-of-war between doctors and third party sellers for the sale of contact lenses.”<sup>32</sup> It was also envisioned that prescribers would remain diligent in ensuring that patients did not receive lenses for which they had not been prescribed, since it is in both prescribers’ self-interest and the health and safety interests of their patients to prevent this from occurring.<sup>33</sup> In this manner, the passive-verification system was perceived, to a certain extent, to be self-enforcing, as prescribers would have both a financial interest and an ethical duty to police invalid, incorrect, or expired prescriptions.<sup>34</sup>

### **C. Initial Request for Comments in 2015**

As part of its periodic review of its rules and guides, on September 3, 2015, the Commission solicited comments on the Contact Lens Rule, seeking input on: the economic impact of, and continuing need for, the Rule; the benefits of the Rule to consumers purchasing contact lenses; the burdens the Rule places on entities subject to its requirements; the impact the Rule has had on the flow of information to consumers; the degree of industry compliance with the Rule; the need for any modifications to increase

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<sup>31</sup> See, e.g., FCLCA Subcomm. Hearing, *supra* note 17 (statements of Howard Beales, Federal Trade Commission); *id.* (statements of J. Pat Cummings, American Optometric Association) (“And the problem with passive verification is that people will get contact lenses without a prescription.”).

<sup>32</sup> H.R. Rep. No. 108-318, at 5.

<sup>33</sup> Contact Lens Rule, 69 FR at 40498.

<sup>34</sup> FCLCA Subcomm. Hearing, *supra* note 17 (statements of Howard Beales, Federal Trade Commission) (stating that passive verification is in many respects self-enforcing). See also *id.* (statements of Jonathan Coon, 1-800 CONTACTS) (explaining to the Committee that from their experience with an existing passive verification-system in California, doctors have motivation to block invalid-prescription sales. “So they tell us if there is any problem with the prescription, if it’s expired, it’s invalid, whatever the problem is with the prescription. If they can tell us, you can believe they tell us absolutely every time.”).

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.<sup>35</sup> The comment period for this initial request closed on October 26, 2015. The Commission received approximately 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 consumers.<sup>36</sup>

#### **D. Notice of Proposed Rulemaking in 2016**

After a review of comments, surveys, other submitted information, and its own enforcement experience, the Commission determined that the overall weight of the evidence demonstrated a need to improve compliance with the Rule's automatic prescription-release requirement, as well as a need to create a mechanism for monitoring and enforcing the Rule.<sup>37</sup> To achieve this, the Commission issued a Notice of Proposed Rulemaking ("NPRM") on December 7, 2016 that proposed to add a signed-acknowledgment requirement.<sup>38</sup> The signed-acknowledgment requirement was to be triggered once the prescriber presented the prescription to the patient, and the acknowledgment form could be in either paper or electronic format. As proposed, the acknowledgment form was to be entitled "Patient Receipt of Contact Lens Prescription"

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<sup>35</sup> Contact Lens Rule Request for Comment ("RFC"), 80 FR 53272 (Sept. 3, 2015).

<sup>36</sup> Comment figures are approximations because identical comments are sometimes submitted more than once. RFC comments are available at <https://www.ftc.gov/policy/public-comments/2015/09/initiative-621>.

<sup>37</sup> Notice of Proposed Rulemaking, 81 FR 88526 (Dec. 7, 2016) [hereinafter NPRM].

<sup>38</sup> *Id.* The NPRM also proposed a technical amendment, to remove the words "private label" from § 315.5(e) to conform the language of the Rule to that of the FCLCA.

(“Signed Acknowledgment”), and state, “My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice.” Prescribers would be required to maintain copies of the acknowledgment forms in paper or electronically for not less than three years.

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

In response to its NPRM, the Commission received over 4,000 additional comments, many from prescribers concerned about the impact of the proposed signed-acknowledgment requirement.<sup>39</sup> After considering these and other comments, the Commission determined that certain issues deserved additional discussion and examination. To obtain additional input and more fully consider commenter concerns, the Commission solicited additional comments<sup>40</sup> and held a public workshop on the Contact Lens Rule and the Evolving Contact Lens Marketplace on March 7, 2018. The workshop included six panels, covering issues relating to the overall contact lens marketplace, health and safety, competition, purchasing and verification, the proposed Signed Acknowledgment and consumer choice, and the future of contact lens prescribing

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<sup>39</sup> NPRM comments available at <https://www.ftc.gov/policy/public-comments/2016/10/initiative-677>.

<sup>40</sup> Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 FR 57889 (Dec. 8, 2017).

and selling.<sup>41</sup> In response to the Commission’s request and workshop, the Commission received approximately 3,400 additional comments from a wide range of commenters, including numerous consumers and prescribers, as well as industry associations, state attorneys general, contact lens manufacturers, and contact lens sellers.<sup>42</sup>

#### **E. Supplemental Notice of Proposed Rulemaking**

After reviewing the comments submitted in response to the public workshop and Notice of Proposed Rulemaking, the Commission issued a Supplemental Notice of Proposed Rulemaking (“SNPRM”) on May 28, 2019 that modified its previous proposal for a Signed Acknowledgment by instituting a more flexible Confirmation of Prescription Release provision.<sup>43</sup> In addition, the SNPRM put forth new proposals to modify the Rule by: (a) adding a definition of the term “provide to the patient a copy,” to allow the prescriber to provide the patient with a digital copy of the patient’s prescription in lieu of a paper copy; (b) providing forty business hours as the time period for which a prescriber must provide a prescription upon request to a person designated to act on behalf of the patient; (c) creating new message delivery and recordkeeping requirements for sellers using automated telephone verification messages; (d) amending and clarifying the prohibition on seller alteration of prescriptions; and (e) requiring that sellers provide a method that would allow patients to present their prescriptions to the seller.

The Commission requested comment on its SNPRM proposal; the sixty-day comment period closed on July 29, 2019. In response to its SNPRM, the Commission

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<sup>41</sup> Workshop transcripts available at <https://www.ftc.gov/news-events/events-calendar/2018/03/contact-lens-rule-evolving-contact-lens-marketplace>.

<sup>42</sup> Workshop comments available at <https://www.ftc.gov/policy/public-comments/2018/01/initiative-733>.

<sup>43</sup> Supplemental Notice of Proposed Rulemaking, 84 FR 24664 (May 28, 2019) [hereinafter SNPRM].

received approximately 200 unique comments (and approximately 900 comments total) from a variety of stakeholders, including prescribers and prescriber-trade organizations, contact lens manufacturers, contact lens sellers, legislators, state attorneys general, economic think tanks and academics, consumer-interest organizations, and individual consumers themselves.<sup>44</sup> The majority of commenters opined on the Confirmation of Prescription Release proposal, and many also commented on the Commission's new proposals regarding prescription verification and alteration. This Statement of Basis and Purpose for the Final Rule summarizes the relevant comments received in response to the proposals set forth in the NPRM and SNPRM and explains the Commission's analyses and decisions to amend or not amend the Rule.

## **II. Final Rule Pertaining to Confirmation of Prescription Release**

The following sections discuss the Confirmation of Prescription Release proposal in the SNPRM, the comments to the SNPRM in support of and opposition to the Confirmation of Prescription Release proposal, the Commission's analysis and conclusions, and the amendments to the Final Rule instituting a Confirmation of Prescription Release. Because many of the comments focused on the Commission's basis for its SNPRM proposal, and whether that basis is supported by evidence in the record, the Commission also reiterates the basis set forth in the SNPRM and discusses related comments and subsequent determinations in this Statement of Basis and Purpose for the final amended Contact Lens Rule.

The Commission's authority to modify the Rule and implement a Confirmation of Prescription Release requirement derives from the FCLCA, which directed the FTC to

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<sup>44</sup> SNPRM comments available at <https://www.regulations.gov/docket?D=FTC-2019-0041>.

prescribe implementing rules, and authorized the Commission to investigate and enforce the Act in the same manner, by the same means, and with the same jurisdictional powers and duties as a trade regulation rule under the Federal Trade Commission Act.<sup>45</sup>

Congress clearly intended that prescriptions be provided to all consumers at the completion of the contact lens fitting process.<sup>46</sup> Survey evidence, the record of these proceedings, and the Commission’s own experience with the Rule indicate that is not occurring at anywhere near the rate Congress intended. Consequently, the Commission believes that imposing a Confirmation of Prescription Receipt requirement is critical to effectuate congressional intent to the fullest extent.<sup>47</sup>

In a comment to the NPRM, the American Optometric Association (“AOA”) contended that the Commission does not have the authority to add requirements to the Rule that are not found in the text of the FCLCA.<sup>48</sup> According to the AOA, because the FCLCA is a statute that “carefully enumerates specific substantive requirements but not others”—as opposed to a general grant of authority—the agency charged with administering the FCLCA “should not add additional requirements that Congress did not enact.”<sup>49</sup>

The Commission does not agree with this interpretation. As noted above, the FCLCA contains an express delegation of authority to the FTC to craft rules to carry out

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<sup>45</sup> 15 U.S.C. 7601-7610 (Pub. L. 108-164).

<sup>46</sup> 15 U.S.C. 7601; *see also* H.R. Rep. No. 108-318, at 4 (2003) (“The practice of optometrists withholding the prescription has limited the consumer’s ability to shop for the best price and has [adversely] impacted competition.”).

<sup>47</sup> *See* H.R. Rep. No. 108-318, at 6 (2003) (“The goal of this legislation is to allow consumer access to their contact lens prescriptions....”).

<sup>48</sup> American Optometric Association (NPRM Comment #3830).

<sup>49</sup> *Id.*

the Act.<sup>50</sup> Pursuant to this delegation, the FTC has broad rulemaking authority to implement requirements for the purpose of preventing unfair or deceptive acts or practices in or affecting commerce, including failure to provide patients with copies of their prescriptions.<sup>51</sup> The proposed modification requiring that patients sign a Confirmation of Prescription Release is consistent with the statute and falls well within the Commission’s statutory jurisdiction under the FCLCA.<sup>52</sup>

#### **A. Proposed Modifications in the SNPRM**

The SNPRM proposed to amend the NPRM’s signed-acknowledgment proposal by replacing that requirement with a shorter and more flexible Confirmation of Prescription Release provision. Rather than requiring, as proposed in the NPRM, that prescribers request that each contact lens patient sign a form with mandatory language acknowledging receipt of the prescription and an understanding of the right to purchase

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<sup>50</sup> 15 U.S.C. 7607.

<sup>51</sup> *See id.* (directing the FTC to “prescribe rules pursuant to section 57a of this title to carry out [the FCLCA]”); 15 U.S.C. 57a(a)(1)(B) (authorizing the FTC to prescribe “rules which define with specificity acts or practices which are unfair or deceptive acts or practices in or affecting commerce,” including rules that contain “requirements prescribed for the purpose of preventing such acts or practices”); 15 U.S.C. 7601(a) (mandating that when a prescriber completes a contact lens fitting, the prescriber “whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription”).

<sup>52</sup> 15 U.S.C. 7601(a), 7607. AOA’s stance that a statute’s enumeration of some requirements but not others necessarily signifies that Congress deliberately excluded the non-included requirements is also incorrect in the rulemaking context. It is well established that the canon of statutory interpretation *expressio unius est exclusion alterius* (“the expression of one is the exclusion of others”) does not have force in the administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved. *See Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014); *St. Marks Place Hous. Co. v. U.S. Dep’t of Hous. & Urban Dev.*, 610 F.3d 75 (D.C. Cir. 2010); *AFL-CIO v. Chao*, 409 F. 3d 377 (D.C. Cir. 2005); *Mobile Comm’cns Corp. of Am. v. FCC*, 77 F.3d 1399, 1404-05 (D.C. Cir. 1996); *see also Farrell v. Pompeo*, No. 17-490, 2019 U.S. Dist. LEXIS 205831, \*25-27 (D.D.C. Nov. 27. 2019).

lenses elsewhere,<sup>53</sup> in the SNPRM the Commission proposed requiring prescribers instead to do one of the following:

- (A) Request that the patient acknowledge receipt of the contact lens prescription by signing a separate statement confirming receipt of the contact lens prescription;
- (B) Request that the patient sign a prescriber-retained copy of a contact lens prescription that contains a statement confirming receipt of the contact lens prescription;
- (C) Request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming receipt of the contact lens prescription; or
- (D) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.<sup>54</sup>

The Commission's proposal provided sample language for confirmation options (A), (B), and (C),<sup>55</sup> but also allowed prescribers to craft their own wording of the signed confirmation for these options if they so desired. Unlike the NPRM's signed-acknowledgment proposal, which applied to all prescribers, the SNPRM's Confirmation

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<sup>53</sup> NPRM, 81 FR at 88559 (The form would have stated: "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.").

<sup>54</sup> SNPRM, 84 FR at 24667.

<sup>55</sup> The Commission said it had no wish to burden prescribers with the task of formulating adequate confirmation language if they would prefer to use a sentence from the language the Commission previously proposed: "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting." The Commission said use of such language would satisfy the proposed requirement. SNPRM, 84 FR at 24683.

of Prescription Release proposal only applied to prescribers with a financial interest in the sale of contact lenses.<sup>56</sup>

**B. Basis for SNPRM Confirmation of Prescription Release Proposal**

The Commission explained in the SNPRM that it based its Confirmation of Prescription Release proposal on a variety of evidence, including: multiple consumer surveys consistently showing prescriber non-compliance with, and lack of consumer awareness of, the Rule's prescription-release requirement; numerous accounts of prescribers' failure to release prescriptions; the persistently high number of verifications, many of which would be unnecessary were consumers in possession of their prescriptions; the regulatory structure of the contact lens market, which requires a consumer to obtain lenses pursuant to a prescription while permitting prescribers to sell what they prescribe; and the lack of credible empirical evidence rebutting or contradicting the evidence that prescribers are not automatically releasing prescriptions, and that consumers are not fully aware of their rights.<sup>57</sup> The Commission also noted that the potential benefit of increasing the number of patients in possession of their prescriptions is substantial for consumers, sellers, and prescribers: namely, increased flexibility and choice for consumers; a reduced verification burden for prescribers and sellers; and a reduced likelihood of errors associated with incorrect, invalid, and expired prescriptions and, consequently, improved patient safety.<sup>58</sup> The Commission further explained that it faces serious challenges enforcing the Rule and monitoring compliance because it often comes down to the word of the patient against the word of the prescriber,

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<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 24680-81.

<sup>58</sup> *Id.* at 24681.

which might require the Commission to issue administrative subpoenas and conduct investigational hearings—which could be resource-intensive for the Commission and costly, time-consuming, and disruptive for prescribers—in order to investigate each potential violation.<sup>59</sup> The Commission thus concluded that some form of retained documentation is necessary to improve its ability to enforce and monitor prescriber compliance with the prescription-release requirements.<sup>60</sup>

The Commission also determined that signage—an alternative suggested by NPRM commenters—was not an appropriate or effective means of ensuring that patients receive their prescriptions as required by law.<sup>61</sup> Lastly, the Commission determined that despite commenter concerns, the burden to obtain signatures and retain records would be relatively minimal and outweighed by the benefits.<sup>62</sup> The Commission, however, was receptive to an NPRM commenter recommendation to modify the signed-acknowledgment proposal in order to further reduce the burden and allow for greater flexibility,<sup>63</sup> and thus the SNPRM’s Confirmation of Prescription Release proposal included three new options for prescribers to obtain or establish proof of prescription release and exempted prescribers who lacked a financial interest in the sale of contact lenses.<sup>64</sup> According to the Commission, the Confirmation of Prescription Release proposal retained most of the benefits of the NPRM’s signed-acknowledgment proposal,

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<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 24681-82.

<sup>63</sup> The recommendation was submitted by the National Association of Optometrists and Opticians in its comments to the Contact Lens Workshop and the NPRM, *see id.* at 24680 (citing National Association of Optometrists and Opticians (WS Comment #3208)).

<sup>64</sup> SNPRM, 84 FR at 24683.

but would be less disruptive and burdensome for prescribers.<sup>65</sup>

### **C. Comments on the Confirmation of Prescription Release Proposal and the Basis for Such Proposal**

Commenter response to the Commission's proposal in the SNPRM was varied. Some commenters applauded the proposed amendments as improvements to the prior signed-acknowledgment proposal, and as a balanced response to competing interests of consumers, sellers, and prescribers.<sup>66</sup> Some, for instance, praised the confirmation proposal as an attempt to increase consumer access to prescriptions while making it easier and more efficient for prescribers to adhere to the patient-acknowledgment requirement by allowing flexible methods for obtaining the patient's signature.<sup>67</sup> Other commenters, however, asserted that the proposal watered down prescriber obligations and would thus be less effective than the NPRM's signed-acknowledgment proposal in

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<sup>65</sup> *Id.*

<sup>66</sup> R Street Institute (SNPRM Comment #15) ("The Commission's proposal is both reasonable and not overly burdensome."); Grimm (SNPRM Comment #36) ("There is no doubt that the modified Contact Lens Rule should be embraced by prescribers, sellers, and consumers as an improvement to consumer products trade rules."); Americans for Tax Reform (SNPRM Comment #72) ("These changes strike the correct balance between promoting the free market and protecting important consumer rights."); Lens.com (SNPRM Comment #85) ("We believe you have struck the correct balance . . . ."); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89) ("What the FTC is proposing is a common sense, minimally-burdensome rule that optometrists, ophthalmologists, and consumers alike can and should support."); Taxpayers Protection Alliance (SNPRM Comment #118) ("Although we are often critical of government overreach and work hard to make government smaller, we believe that the FTC's proposed Contact Lens Rule is a government rule that works for taxpayers and consumers and creates an open transparent contact lens market in the US where taxpayers have real choice and there is real competition in the marketplace."); Attorneys General of 27 States (SNPRM Comment #139) ("We believe the proposed modifications in the SNPRM are reasonable modifications that balance the interests of consumers, eye care professionals, and the eye care industry.").

<sup>67</sup> Anonymous (SNPRM Comment #63); Rawson (SNPRM Comment #68) ("This proposed rule allows prescribers the ability to model the rule to best fit their practice, but still give the consumers the protection and the knowledge they need.").

ensuring that consumers receive their prescriptions and are aware of their rights.<sup>68</sup> And several commenters, primarily contact lens prescribers, stated that despite the increased flexibility, the Confirmation of Prescription Release proposal still created too much of a burden for prescribers, and they criticized the Commission's approach and the evidence relied upon.<sup>69</sup>

**1. Comments About the Need for the Confirmation of Prescription Release and Whether Prescribers Are Complying with the Rule's Automatic Prescription Release Requirement**

**a. Survey Evidence as Proof of Non-Compliance**

Many of the SNPRM comments focused on the need for a Signed Acknowledgment or Confirmation of Prescription Release, and on whether evidence in the record supports the Commission's determination that prescribers are not complying with the Rule's prescription-release requirement. Several commenters, such as 1-800 CONTACTS, Consumer Action, and the Attorneys General of Twenty-Seven States, contended (as they did in comments responding to either the NPRM, the Contact Lens Workshop, or both)<sup>70</sup> that prescriber noncompliance remains a problem, and that millions of Americans are not receiving their prescriptions after a contact lens fitting.<sup>71</sup> The Attorneys General of Twenty-Seven States, for instance, commented that consumers in

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<sup>68</sup> Consumer Reports (SNPRM Comment #133); 1-800 CONTACTS (SNPRM Comment #135).

<sup>69</sup> American Optometric Association (SNPRM Comment #96); Reeder (SNPRM Comment #55) (even signature on prescription or patient receipt is burdensome); Kegler (SNPRM Comment #99) (proposal will still place financial and administrative burdens on prescribers).

<sup>70</sup> See 1-800 CONTACTS (NPRM Comment #3898); 1-800 CONTACTS (WS Comment #3207); Consumer Action (NPRM Comment #3721); Comments of the Attorneys General of 20 States (NPRM Comment #3804).

<sup>71</sup> 1-800 CONTACTS (SNPRM Comment #135); Attorneys General of 27 States (SNPRM Comment #139).

their states continue to report that prescribers are failing to automatically provide patient prescriptions in writing.<sup>72</sup> Likewise, the online seller 1-800 CONTACTS submitted a new survey of consumers, conducted for it by the polling firm Dynata (formerly known as Survey Sampling International), showing that prescriber compliance has not markedly improved, despite the attention focused on automatic-prescription-release obligations since the FTC initiated its rule review in 2015.<sup>73</sup> According to the new survey, nearly 49% of contact lens patients report that their prescribers did not automatically give them their prescription after their eye examination.<sup>74</sup> Of those who did not receive their prescription automatically, a little more than half received it after requesting it, while 43% never received their prescription.<sup>75</sup> Extrapolating this data to the general population of 45 million U.S. contact lens users<sup>76</sup> would mean there are approximately 22 million annual violations of the Contact Lens Rule, and that each year more than 9.4 million contact lens users do not receive their prescriptions.<sup>77</sup> The 2019 consumer survey data is consistent with several prior surveys of contact lens users conducted in 2014, 2015, 2016, and 2017 on behalf of 1-800 CONTACTS and the consumer rights organization

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<sup>72</sup> Attorneys General of 27 States (SNPRM Comment #139).

<sup>73</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>74</sup> 1-800 CONTACTS (SNPRM Comment #135, Ex. B). The poll was of 1011 contact lens users between the ages of 18-49, and the relevant questions asked were “At your last eye exam, did the eye care provider provide you with a copy of your contact lens prescription?” and “In order to obtain a copy of your prescription, did you have to ask your eye care provider for it?” Approximately 41% said they received it automatically, 49% said they did not, and 10% did not recall or were unsure.

<sup>75</sup> *Id.*

<sup>76</sup> Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, <https://www.cdc.gov/contactlenses/fast-facts.html>.

<sup>77</sup> This is based on the estimate—long used to calculate the financial burden of the Rule for Paperwork Reduction Act purposes—that consumers obtain one contact lens prescription per year. *See, e.g.*, SNPRM, 84 FR at 24692; Paperwork Reduction Act Proposed Collection; Comment Request, 81 FR at 31940; Paperwork Reduction Act Proposed Collection; Comment Request, 78 FR at 9392.

Consumer Action,<sup>78</sup> as well as a survey of eyeglass wearers (who, per the FTC’s Eyeglass Rule, are also to automatically receive their prescriptions following a refractive eye exam) conducted on behalf of Warby Parker in 2015.<sup>79</sup>

Some commenters also pointed to previously-submitted evidence indicating that many U.S. contact lens users are still unaware of their right to automatically receive their prescriptions and take them elsewhere for filling.<sup>80</sup> While commenters to the SNPRM did not submit updated polling data on consumer awareness, several cited previously-submitted data indicating that between 46-60% of consumers are unaware that under federal law a prescriber is required to provide the patient with a copy of their prescription after they complete their contact lens exam.<sup>81</sup>

Another commenter, the National Hispanic Medical Association (“NHMA”), noted that polls show that Hispanic patients are disproportionately impacted by prescribers’ failure to release prescriptions, and are less likely to understand their rights under the FCLCA.<sup>82</sup> According to the NHMA, “Our community continually has been victimized and denied their prescriptions by prescribers and doctors at a higher rate than most other Americans. We strongly believe that more must be done to ensure patients are informed of their rights and given copies of their prescriptions.”<sup>83</sup>

A number of SNPRM commenters, however, were critical of the polling data

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<sup>78</sup> SNPRM, 84 FR at 24671-72.

<sup>79</sup> NPRM, 81 FR at 88531.

<sup>80</sup> Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101); 1-800 CONTACTS (SNPRM Comment #135).

<sup>81</sup> Consumer Action (SNPRM Comment #101) (“Our survey showed a fundamental lack of understanding by consumers about their automatic right to receive a copy of their prescription”); 1-800 CONTACTS (SNPRM Comment #135); *see* SNPRM 84 FR at 24672 (discussing polls of consumer knowledge of their rights).

<sup>82</sup> National Hispanic Medical Association (SNPRM Comment #146).

<sup>83</sup> *Id.*

provided to, and relied upon by, the Commission. The American Academy of Ophthalmology (“AAO”) asserted that data showing prescriber non-compliance consisted of “industry-sponsored surveys” and was therefore unreliable.<sup>84</sup> AAO added that it is “unaware of issues” with prescribers failing to release prescriptions, and stated its members “know that ophthalmology has a strong record of compliance.”<sup>85</sup> Likewise, the American Society of Cataract and Refractive Surgery (“ASCRS”) asserted that there is no independent third-party evidence suggesting physicians are not providing prescriptions to patients, and that the Commission is basing compliance on “survey polls sponsored by stakeholders with financial interest in the sale of contact lenses.”<sup>86</sup> According to the ASCRS, before amending the Rule, the Commission should obtain data from a disinterested organization.<sup>87</sup>

The AOA was highly critical of polling data supplied by 1-800 CONTACTS, and stated that since the online seller, in its advertising, encouraged consumers to “skip the trip to the optometrist” and instead renew prescriptions online (via telemedicine), the online seller has a demonstrated bias against optometrists that taints the material it submits.<sup>88</sup> The AOA further stated that some consumer survey findings may be misleading because it is “very typical” for consumers to request their prescriptions before their contact lens fitting is complete, and thus before prescribers are obligated—under the Rule and the FCLCA—to release them to consumers.<sup>89</sup> Therefore, some consumers might indicate on a survey that they were required to ask for their prescriptions when, in

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<sup>84</sup> American Academy of Ophthalmology (SNPRM Comment #136).

<sup>85</sup> *Id.*

<sup>86</sup> American Society of Cataract and Refractive Surgery (SNPRM Comment #127).

<sup>87</sup> *Id.*

<sup>88</sup> American Optometric Association (SNPRM Comment #96).

<sup>89</sup> *Id.*

fact, they asked before they were entitled to receive them. As support for this contention, AOA stated that it surveyed some of its members and found that 91.7% “indicated that there are times when a patient will ask for his/her prescription prior to the finalization of the contact lens fitting.”<sup>90</sup>

The Commission recognizes that some consumers may think they had to ask for their prescriptions when, in fact, they would have received them when their fittings were complete. However, the AOA did not suggest, nor provide any data or information, as to how often this may occur, and thus how much it might skew the results of consumer surveys. As a result, the Commission is unable to estimate what portion of the 49% who stated they did not automatically receive their prescription—in the most recent survey—gave that response because they misunderstood when they were entitled to receive their prescription.<sup>91</sup>

Moreover, even if the Commission were to disregard evidence of consumers who obtained their prescriptions only after asking for them, five consumer surveys from 2015 to 2019 (six if the Warby Parker eyeglass wearers’ survey is included) indicate that

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<sup>90</sup> *Id.* The AOA reported this result in its comment, and it stated that its survey was of 629 prescribers, but did not provide the FTC with the underlying survey data, information about the manner in which the survey was conducted, how the 629 prescribers were selected, or the specific questions that were asked.

<sup>91</sup> The Commission also notes that eyeglass patients are entitled to their prescriptions immediately following their exam (since they do not have to wait for a fitting), and thus would rarely ask for their prescriptions before they are entitled to them, and yet two 2015 surveys of eyeglass wearers—one on behalf of Warby Parker, the other for 1-800 CONTACTS—found that 47% and 66%, respectively, of eyeglass patients who visited an optometrist reported that they were not automatically provided a prescription at the end of their exam. NPRM, 81 FR at 88531 (citing Warby Parker (Comment #813 on the Ophthalmic Practice Rule), available at <https://www.ftc.gov/policy/public-comments/initiative-624>); 1-800 CONTACTS (RFC Comment #568, Ex. B). This would seem to indicate that most consumer reports that they did not receive their prescriptions are not based on a misunderstanding of when they are supposed to receive them.

between 21%-36% of consumers—approximately 9.5 to 16.2 million contact lens users each year—did not receive their prescriptions at all after getting fitted for their lenses.<sup>92</sup> This level of non-compliance on its own supports the Commission’s recommendation. As for commenter criticism that consumer surveys were submitted by interested parties, the Commission reiterates what it stated in the SNPRM: while cognizant of the interests of submitting parties, the Commission, whenever possible, examines the underlying survey data and methodology to gauge a survey’s usefulness and considers factors such as how many people are queried, how the questions are phrased, and whether the surveys are conducted in-house or by independent and established third-party polling firms.<sup>93</sup>

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<sup>92</sup> This approximation is based on the current estimate that there are 45 million contact lens users in the United States. Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, <https://www.cdc.gov/contactlenses/fast-facts.html>. The results from the individual surveys are as follows: (1) June 2019 survey by Dynata on behalf of 1-800 CONTACTS of 1011 contact lens users found that 21% said they never received their prescriptions (1-800 CONTACTS (SNPRM Comment #135)); (2) January 2017 survey by Caravan ORC International on behalf of Consumer Action of 2018 adults found that 31% of contact lens users said that at their last eye exam, their doctor did not provide them with a paper copy of their prescription (Consumer Action (NPRM Comment #3721)); (3) December 2016 survey of 1000 contact lens users by Survey Sampling International (“SSI”) on behalf of 1-800 CONTACTS found that 24% of consumer respondents said they did not receive their prescription (1-800 CONTACTS (NPRM Comment #3898)); (4) October 2015 SSI survey of 500 contact lens users and 303 eyeglass users on behalf of 1-800 CONTACTS found that 36% of contact lens users and 39% of eyeglass wearers said they did not receive their prescription (1-800 CONTACTS (RFC Comment #568, Ex. B)); (5) May 2015 SSI survey of 2000 contact lens wearers found that 34% said they did not receive their prescription (1-800 CONTACTS (RFC Comment #568, Ex. C)); and (6) November 2014 SSI survey of 2000 contact lens wearers found that 34% said they did not receive their prescription (1-800 CONTACTS (RFC Comment #568, Ex. C)). As noted in the SNPRM, the manner in which a few of the questions were phrased in the 2014 and 2015 surveys raised some Commission concerns, since some questions were leading, lacked an “I don’t know” response option, and used a term—“hard copy”—which not all consumers may understand. The more recent surveys represented an improvement because they included an option for respondents to acknowledge that they do not recall whether they received their prescriptions, and used the term “paper copy” rather than “hard copy.” SNPRM, 84 FR at 24672.

<sup>93</sup> SNPRM, 84 FR at 24672.

The Commission also recognizes that all surveys may have methodological limitations, and, in this instance, does not treat any one survey as controlling. The Commission, however, also recognizes that multiple surveys conducted by different sources at different times with similar results bolster the credibility of each individual survey, as does the fact that in this matter, one survey, submitted by Consumer Action and conducted by the third-party polling firm Caravan ORC International, is not from a party with a direct financial stake in the contact lens industry.<sup>94</sup>

The Commission also notes that despite multiple opportunities and requests for comment since 2015, the Commission has yet to find or receive any reliable consumer-survey data rebutting or contradicting the submitted survey findings, or establishing that consumers consistently receive their prescriptions. The only empirical evidence of prescriber compliance in the record is a survey of fifty-seven “high volume” prescribers submitted by AOA in response to the NPRM, which found that 93% responded “yes” when asked, “Do you follow Federal law and provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting?”<sup>95</sup> For the reasons stated in the SNPRM,<sup>96</sup> the Commission does not accord this survey significant weight, and finds

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<sup>94</sup> The AOA had previously noted, in response to the NPRM, that Consumer Action has received corporate financial support from, among others, 1-800 CONTACTS. *Id.* Consumer Action, however, is a long-established non-profit consumer advocacy organization without a financial interest in the outcome of this Rule review.

<sup>95</sup> SNPRM, 84 FR at 24672; American Optometric Association (WS Comment #3303, Ex. B). This survey appears to have been conducted by the AOA itself rather than an outside polling firm. It is not clear from the AOA’s submission how the fifty-seven optometrists were selected for the survey, what it means to be a “high volume” optometrist, or why high-volume optometrists were chosen.

<sup>96</sup> SNPRM, 84 FR at 24673 (noting concerns about the small sample size, lack of detail as to how prescriber respondents were recruited, and that the way the question is phrased allows prescribers to truthfully answer that they provide patients with a copy of their

that it does not counter the multiple consumer surveys conducted over a number of years showing prescriber non-compliance. The Commission accords the empirical data from multiple consumer surveys significant weight in establishing that a substantial percentage of prescribers are not complying with the automatic-prescription-release provision of the Rule.

Apart from the empirical data discussed above, none of the commenters submitted new evidence relating to prescriber compliance. Many individual prescribers, however, continue to comment that they always comply with the requirement, as do all the prescribers they know, and therefore they believe that the Commission is looking to solve a non-existent problem.<sup>97</sup> Some prescribers also reiterated that, in their experience, consumers are well aware that they can buy lenses elsewhere so there is no need to educate them further about their rights.<sup>98</sup> And a few prescribers opined that the requirement was a “waste of time” because, in their experience, consumers would rather not have a copy of their prescription and know that they can request a copy whenever they want.<sup>99</sup>

The Commission has considered these comments but does not believe they establish that prescribers, on the whole, are complying with the automatic-release requirement, or that consumers are fully aware of their prescription-portability rights.

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prescription even if they do not do so for *every* patient, and even if they only do so when the patient requests one).

<sup>97</sup> See, e.g., Abert (SNPRM Comment #20); Hyndman (SNPRM Comment #21) (“every OD I know follows” the FCLCA requirements); Fair (SNPRM Comment #26) (“I have ALWAYS and will continue to comply fully with the prescription release requirements of the 2003 Fairness to Contact Lens Consumers Act.”); Hughes (SNPRM Comment #113) (most optometrists comply); Ridder (SNPRM Comment #720) (every patient gets their prescription whether they order or ask for it or not).

<sup>98</sup> Abert (SNPRM Comment #20); Jones (SNPRM Comment #48).

<sup>99</sup> Sikes (SNPRM Comment #114); Morey (SNPRM Comment #142).

Any prescriber may indeed comply with the Rule but cannot speak for other eye care providers in the United States, nor for contact lens consumers.<sup>100</sup> In addition, several previous comments from prescribers and prescriber organizations who assert that they comply with the Rule actually revealed that many prescribers do not fully understand or comply with the Rule’s requirement that prescriptions be provided “whether or not requested by the patient.”<sup>101</sup>

The Commission does not accord any weight to the comments that consumers do not want their prescriptions. As evidenced by the numerous NPRM comments from consumers urging the Commission to take action to ensure they are given their prescriptions, it cannot be doubted that many consumers have a compelling desire to have them.<sup>102</sup> And more importantly, Congress made the determination that prescribers must provide patients with their prescriptions automatically, “whether or not requested by the patient.”<sup>103</sup>

**b. Lack of Consumer Complaints as Evidence of Compliance**

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<sup>100</sup> By one estimate, there are approximately 43,000 optometrists and 16,700 ophthalmologists in the U.S. FTC, *The Contact Lens Rule and the Evolving Contact Lens Marketplace*, Panel I: Overview of the Contact Lens Marketplace Tr. at 6 (Mar. 7, 2018), [https://www.ftc.gov/system/files/documents/public\\_events/1285493/panel\\_i\\_overview\\_of\\_the\\_contact\\_lens\\_marketplace.pdf](https://www.ftc.gov/system/files/documents/public_events/1285493/panel_i_overview_of_the_contact_lens_marketplace.pdf) [hereinafter CLR Panel I Tr.].

<sup>101</sup> See SNPRM, 84 FR at 24673-74, discussing how a number of prescribers commented that they always *offer* prescriptions to consumers, or provide them *on request*.

<sup>102</sup> See, e.g., Boue (NPRM Comment #1806); Collins (NPRM Comment #1811); Hamilton (NPRM Comment #1835); Acton (NPRM Comment #2070); Dunbar (NPRM Comment #2652); Capuano (NPRM Comment #2722); Muckley (NPRM Comment #2768); Taravella (NPRM Comment #2892); Martinez (NPRM Comment #2894); Ballou (NPRM Comment #3331). See also SNPRM, 84 FR at 24671 (recounting comments from dozens of consumers complaining that they were denied their prescriptions).

<sup>103</sup> FCLCA, 15 U.S.C. 7601(a)(1).

Some commenters reiterated the argument—raised and discussed in some detail in the SNPRM<sup>104</sup>—that the lack of consumer complaints to the FTC about prescriber non-compliance is evidence that prescribers are releasing prescriptions as required.<sup>105</sup> In the SNPRM, the Commission explained that it did not equate the lack of complaints with compliance because based on its experience, the vast majority of injured or impacted consumers do not register complaints with the government and, for various reasons, even fewer are likely to file a formal complaint about a prescriber’s failure to release their prescription.<sup>106</sup> The Commission also noted that more than fifty consumers submitted comments to the NPRM recounting personal stories of prescribers withholding their prescriptions, yet none of these commenters had previously registered complaints with the FTC.<sup>107</sup>

In response, the AOA commented that if complaints to the FTC are not a good bellwether of prescriber compliance because consumers are unlikely to file formal complaints, the FTC should simplify and improve its complaint-reporting system.<sup>108</sup> The AOA deemed it unfair for the Commission to rely on consumer survey data as evidence of prescribers’ failure to release prescriptions, but not rely on the absence of consumer complaints as evidence that prescribers are automatically providing prescriptions.<sup>109</sup> The AOA stated the Commission should make an effort to make consumer complaint data—

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<sup>104</sup> SNPRM, 84 FR at 24674-75.

<sup>105</sup> Letter from Sens. Jack Reed and Sheldon Whitehouse (SNPRM Comment #6); Mass Mail Campaign (SNPRM Comment #25); Hanian (SNPRM Comment #27); Letter from 20 U.S. Senators (SNPRM Comment #38); Letter from Sen. Lisa Murkowski (SNPRM Comment #49); Levinson (SNPRM Comment #73); Cinalli (SNPRM Comment #93).

<sup>106</sup> SNPRM, 84 FR at 24674-75.

<sup>107</sup> *Id.* at 24675.

<sup>108</sup> American Optometric Association (SNPRM Comment #96).

<sup>109</sup> *Id.*

or lack thereof—more representative by providing a dedicated FCLCA complaint line for contact-lens-related issues.<sup>110</sup> At the same time, however, the AOA stated that since “it is very typical” for patients to ask for their prescription before their contact lens fitting is complete, consumer complaints cannot necessarily be viewed as accurate indications of non-compliance.<sup>111</sup>

The Commission does not find these arguments persuasive. As noted in the SNPRM, the Commission has gleaned, through its extensive experience with consumer complaints and deceptive practices, that the vast majority of injured or impacted consumers do not file complaints with the government.<sup>112</sup> And with the exception of the Telemarketing Sales Rule (often referred to as “Do Not Call”), consumer complaints about FTC rule violations are rarer still, perhaps because they require that consumers

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<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> SNPRM, 84 FR at 24675. Consumer reticence to complain, particularly to a government entity, is well documented. As one example, an FTC survey revealed that in 2017 there were an estimated 61.8 million incidents of fraud in the United States with approximately 40 million individual victims and average losses of \$100 or more, yet the FTC received just 1.2 million complaints of fraud from consumers, approximately 1.9% of all incidents. Keith B. Anderson, FTC, “Mass Market Consumer Fraud in the United States, A 2017 Update,” 24, 56 (Oct. 2019); FTC, “Consumer Sentinel Network Data Book 2017,” Number of Reports by Type, <https://www.ftc.gov/site-information/open-government/data-sets#csn>. It is likely these figures actually overstate the percentage of frauds reported to the FTC, since the FTC’s fraud surveys are limited to specific types of fraud, while there is no such limitation on complaints of fraud from consumers. *See also* Keith B. Anderson, FTC, “Consumer Fraud in the United States: An FTC Survey” 80 (2004), <http://www.ftc.gov/reports/consumer-fraud-united-states-ftc-survey>, (indicating that only 8.4% of U.S. fraud victims complained to an official source, with only 1.4% complaining to the FTC); Marc A. Grainer et al., “Consumer Problems and Complaints: a National View,” 6 *Advances in Consumer Res.* 494 (1979) (noting that “only a small, vocal minority of consumers complain about the problems they experience,” and even fewer (less than 10% of complaints) complain to the government), <http://acrwebsite.org/volumes/9603/volumes/v06/NA-06>; John Goodman & Steve Newman, “Understand Customer Behavior and Complaints,” *Quality Progress*, Jan. 2003, at 51 (finding that for problems that resulted in a relatively minor inconvenience or a

know what an FTC rule specifies and how it has been violated.<sup>113</sup> While the Commission continues to regard consumer complaints as valuable and informative, they often represent the tip of the iceberg.

Furthermore, for reasons discussed in detail in the NPRM, the Commission does not believe its complaint-reporting system bears principal responsibility for the shortage of complaints about prescriber violations of the Contact Lens Rule.<sup>114</sup> While the FTC does not have a dedicated complaint system solely for FCLCA violations, as sought by the AOA, the FTC Complaint Assistant is configured to capture and report all contact lens-related complaints, whether they originate from consumers, prescribers, sellers, or others.<sup>115</sup>

More to the point, multiple surveys have established that a high percentage of contact lens wearers (46-60%, according to submitted data) do not realize they are entitled to receive their prescription,<sup>116</sup> and thus would not be aware that an incident about which they should complain had occurred. Many other consumers might be unaware of where to direct a complaint when they do not receive a prescription. Even consumers who are aware that they have a right to their prescription, and know they can

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small loss of money, only 3% of consumers complained),  
[http://web.ist.utl.pt/~ist11038/CD\\_Casquilho/PRINT/qp0103goodman.pdf](http://web.ist.utl.pt/~ist11038/CD_Casquilho/PRINT/qp0103goodman.pdf)

<sup>113</sup> See generally, FTC, “Consumer Sentinel Network Data Book 2017,” Number of Reports by Type, <https://www.ftc.gov/site-information/open-government/data-sets#csn>. FTC, “Consumer Sentinel Network Data Book for January-December 2016” (2017), [https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-january-december-2016/csn\\_cy-2016\\_data\\_book.pdf](https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-january-december-2016/csn_cy-2016_data_book.pdf).

<sup>114</sup> NPRM, 81 FR at 88554-55.

<sup>115</sup> The Commission also notes that if, as the AOA asserts, some consumers would complain that they did not receive their prescriptions before they were, in fact, entitled to them, creating a dedicated system for FCLCA complaints would not make the number of complaints any more or less reflective of prescriber compliance.

<sup>116</sup> SNPRM, 84 FR at 24675.

file a complaint with the FTC, may be unlikely to file one if they ultimately receive their prescription *after they have asked their provider for it*. From the consumers' perspective, they have resolved their problem and may perceive little benefit to themselves from filing a complaint with the government, even if the method for filing one was more streamlined or convenient. Consumers may also not want to risk antagonizing their providers or subjecting them to legal penalties. Thus, for evaluating Contact Lens Rule compliance, the Commission has considered the low rate of consumer complaints filed with the FTC's Complaint Assistant, but remains convinced this is less probative of the scope of the problem than other evidence.<sup>117</sup>

**c. Number of Verifications as Evidence of Non-Compliance with the Automatic Prescription Release Requirement**

In the SNPRM, the Commission noted that it would accord the number of verifications less weight than it had in the NPRM as evidence of prescriber non-compliance out of a recognition that some consumers—even if in possession of their prescription—may find it easier to type in their specifications than present a prescription to the seller, and because some online contact lens sellers do not have a mechanism for consumers to present their prescriptions.<sup>118</sup> In its comment to the SNPRM, the AOA contended that the high number of verifications should not be accorded *any* weight at all for those reasons. As additional support for this contention, the AOA cited internal prescriber complaint data showing that the percentage of prescriber complaints about “problematic verification calls” has increased from roughly 6% to 17% in the past four

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<sup>117</sup> Consumer surveys may also be more reliable since consumers questioned at random are less likely to have a personal interest in stating that they did not receive their prescription.

<sup>118</sup> SNPRM, 84 FR at 24674.

years; it attributed much of this increase to the emergence of an online seller that does not permit patient prescription presentation.<sup>119</sup> According to the AOA, the increase in complaints about verification, and the high percentage of such complaints about the online seller, demonstrate that a “high volume of verification calls are occurring based on a prescription that was never written,” and therefore the number of verification calls is “simply not an appropriate measure for assessing contact lens prescription requirements and should be afforded no weight.”<sup>120</sup>

The Commission is aware of the issues raised by the AOA, but still believes that the high number of verifications is an indication that many consumers are not receiving their prescriptions from their prescribers. While a few new online sellers do not permit prescription presentation, these sellers’ share of the overall contact lens sales is still quite small, even if their share of prescriber complaints, according to the AOA, is disproportionately large.<sup>121</sup> Sellers with far greater sales, such as 1-800 CONTACTS and Walmart, actively encourage consumers to present their prescriptions, and 1-800 CONTACTS has even at times offered consumers discounts for doing so, because it is

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<sup>119</sup> American Optometric Association (SNPRM Comment #96).

<sup>120</sup> *Id.*

<sup>121</sup> 1-800 CONTACTS accounts for approximately 10% of overall retail contact lens sales in the United States, and as much as 60-65% of online sales. The next closest online competitor has less than a quarter of the sales of 1-800 CONTACTS. *See* Fed. Trade Comm’n, The Contact Lens Rule and the Evolving Contact Lens Marketplace, Panel IV: Examining the Verification Process Tr. at 17 (Mar. 7, 2018), [https://www.ftc.gov/system/files/documents/public\\_events/1285493/panel\\_iv\\_examining\\_the\\_verification\\_process.pdf](https://www.ftc.gov/system/files/documents/public_events/1285493/panel_iv_examining_the_verification_process.pdf) [hereinafter CLR Panel IV Tr.] (statement of Cindy Williams, 1-800 CONTACTS General Counsel). Walmart accounts for between 6-10% of all U.S. contact lens sales. Complaint Counsel’s Post-Trial Brief and Exhibits, *In the Matter of 1-800 CONTACTS*, 5, (June 22, 2017), <https://www.ftc.gov/system/files/documents/cases/d09372ccfindingsoffact.pdf>; Respondent 1-800 CONTACTS Proposed Findings of Fact and Conclusions of Law, *In the Matter of 1-800 CONTACTS*, 59 (June 22, 2017), <https://www.ftc.gov/system/files/documents/cases/d09372respfindingsoffact.pdf>.

faster and less expensive than verification.<sup>122</sup> Yet despite that encouragement, roughly 73% of overall sales by third-party sellers continues to occur via verification.<sup>123</sup> Therefore, while the Commission will accord the high number of verifications less weight than it did in the NPRM, the Commission cannot dismiss its significance altogether as an indicator that consumers are not always provided their prescriptions, and will consider it as one of several factors in weighing the evidence of non-compliance in the record. The Commission also notes that even if the high number of verifications were disregarded altogether, the Commission's overall assessment of prescriber compliance, and the need for Rule modifications, would not change.

## **2. Comments About the Need to Improve the Commission's Ability to Monitor Compliance and Enforce the Rule**

Several commenters focused on the need to create an auditable record that would enable the Commission to monitor compliance and better enforce the automatic-release provision.<sup>124</sup> One commenter, the Coalition for Contact Lens Consumer Choice, stated the Confirmation of Prescription Release proposal gives prescribers more leeway to design a system of confirmation of prescription release, but "the important thing is that

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<sup>122</sup> National Association of Optometrists and Opticians (SNPRM Comment #129) ("Because of the cost and time it takes to verify a prescription when the script is not available, typically an online seller encourages such uploading and this process aids in consumer satisfaction and quicker, more accurate service."); 1-800 CONTACTS (SNPRM Comment #135) (1-800 CONTACTS encourages its customers to upload their prescriptions). *See also* CLR Panel IV Tr., *supra* note 121, at 6-7 (statement of Jennifer Sommer of Walmart); *id.* at 6-7, 22 (statement of Cindy Williams of 1-800 CONTACTS).

<sup>123</sup> Paperwork Reduction Act Proposed Collection, Comment Request, 84 FR at 32171. *See also* 1-800 CONTACTS (NPRM Comment #3898) (stating that 70% of online orders require verification).

<sup>124</sup> Bosley (SNPRM Comment #58); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); National Hispanic Medical Association (SNPRM Comment #146).

prescribers are still required to have patients affirmatively acknowledge release. . . . This is critical to increase enforcement of the law and to ensure that bad actors are identified quickly without inconveniencing those who are obeying the law.”<sup>125</sup> The commenter Citizen Outreach agreed, stating that the only way to ensure compliance with automatic release is by requiring consumers to sign a confirmation, and suggested that failing to require a consumer’s signed confirmation would be a loophole “large enough for ‘bad actors’ to drive a truckload of contact lenses through.”<sup>126</sup> Likewise, the Attorneys General of Twenty-Seven States commented that the proposed Confirmation of Prescription Release modifications “strengthen the Commission’s ability to verify compliance with the CLR [which] ensures more contact lens consumers have the necessary information to make informed decisions, spurring competition and consumer choice.”<sup>127</sup>

Other commenters, however, felt that the FTC already has sufficient mechanisms to enforce the Contact Lens Rule, and should bring enforcement actions against so-called “outliers” who are violating the Rule, rather than imposing new requirements on all contact lens prescribers.<sup>128</sup> Some suggested that the Confirmation of Prescription Release requirements should be imposed only on those found to be violating the prescription-

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<sup>125</sup> Coalition for Contact Lens Consumer Choice (SNPRM Comment #89).

<sup>126</sup> Citizen Outreach (SNPRM Comment #78).

<sup>127</sup> Attorneys General of 27 States (SNPRM Comment #139).

<sup>128</sup> Mass Mail Campaign (SNPRM Comment #25); Ohio Optometric Association (SNPRM Comment #47); Hardy (SNPRM Comment #60) (“Is it a fair idea to punish 100% of optometrists and ophthalmologists for the actions of a fraction of 1%”); American Optometric Association (SNPRM Comment #96); American Academy of Ophthalmology (SNPRM Comment #136) (practices will have to comply with the new burdens even if they have complied with prescription-release for over a decade).

release requirement.<sup>129</sup> “By refocusing these ideas as penalties, rather than mandates,” according to AAO, “the FTC can ensure that they are not inflicting burdens on prescribers that have a record of compliance with the prescription release requirement in the CLR.”<sup>130</sup> AOA believes that the FTC already has sufficient authority and investigative tools at its disposal, and suggested the Commission could use its ability to issue administrative subpoenas to investigate prescribers who might be violating the Rule.<sup>131</sup> One prescriber also commented that he was skeptical that prescribers who currently disregard the prescription-release requirement would comply with the confirmation requirement,<sup>132</sup> a concern previously raised and discussed in the SNPRM.<sup>133</sup>

Some commenters also criticized the FTC for, in their words, trying to acquire new authority to target small and mid-sized businesses, and stated this ran counter to the current trend for Congress and other federal agencies to “recognize the need to alleviate the administrative burden that federal programs place on physician practices.”<sup>134</sup> And several commenters asserted that the Commission should not focus on enforcing

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<sup>129</sup> American Optometric Association (SNPRM Comment #96); American Academy of Ophthalmology (SNPRM Comment #136).

<sup>130</sup> American Academy of Ophthalmology (SNPRM Comment #136). The AAO suggested that the acknowledgment and record-keeping provisions should be imposed on prescribers who have had multiple complaints, and whose non-compliance was verified after allowing prescribers an avenue to respond and defend themselves.

<sup>131</sup> American Optometric Association (SNPRM Comment #96).

<sup>132</sup> Steinemann (SNPRM Comment #138).

<sup>133</sup> SNPRM, 84 FR at 24676, 24681.

<sup>134</sup> American Society of Cataract and Refractive Surgery (SNPRM Comment #127). *See also* Letter from 20 U.S. Senators (SNPRM Comment #38); Letter from Sen. Lisa Murkowski (SNPRM Comment #49).

requirements against prescribers while contact lens sellers, in their view, are violating Rule provisions in far greater numbers.<sup>135</sup>

After considering these comments, the Commission continues to believe that some form of retained documentation is necessary to improve the Commission's enforcement and monitoring ability. As previously noted, the Commission currently faces challenges in enforcing the Rule. Prescribers, whether intentionally or not, currently can fail to release prescriptions yet risk little because consumers are unlikely to file a complaint if they ask for and subsequently receive a prescription. When a consumer does complain to the FTC, typically the only evidence is the word of the consumer against that of the prescriber, making it difficult for the Commission to establish with a degree of certainty whether a violation has occurred. This fact has played a significant role in the lack of Rule enforcement against prescribers over the last fifteen years, and may be a contributing factor to the high number of contact lens patients who do not currently receive their prescriptions automatically as required by law.

While the AOA suggests that the Commission can use its current authority to issue administrative subpoenas and conduct investigative hearings to explore possible Rule violations, an examination of a prescriber's Confirmation of Prescription Release records allows a much more efficient means of determining whether a prescriber is

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<sup>135</sup> McManus (SNPRM Comment #18); Ulrich (SNPRM Comment #19) (FTC is punishing the wrong actors); Gilberg (SNPRM Comment #46); American Optometric Association (SNPRM Comment #96); American Academy of Ophthalmology (SNPRM Comment #136).

complying with the Rule, and is much less disruptive and burdensome for the prescriber.<sup>136</sup>

As for the assertion that prescribers who do not currently comply with prescription release are unlikely to comply with the confirmation requirement, the difference is that in the latter instance, there would be a way to check compliance. If the Commission has concerns about a prescriber's compliance, it can request patient confirmations or proof of digital delivery, or a sample of such, which should resolve most questions as to whether the prescriber provided prescriptions in accordance with the law. In this way, it would benefit prescribers because they would have a relatively quick and inexpensive way to show the FTC they complied with their automatic-release obligations.

Further, the Commission is not attempting to expand its authority to target small businesses. The Commission already possesses the authority under the FCLCA to enforce the Rule for all contact lens prescribers, large and small. The Commission's Final Rule institutes a more effective mechanism for enforcing and evaluating the authority it already has. And while the Commission recognizes the need to avoid unnecessary government regulations, the Rule itself is, as one commenter put it, "deregulatory" in nature since its purpose is to restore free market competition, not to rein it in.<sup>137</sup> If the Rule, as currently applied and enforced, is failing to meet this congressionally mandated goal in some respects, it is the duty of the Commission to find a more effective manner to realize that purpose.

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<sup>136</sup> Serving administrative subpoenas on a wide-scale basis to prescribers who might not be releasing prescriptions, and requiring that a prescriber identify all of her contact lens customers for the last several months so they could be interviewed, would likely be criticized as excessive and heavy-handed.

<sup>137</sup> National Taxpayers Union (SNPRM Comment #149).

With regard to the argument that it is unjust to focus on enforcing the automatic-release provision while not enforcing regulations that apply to sellers, the Commission does not agree with this premise. The Commission is aware of complaints about seller misconduct and is implementing several changes in this Final Rule to improve seller compliance. The Commission has also brought enforcement actions against sellers for violating the Rule and expects it will bring others in the future.<sup>138</sup> Moreover, seller non-compliance does not excuse prescriber non-compliance, nor does it provide a justification for the Commission to reject taking action to improve compliance with a different requirement in the Rule.

### **3. Comments About Whether the Structure of the Contact Lens Market Creates a Need for Verifiable Enforcement of Automatic Prescription Release**

Many SNPRM commenters focused on the structure of the contact lens market and whether a system in which prescribers sell the items they prescribe creates an

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<sup>138</sup> See, e.g., *U.S. v. Duskin*, No. 1:18-cv-07359 (N.D. Cal. Dec. 6, 2018) (consent); *U.S. v. Kim*, No. 1:11-cv-05723 (E.D.N.Y. Feb 7, 2012) (consent); *U.S. v. Royal Tronics, Inc.*, No. 0:11-cv-62491 (S.D. Fla. Jan. 27, 2012) (consent); *U.S. v. Thy Xuan Ho*, No. 1:11-cv-03419 (D. Minn. Dec. 27, 2011) (consent); *U.S. v. Gothic Lens, LLC*, No. 1:11-cv-00159 (N.D. Ga. Feb. 3, 2011) (consent); *U.S. v. Jokeshop, LLC*, No. 1:11-cv-11221 (D. Mass. Nov. 29, 2011) (consent); *U.S. v. Contact Lens Heaven, Inc.*, No. 0:08-cv-61713 (S.D. Fla. Dec. 3, 2008) (consent); *U.S. v. Chapin N. Wright, II*, No. 1:08-cv-11793 (D. Mass. Oct. 31, 2008) (consent); *U.S. v. BeWild, Inc.*, No. 2:07-cv-04896 (E.D.N.Y. Dec. 3, 2007) (consent); *U.S. v. Pretty Eyes, LLC*, No. 1:07-cv-02462 (D. Colo. Nov. 28, 2007) (consent); *U.S. v. Walsh Optical, Inc.*, No. 2:06-cv-03591 (D.N.J. Aug. 30, 2006) (consent); see also FTC Sends Warning Letters to Sellers of Cosmetic Contacts: All Contact Lens Purchases Require a Prescription from a Medical Professional, <https://www.ftc.gov/news-events/press-releases/2019/10/ftc-sends-warning-letters-sellers-cosmetic-contacts-all-contact>; FTC Issues Warning Letters Regarding the Agency's Contact Lens Rule, <https://www.ftc.gov/news-events/press-releases/2016/04/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule>.

inherent conflict that requires additional corrective action by the Commission.<sup>139</sup> U.S. Senator Ron Wyden, for example, commented that Congress passed the FCLCA “to address a distorted contact lens marketplace that had seen freedom of choice eroded as prescribers largely sold the contact lenses they prescribed,”<sup>140</sup> and another commenter wrote, “The system here in the US for buying contact lenses is stacked against consumers because the people who issue you your prescription are also allowed to sell you contact lenses at the very same time. Consumers who don’t know their rights are getting ‘trapped in the exam chair’ so to speak, unaware that they can buy lenses elsewhere for lower prices.”<sup>141</sup> According to the Information Technology & Innovation Foundation, which describes itself as a nonpartisan research and educational institute, “the profession has both a powerful economic interest (profits) and a powerful tool (the prescription) to make it more difficult for consumers to buy their lenses from lower-cost providers.”<sup>142</sup> In fact, a number of commenters support the Commission’s proposal because, while regulatory in nature, it is designed to promote free market competition and protect consumers’ ability

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<sup>139</sup> Citizen Outreach (SNPRM Comment #78) (prescribers’ ability to sell what they prescribe ensures a “captive market”); Lens.com (SNPRM Comment #85) (“the current system is rigged against consumers and companies who compete with prescribers”); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Taxpayers Protection Alliance (SNPRM Comment #118); Information Technology & Innovation Foundation (SNPRM Comment #103); National Hispanic Medical Association (SNPRM Comment #146).

<sup>140</sup> Letter from Sen. Ron Wyden (SNPRM Comment #5); *see also* Taxpayers Protection Alliance (SNPRM Comment #118) (“Congress passed the bipartisan Fairness to Contact Lens Consumers Act to protect contact lens wearers. The result was less market distortion and more competition, leading to more choices and lower prices for consumers.”).

<sup>141</sup> National Hispanic Medical Association (SNPRM Comment #146).

<sup>142</sup> Information Technology & Innovation Foundation (SNPRM Comment #103).

to purchase from the seller of their choice.<sup>143</sup> One commenter wrote that the only solution to what she termed “the inherent structural problem that continues to cause friction between providers and patients” is to prohibit prescribers from selling contact lenses.<sup>144</sup>

The AOA, on the other hand, disputes the premise that the contact lens market is unique, and argues that the fact that prescribers sell what they prescribe does not create an impetus for corrective regulation.<sup>145</sup> According to the AOA, health care professionals in certain other areas—such as ambulatory surgery centers, orthopedic centers, and dental service providers, among others—also sell what they prescribe or recommend for treatment. Furthermore, according to the AOA, helping patients “obtain treatment while in their doctor’s office builds strong doctor-patient relationships and promotes patient-centered care.”<sup>146</sup> The AOA therefore concludes that “the Commission seems to have used the inaccurate belief that contact lens prescribers’ role in the market is entirely unique as a justification for implementing new regulations on physicians,” and thus, “the entire argument for supporting prescriber rule changes must be reevaluated.”<sup>147</sup>

Several commenters also felt that the contact lens market is functioning properly,

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<sup>143</sup> See Americans for Tax Reform (SNPRM Comment #72) (“These changes strike the correct balance between promoting the free market and protecting important consumer rights.”); Citizen Outreach (SNPRM Comment #78); Taxpayers Protection Alliance (SNPRM Comment #118) (“Although we are often critical of government overreach and work hard to make government smaller, we believe that the FTC’s proposed Contact Lens Rule is a government rule that works for taxpayers and consumers.”); National Taxpayers Union (SNPRM Comment #149) (“From the perspective of free-market, limited government advocates, the Contact Lens Rule has been one of the most balanced and successful examples of ‘deregulatory rulemaking’ in the FTC’s history.”).

<sup>144</sup> Carafas (SNPRM Comment #39).

<sup>145</sup> American Optometric Association (SNPRM Comment #96).

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

as evidenced by the relatively large number of contact lens sellers, and by lens prices that appear competitive, and thus there is no need for FTC intervention to modify the Rule.<sup>148</sup> As support for this position, the AOA submitted a price-comparison analysis that it stated showed that the average price difference for contact lenses between online sellers and office prescribers was just thirty-two cents.<sup>149</sup> According to the AOA, this demonstrates that the market is highly competitive, and thus the FCLCA and Rule are working as intended and, consequently, there is no need for Rule modification and a Confirmation of Prescription Release.<sup>150</sup>

The Commission does not share this assessment. While there are now a number of different types of sellers, and the market has become more competitive than it was before the Rule,<sup>151</sup> prescribers still possess a significantly higher share of contact lens sales than online sellers, mass merchandisers, or retail chains,<sup>152</sup> even though prescriber prices, on the whole, are consistently higher.<sup>153</sup> The AOA's assessment appears to be

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<sup>148</sup> Warner (SNPRM Comment #9); Ohio Optometric Association (SNPRM Comment #47); Cutter (SNPRM Comment #81); American Optometric Association (SNPRM Comment #96).

<sup>149</sup> American Optometric Association (SNPRM Comment #96).

<sup>150</sup> *Id.*

<sup>151</sup> CLR Panel I Tr., *supra* note 100, at 3-5 (remarks of Steve Kodey and accompanying slides, US Optical Market Overview).

<sup>152</sup> Approximately 39% of all contact lenses sales revenue in the U.S. occurs at independent eye care professionals, compared to 18% at conventional chains, 25% at mass merchants and wholesale clubs, and 16% online. Vision Council, U.S. Optical Market Eyewear Overview 4 (2018), [https://www.ftc.gov/sites/default/files/filefield\\_paths/steve\\_kodey\\_ppt\\_presentation.pdf](https://www.ftc.gov/sites/default/files/filefield_paths/steve_kodey_ppt_presentation.pdf). It is also worth noting that while the contact lens retail market has evolved since 2004, it may well have changed *less* dramatically than many other retail industries have since the Internet revolution began diverting sales from brick and mortar to online merchants.

<sup>153</sup> *See* CLR Panel I Tr., *supra* note 100, at 9 (remarks of Wallace Lovejoy and accompanying slides, Contact Lens Price Ranges By Sales Channel); *see also* Opinion of the Commission, *In the Matter of 1-800 CONTACTS*, 4 (“Among brick-and-mortar retailers, independent ECPs typically have the highest prices for contact lenses . . .”),

based on lens price per-packet, rather than per-day or per-year.<sup>154</sup> The Commission does not believe per-packet pricing is a fair method of comparison, because it compares some lenses that are effectively sold in a multi-month supply with lenses that are only sold as a single month's supply. The Commission conducted a re-analysis of the AOA's data by aggregating to a consistent time-frame in order to compare what consumers might actually spend to wear lenses on a regular basis. This re-analysis—using the data supplied by AOA—determined that the average annual prices of contacts were from \$9 to \$40 more expensive if purchased from a private practice than from the leading online seller.<sup>155</sup> The price difference for an annual supply of lenses was even starker between a private practitioner and a leading mass merchandiser, with private practitioners averaging between \$62 and \$92 more for an annual supply.<sup>156</sup> Likewise, at the Commission's Contact Lens Workshop, an eye care consultant presented a price survey for sixteen leading contact lens brands and concluded that an annual supply of lenses purchased

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[https://www.ftc.gov/system/files/documents/cases/docket\\_no\\_9372\\_opinion\\_of\\_the\\_commission\\_redacted\\_public\\_version.pdf](https://www.ftc.gov/system/files/documents/cases/docket_no_9372_opinion_of_the_commission_redacted_public_version.pdf).

<sup>154</sup> The Commission has not been able to precisely replicate the thirty-two-cent-difference figure stated by AOA. But by comparing average packet prices in the data supplied, the difference between private practices and online sellers is 35 cents. For the reasons stated, however, the Commission does not believe this figure is an appropriate comparison measure.

<sup>155</sup> The average depends on whether a consumer purchased an annual supply all at once (in which case they received a discount from the online retailer) or in individual package increments. The Commission also notes that prices at the “Leading Online Retailer,” which, based on sales and market share, could be 1-800 CONTACTS, might not represent the average online price for contact lenses, and prices at 1-800 CONTACTS, by its own admission, are typically higher than those of both other online sellers and retail club stores. Brief of 1-800 CONTACTS, *1-800 CONTACTS v. Federal Trade Commission* (2d Cir. June 12, 2019); *see also* Opinion of the Commission, *In the Matter of 1-800 CONTACTS*, 4, [https://www.ftc.gov/system/files/documents/cases/docket\\_no\\_9372\\_opinion\\_of\\_the\\_commission\\_redacted\\_public\\_version.pdf](https://www.ftc.gov/system/files/documents/cases/docket_no_9372_opinion_of_the_commission_redacted_public_version.pdf).

<sup>156</sup> The data derives from the ABB Optical Group, Soft Lens Retail Price Monitor (First Quarter 2019).

online averaged \$17.56 less than at an independent prescribers' office, and lenses purchased from a shopper's club averaged \$42.44 less.<sup>157</sup>

There can be valid reasons for differences in prices among sellers (some sellers may offer more convenience, options, or better customer service), and the Commission does not view price differences between private eye care practitioners and third-party sellers, in and of itself, as dispositive evidence that the market is not functioning in a competitive manner. But the Commission disagrees that the submitted pricing data is proof that the market *is* functioning in a perfectly competitive manner, and is proof that prescribers are providing patients with their prescriptions.

The Commission is also aware that there are other health care professionals who may sell what they prescribe or recommend for treatment, and has not based its proposal solely on a belief that contact lens prescribers' role and market is unique. Rather, the Commission has considered the structure of the market as a contributing factor in an overall evaluation of the need for improved Rule compliance and enforcement. It must be acknowledged—as it was by Congress when it enacted the FCLCA and directed the FTC to implement the Rule—that it is not in prescribers' self-interest for their patients to take prescriptions elsewhere to buy lenses.<sup>158</sup> And while it is true that some health care

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<sup>157</sup> CLR Panel I Tr., *supra* note 100, at 9 (remarks of Wallace Lovejoy and accompanying slides, Contact Lens Price Ranges By Sales Channel).

<sup>158</sup> *See* H.R. Rep. No. 108-318, at 4-5 (stating that “[t]he practice of optometrists withholding the prescription has limited the consumer’s ability to shop for the best price and has impacted competition” and that obstacles to free market competition are rooted in an “inherent conflict of interest” in that “[u]nlike medical doctors who are prohibited from selling the drugs they prescribe, eye doctors and optometrists . . . are able to fill the contact lens prescriptions they write”); *see also* 149 Cong. Rec. H11564-65 (daily ed. Nov. 19, 2003) (statement of Rep. Stark) (“Eye doctors cite health concerns, but the fact is they have a strong financial incentive to restrict consumer access to the contact lens market.”).

professionals in other fields sell products that they prescribe or recommend for treatment, the sheer volume of contact lens prescribers' revenue and profit derived from the sale of contact lenses—16-32% of revenue, by some accounts<sup>159</sup>—creates a powerful incentive to keep those sales in house.

#### **4. Comments About the Text of the Proposed Confirmation of Prescription Release, and the Options to Include the Confirmation as Part of a Patient's Prescription or Sales Receipt**

As noted previously, unlike the two-sentence signed-acknowledgment proposal from the NPRM,<sup>160</sup> the SNPRM's Confirmation of Prescription Release proposal did not mandate specific text for the patient's signed confirmation. Instead, the SNPRM, for convenience, provided optional sample language that prescribers could use but left it up to individual prescribers to draft their own confirmation language if they so preferred.<sup>161</sup> The Commission proposed this flexibility in response to commenter concerns that the language of the NPRM's signed-acknowledgment interfered with the prescriber-patient relationship by imparting the impression that prescribers had done something wrong. By permitting prescribers to draft their own confirmation language or use the provided,

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<sup>159</sup> Harris Williams & Co., Vision Industry Update, at 4 (Mar. 2017); Harris Williams & Co., Vision Industry Overview, at 3 (Jan. 2015). Contact Lens Spectrum has estimated the percentage of gross practice revenue from contact lenses to be 30%, and the net practice revenue at 26%, but the estimate does not specify how much of that was derived from sales of lenses versus professional fees for contact lens fittings and examinations. Contact Lens Spectrum, at 19 (Jan. 2019), <https://bt.editionsbyfry.com/publication/frame.php?i=552776&p=&pn=&ver=html5>. See also Ken Kriviac, How to Hubble-Proof Your Contact Lens Practice, Review of Optometric Business (Jan. 17, 2018) (optometrist stating that 17% of his practice's total revenue is generated from the sale of contact lens related materials, with another 8% from related professional fees), <https://reviewob.com/can-hubble-proof-contact-lens-practice/>.

<sup>160</sup> NPRM, 81 FR at 88559.

<sup>161</sup> SNPRM, 84 FR at 24683. The sample language provided by the Commission consisted of the following: "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting."

shortened sample language, the Commission aimed to allow prescribers to use wording that they believe would be less likely to reflect negatively on the prescribers' conduct.<sup>162</sup> The Commission also proposed to allow prescribers to include the confirmation as part of a patient's prescription or sales receipt.<sup>163</sup>

One commenter, the National Association of Optometrists and Opticians ("NAOO"), praised the new options and flexibility, stating it would "assist the industry in, and lighten the burdens of, compliance."<sup>164</sup> The NAOO also approved of the FTC sample confirmation language, calling it a "concise statement of the point of the Rule," and predicting it would be used by most of its members.<sup>165</sup> The NAOO did suggest, however, that to avoid potential confusion from a confirmation statement containing additional acknowledgments or unnecessary information, the Rule should clarify that the patient's confirmation statement should not contain any message or acknowledgment other than that relating to confirmation of prescription release.<sup>166</sup> The NAOO also suggested that in instances where a consumer refused to sign the confirmation, the Commission should allow the prescriber to note the refusal and the reason for it as evidence of compliance.<sup>167</sup>

Other commenters felt that even with the new confirmation-language flexibility, requiring patients to confirm receipt of their prescriptions would imply that prescribers

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<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

had been improperly withholding them.<sup>168</sup> One prescriber commented, “Why would I need to get a signature of my patient to confirm they received a prescription unless I was doing something wrong that required proof.”<sup>169</sup> Others felt that the requirement still unfairly forced them to aid their competition by reminding consumers that they could take their prescriptions to other sellers to have them filled.<sup>170</sup>

In contrast, some commenters felt that allowing prescribers to draft their own language, and removing the second sentence of the acknowledgment (the requirement that patients confirm the statement: “I understand I am free to purchase contact lenses from the seller of my choice”), greatly reduced the effectiveness of the new proposal.<sup>171</sup> The online seller 1-800 CONTACTS, in particular, asserted that removal of the second sentence significantly reduced the educational benefit of the requirement since consumers who were unaware they had a right to their prescription would not be so informed. 1-800 CONTACTS also stated that eliminating the second sentence made it less likely prescribers would release prescriptions directly after the fitting is complete, and

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<sup>168</sup> Abert (SNPRM Comment #20) (“The additional time required for this unneeded paperwork would disrupt the patient-doctor relationship by communicating to the patients that they should be wary of their physician, and assume that their doctor is a violator of Federal law.”); Ohio Optometric Association (SNPRM Comment #47) (“The proposal, even in its latest form, will . . . cast public doubt on the integrity of the optometrists and ophthalmologists . . . .”); Cutter (SNPRM Comment #81); Ritzel (SNPRM Comment #157) (“The idea of me having to have a patient sign a form certifying that I actually gave them a copy of their contact lens prescription—because “Big Brother” is watching—is insulting to myself as a person, and to my profession.”).

<sup>169</sup> Cutter (SNPRM Comment #81).

<sup>170</sup> Sanders (SNPRM Comment #61) (“It’s akin to having Target have a big sign next to their own that states, ‘You can get everything here at Walmart as well!’”); Poulter (SNPRM Comment #131) (“It is no more necessary for providers to inform patients of their right to purchase elsewhere than it is for a dentist to let a patient know he can purchase a crown from another party, then return to the dentist to have it placed.”).

<sup>171</sup> Consumer Reports (SNPRM Comment #133); 1-800 CONTACTS (SNPRM Comment #135).

prescribers would instead wait until patients had purchased lenses before giving them their prescriptions and obtaining Confirmations of Prescription Release.<sup>172</sup> 1-800 CONTACTS also said there is no reason the second sentence would “sow consumer doubt or harm prescribers’ reputations” unless the prescriber had previously been withholding prescriptions.<sup>173</sup> The online seller therefore proposed that instead of leaving the wording up to prescribers, the confirmation requirement should again specify the wording required and include the second sentence from the acknowledgment proposal—albeit with a minor adjustment—so as to state, “I understand that I am free to purchase contact lenses from my eye care professional or the seller of my choice.”<sup>174</sup> Inclusion of the option to purchase from the “eye care professional” might alleviate some concern that the notice was instructing consumers to buy from someone other than their prescriber.

The consumer advocacy organization Consumer Reports also opposed permitting prescribers to devise their own language of confirmation, and opposed allowing prescribers to make the confirmation part of a prescription copy or sales receipt (Confirmation of Prescription Release options (B) and (C)).<sup>175</sup> Instead, Consumer Reports stated that the confirmation should remain a stand-alone document, and suggested requiring the statement, “My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I should give a

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<sup>172</sup> 1-800 CONTACTS (SNPRM Comment #135) (According to a survey conducted by an independent polling firm on behalf of 1-800 CONTACTS, 38% of consumers who are given their prescription receive it at the same time or only after they have already purchased lenses from the prescriber).

<sup>173</sup> *Id.* (“Because the Confirmation does not require that prescribers provide consumers with any notice of their rights, but merely requires that consumers acknowledge receipt by signature, it is far less likely to either educate consumers or discourage prescribers from pressuring consumers into buying lenses.”).

<sup>174</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>175</sup> Consumer Reports (SNPRM Comment #133).

copy of my prescription to the contact lens seller I choose.”<sup>176</sup> According to Consumers Reports, there are “clear advantages to standardized wording,” and by instructing consumers to present their prescription to sellers, this would further promote the Commission’s goal of reducing verifications.<sup>177</sup> Consumer Reports opined that a statement of confirmation added to the prescriber’s copy of the prescription, or added to an examination receipt, might not be noticed by the patient.<sup>178</sup>

Some commenters also opined that when prescribers satisfy the confirmation by releasing the prescription electronically (option (D)), prescribers should still provide consumers with a statement advising them that they have a right to their prescription and have the option to buy lenses elsewhere.<sup>179</sup> And many commenters raised concerns about whether to allow option (D) altogether, as discussed in more detail below.

With respect to allowing options (B) and (C), and permitting prescribers to craft their own wording, the Commission acknowledges that the confirmation proposal may provide less of an immediate educational benefit than the NPRM’s proposed Signed Acknowledgment. By permitting prescribers to include the confirmation on the prescription itself, or on a sales receipt, it is indeed possible that some consumers will fail to understand its purpose, or what it is they are signing. And by not requiring that the confirmation include a sentence specifically informing consumers of their right to have prescriptions filled elsewhere, and not requiring a notice to this effect with digital delivery, some consumers may remain unaware of prescription portability.

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<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*; 1-800 CONTACTS (SNPRM Comment #135).

The Commission, however, continues to believe that the benefit from providing prescribers with greater flexibility, reducing the possible paperwork burden, and limiting potential interference with the prescriber-patient relationship, justifies the trade-off. As noted in the SNPRM, the Confirmation of Prescription Release will maintain much of the effectiveness and enforceability of the Signed Acknowledgment, while reducing the impact on prescribers.<sup>180</sup>

The Commission also does not believe that requiring patients to sign a confirmation will provoke doubts about the integrity of their prescribers. While patients might draw the conclusion that some prescribers have not always automatically released prescriptions, there is little reason for patients to conclude that their individual prescriber had failed to do so, especially if their prescriber has always provided them with their prescription. It seems more likely that patients may simply conclude that the law has changed. Furthermore, as noted in the SNPRM, consumers are accustomed to signing acknowledgments or receipts. Many pharmacists require patients to acknowledge that they do not have questions upon receiving a prescription; physicians' offices require visitors to sign in; and patients are accustomed to signing HIPAA acknowledgment forms signifying they received a provider's Notice of Privacy Practices.<sup>181</sup> The Commission is not aware of any evidence that such requirements sow distrust on the part of the person signing the receipt. The Commission believes this will hold true for the Confirmation of Prescription Release, particularly since prescribers can devise their own language of confirmation. The Commission also believes that while it may be advisable for providers to avoid potential patient confusion by not including any other acknowledgments or

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<sup>180</sup> SNPRM, 84 FR at 24683.

<sup>181</sup> *Id.* at 24682.

information on the confirmation document, it is not necessary to expressly prohibit this in the Rule at this time. Such a prohibition might limit the flexibility of the new proposal, and could make it more difficult for providers to avail themselves of options (B) and (C) by including patient confirmation as part of a sales receipt or prescription copy. Moreover, as noted in the SNPRM, while prescribers are free to provide their own language, it would remain a violation for the receipt to include additional information proscribed by the Rule, such as liability waivers or agreements to purchase lenses from the prescriber.<sup>182</sup>

#### **5. Comments About Option (D) and Using Electronic Delivery for Confirmation of Prescription Release**

In the SNPRM, the Commission proposed modifying the Rule to allow prescribers to satisfy the automatic prescription release requirement by providing a digital copy in lieu of a paper copy when the patient gives verifiable affirmative consent.<sup>183</sup> The Commission noted that using online patient portals and other electronic methods to complete the automatic prescription release offered potential benefits for sellers, prescribers, and patients.<sup>184</sup> Patients would be able to access their prescriptions and have electronic copies to send to sellers. With the prescription, a seller would no longer need to submit a verification request, which would benefit prescribers by reducing the volume of requests. However, there were also some concerns about portals, including that patients may not be aware of the portal or have difficulty accessing it.<sup>185</sup> Because the Commission did not have sufficient information to determine whether solely posting a

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<sup>182</sup> *Id.* at 24683.

<sup>183</sup> *Id.* at 24669.

<sup>184</sup> *Id.* at 24668.

<sup>185</sup> *Id.*

contact lens prescription on a patient portal would be sufficient to satisfy the Rule’s obligation for prescribers to provide a copy of the prescription after completing the contact lens fitting, the Commission sought comments on its proposed Rule modification.<sup>186</sup> The Commission also asked for comments on whether prescribers should be required to maintain any records documenting a patient’s verifiable consent to receive a prescription electronically.<sup>187</sup>

**a. Use of Patient Portals and Patient Consent**

Many commenters expressed support for allowing prescribers to use electronic methods, such as a patient portal, to provide prescriptions to patients who consent.<sup>188</sup> Among the potential benefits, commenters noted the reduction in verification calls or requests for additional copies, easier access to and use of a prescription, lower costs, and flexibility for patients and prescribers.<sup>189</sup> Currently, many prescribers already use a portal or other electronic methods to communicate with and, in some instances, provide

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<sup>186</sup> *Id.* at 24669.

<sup>187</sup> *Id.* at 24690.

<sup>188</sup> *See, e.g.*, Liao (SNPRM Comment #2); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101); Information Technology & Innovation Foundation (SNPRM Comment #103); Alcon Vision, LLC (SNPRM Comment #117); National Association of Optometrists and Opticians (SNPRM Comment #129); CooperVision, Inc. (SNPRM Comment #130) (noting that electronic delivery of a prescription is “a common-sense, low burden method of giving patients better access to their prescriptions”); 1-800 CONTACTS (SNPRM Comment #135); Attorneys General of 27 States (SNPRM Comment #139); National Hispanic Medical Association (SNPRM Comment #146); Backus (WS Comment #1650).

<sup>189</sup> Americans for Tax Reform (SNPRM Comment #72); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101); Information Technology & Innovation Foundation (SNPRM Comment #103); National Association of Optometrists and Opticians (SNPRM Comment #129); CooperVision, Inc. (SNPRM Comment #130); Consumer Reports (SNPRM Comment #133).

prescriptions to their patients,<sup>190</sup> and use of electronic methods is expected to increase in the future.<sup>191</sup> For example, one survey found that approximately 64.2% of eye care professionals communicated with patients by text message, of which 26.4% used it to respond to personal questions about the patient's eye health.<sup>192</sup> Because a significant percentage of eye care providers already use electronic communications and portals, the Commission believes that the required, automatic prescription release could be completed effectively through a digital copy when a patient provides verifiable affirmative consent. Verifiable affirmative consent means that a patient must have provided his or her consent to the prescriber in a way that can be later confirmed. A signed consent form, an email from the patient to the prescriber, or an audio recording from a telephone conversation with a patient would be examples of verifiable affirmative consent. Notification through, for example, a posted office sign or a general written notice of office policies or practices

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<sup>190</sup> See, e.g., Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); American Optometric Association (SNPRM Comment #96); National Association of Optometrists and Opticians (SNPRM Comment #129) (stating that practice management systems and electronic health records are easily available at reasonable prices); Sikes (SNPRM Comment #114); Klepfisz (SNPRM Comment #140); Eklund (WS Comment #502); Holland (WS Comment #513); Reed (WS Comment #749); Gitchell (WS Comment #759); Andrews (WS Comment #1014); Carvell (WS Comment #1021); Cecil (WS Comment #1892); Kuryan (WS Comment #3472); Hopkins (NPRM Comment #184); Wilson (NPRM Comment #1310); Grove (NPRM Comment #1702); MacDonald (NPRM Comment #2118); Andrus (NPRM Comment #3345).

<sup>191</sup> FTC, *The Contact Lens Rule and the Evolving Contact Lens Marketplace*, Panel V: Prescription Release & Consumer Choice Tr. at 18-21 (Mar. 7, 2018), [https://www.ftc.gov/system/files/documents/public\\_events/1285493/panel\\_v\\_prescription\\_release\\_and\\_consumer\\_choice.pdf](https://www.ftc.gov/system/files/documents/public_events/1285493/panel_v_prescription_release_and_consumer_choice.pdf) [hereinafter CLR Panel V Tr.].

<sup>192</sup> Jobson Research, *ECP Digital Solutions Study* (2019) (also finding that of those surveyed, approximately 74.4% contacted their patients by email, of which 45.5% used it to respond to personal questions about the patient's eye health). As noted in the SNPRM, another survey showed that approximately 30% of patients were offered access to a portal during their last eye exam and that 29% chose to use the portal. SNPRM, 84 FR at 24668 n.50.

would not constitute affirmative consent because patients have not indicated to the prescriber whether or not they consent.

Several commenters supported the use of electronic methods, but had a variety of concerns or proposed changes. Some thought patients might prefer a paper copy instead of an electronic copy of their prescription, including people who are older, reluctant to use technology or worried about online privacy or identity theft, unable to navigate a cumbersome portal, without internet or smartphone access, or not proficient in English.<sup>193</sup> The Commission shares these concerns and the Final Rule thus maintains the ability for patients who prefer a paper copy for any reason to obtain such a copy. Even if a prescriber offers electronic delivery, a patient could decline to provide consent. Likewise, prescribers who are concerned about the security or costs of electronic methods can continue providing paper copies.<sup>194</sup> The Final Rule neither compels prescribers to offer prescription release by an electronic method nor requires that patients accept their prescription by electronic method when offered by the prescriber.

One seller urged the Commission to require that the prescribers, when seeking affirmative consent, identify to patients the specific method of electronic delivery that would be used.<sup>195</sup> The Commission believes that requiring prescribers to identify the

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<sup>193</sup> R Street (SNPRM Comment #15); Americans for Tax Reform (SNPRM Comment #72); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); American Optometric Association (SNPRM Comment #96); National Hispanic Medical Association (SNPRM Comment #146); National Taxpayers Union (SNPRM Comment #149).

<sup>194</sup> American Optometric Association (SNPRM Comment #96); American Society of Cataract and Refractive Surgery (SNPRM Comment #127).

<sup>195</sup> 1-800 CONTACTS (SNPRM Comment # 135).

specific method or methods<sup>196</sup> would allow patients to make a more informed decision and increase awareness of how the prescription would be provided if they were to consent. It is also possible that a patient prefers one method of electronic communication, but not others.<sup>197</sup> Therefore, the Commission is amending the definition of “Provide to the patient a copy” to require that prescribers who choose to offer an electronic method, identify the specific method or methods to be used and, if a patient consents, have evidence of verifiable affirmative consent to the identified method or methods.

Regarding patient portals specifically, some commenters expressed concerns that: (1) patients would be unaware that their prescription is on a portal; (2) there could be a delay in posting prescriptions to the portal; or (3) prescribers might intentionally make portals difficult to use, post prescriptions without telling their patients, or confuse patients into thinking that they must buy lenses from them.<sup>198</sup> They urged the Commission to require that prescribers notify patients when a prescription is available on the portal, provide instructions on how to access the portal, or confirm that the prescription has been received.<sup>199</sup> The Commission believes that the Final Rule provides adequate safeguards

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<sup>196</sup> A request for consent that states that the prescription would be delivered electronically, but does not state the method, such as email, text, or portal, would not be adequate. If more than one method is offered, prescribers must specifically identify each one.

<sup>197</sup> 1-800 CONTACTS (SNPRM Comment # 135).

<sup>198</sup> R Street (SNPRM Comment #15); Lens.com (SNPRM Comment #85); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101); Information Technology & Innovation Foundation (SNPRM Comment #103); 1-800 CONTACTS (SNPRM Comment #135); National Hispanic Medical Association (SNPRM Comment #146); Senator Mike Lee (SNPRM Comment #159).

<sup>199</sup> R Street (SNPRM Comment #15); Information Technology & Innovation Foundation (SNPRM Comment #103); Consumer Reports (SNPRM Comment #133); 1-800 CONTACTS (SNPRM Comment #135); Senator Mike Lee (SNPRM Comment #159).

for patients who have opted to receive their prescription on a portal. As noted in the SNPRM, the use of a portal or other electronic method does not change the timing of when a prescriber must provide a copy of the contact lens prescription.<sup>200</sup> A prescriber must provide the prescription immediately after the completion of the contact lens fitting, or in the case of a renewal, when a prescriber determines that no change to the existing prescription is required.<sup>201</sup> Furthermore, prescribers can only use a portal to satisfy their obligation under § 315.3(a)(1) when they have affirmative consent to the specific method or methods of electronic delivery. Therefore, patients should be aware that their prescription will be provided electronically using the method to which they consented. The Rule also requires that patients be able to access, download, and print the prescriptions from the portal.<sup>202</sup> If patients were to have any problems with using the portal, they could revoke their consent and request a paper copy.<sup>203</sup> Notwithstanding these safeguards, the Commission encourages prescribers to provide instructions to patients who may encounter difficulties accessing their portal. The Commission believes that the Rule, with the modification to require that prescribers identify the specific electronic method to be used, balances the interests of prescribers and patients by offering a flexible method that could reduce the burden on prescribers and allow patients greater access to their prescriptions.<sup>204</sup>

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<sup>200</sup> SNPRM, 84 FR at 24669 n.54.

<sup>201</sup> *Id.*

<sup>202</sup> The Commission does not have any evidence that prescribers are intentionally making portals difficult for their patients to use. However, such conduct, if it were to occur, could violate the Rule because patients would not be able to access their prescription.

<sup>203</sup> Patients could also request an additional copy under 16 CFR 315.3(a)(3).

<sup>204</sup> Consumer Action appears to encourage the Commission to provide further guidance on portal design in the Rule. SNPRM Comment #101. Given the potential for future developments in technology and the differences among prescribers' practices and current

Furthermore, some commenters want a paper copy to be provided in addition to the electronic copy,<sup>205</sup> but the Commission declines to adopt this suggestion because requiring both copies would undercut a benefit of using electronic methods and be unnecessary for patients who have expressed a preference for an electronic copy. Finally, a commenter states that telemedicine prescribers should not be required to provide paper prescriptions.<sup>206</sup> Although patients who opt for telemedicine might be more comfortable with technology and receiving health care online,<sup>207</sup> some patients may still prefer their prescription on paper. Since telemedicine providers should have been providing a paper copy under the current Rule, continuation of this practice, when a patient does not consent to electronic delivery, should not be impractical or overly burdensome.

**b. Requirement to Maintain Records of Patient Consent**

In the SNPRM, the Commission proposed requiring that prescribers obtain affirmative consent in order to provide a prescription electronically, but did not require that prescribers maintain evidence of consent. In response, several commenters have urged the Commission to require that prescribers maintain records pertaining to patients' affirmative consent.<sup>208</sup> According to some of these commenters, a record of consent

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software, the Commission declines to mandate requirements on portal design. *See* CLR Panel V Tr., *supra* note 191, at 18-21 (discussing the variety of electronic-health-records programs available from “hundreds” of ECH vendors, with each program based on different standards and providing varying degrees of functionality and compatibility).

<sup>205</sup> Americans for Tax Reform (SNPRM Comment #72); Lens.com (SNPRM Comment #85); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101); Consumer Reports (SNPRM Comment #133).

<sup>206</sup> Simple Contacts (SNPRM Comment #87).

<sup>207</sup> *Id.*

<sup>208</sup> Consumer Action (SNPRM Comment #101); Information Technology & Innovation Foundation (SNPRM Comment #103); National Association of Optometrists and Opticians (SNPRM Comment #129); Consumer Reports (SNPRM Comment #133); 1-800 CONTACTS (SNPRM Comment # 135).

would allow more effective compliance monitoring, while the burden of storing such a record would be minimal.<sup>209</sup> By contrast, the AOA states that prescribers should not be required to maintain records of consent because the AOA believes it would be burdensome<sup>210</sup> and “provides no obvious benefit to the patient” since “the likelihood of harm from a patient receiving a contact lens prescription electronically is low to nonexistent.”<sup>211</sup> However, other commenters countered that there is a potential for harm since patients who do not consent might not realize that they received their prescription electronically, or might be unable to access it.<sup>212</sup>

The Commission finds persuasive the arguments in favor of requiring a record of patient consent to electronic delivery. The burden of retaining a record of patient consent should be minimal, since prescribers who opt for electronic delivery of prescriptions will,

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<sup>209</sup> Consumer Action (SNPRM Comment #101) (stating that the cost of storing digital records is not burdensome); Information Technology & Innovation Foundation (SNPRM Comment #103) (stating that the cost of storing a consent form would be virtually zero).

<sup>210</sup> *See also* American Society of Cataract and Refractive Surgery (SNPRM Comment #127) (discussing the administrative burden related to maintaining records of consent). Other commenters contend that the burden of storing these records would be minimal. Information Technology & Innovation Foundation (SNPRM Comment #103).

<sup>211</sup> American Optometric Association (SNPRM Comment #96). The AOA also asserts that “[p]atients do not have to consent to the electronic delivery of other prescriptions.” However, there may be differences between contact lens prescriptions and some other types of medical prescriptions. In many instances, other types of prescriptions being delivered electronically are not being sent to a patient, but rather to a pharmacy that then fills the prescription. When a prescription is sent to a pharmacy, the patient would likely have selected or have knowledge of the receiving pharmacy. In 2013, 57% of prescriptions nationally were sent electronically from physicians to pharmacies, with the rate in some states over 80%. U.S. Dep’t of Health & Human Servs., The Office of the National Coordinator for Health Information Technology, “E-Prescribing Trends in the United States” 8 (2014) (stating also that 96% of all community pharmacies in the U.S. accept e-prescriptions).

<sup>212</sup> R Street (SNPRM Comment #15); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101); National Hispanic Medical Association (SNPRM Comment #146); National Taxpayers Union (SNPRM Comment #149).

in all likelihood, obtain and/or store such consent electronically. Even if they do not, it should not take any longer to obtain and store patient consent to electronic delivery than it would to obtain and store a patient's Confirmation of Prescription Release via options (A), (B) or (C). Furthermore, a prescriber is not required to offer patients a digital prescription. Rather, it is at his or her option. Moreover, consent to receipt of a digital copy would aid in enforcing the Rule since, without a record of consent, there would be no way for the Commission to confirm that patients who were given their prescriptions electronically agreed to such electronic delivery, and had the ability to access their prescriptions in this manner. The Final Rule will thus require that prescribers keep records or evidence of a patient's affirmative consent to a digital copy for at least three years. Although some commenters have sought longer retention periods,<sup>213</sup> three years is a time period consistent with other recordkeeping obligations in the Rule.

## **6. Comments About Alternatives to the Confirmation of Prescription Release**

In addition to the suggestions—discussed previously—that the Commission increase its enforcement of the current Rule, or impose new requirements only as a penalty for specific providers found in non-compliance,<sup>214</sup> some commenters proposed alternative means of ensuring that consumers receive their prescriptions.

### **a. Signage**

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<sup>213</sup> Information Technology & Innovation Foundation (SNPRM Comment #103) (requesting five years); 1-800 CONTACTS (SNPRM Comment # 135) (requesting that the record be kept as long as the affirmative consent is active). State laws could require that prescribers maintain these records for longer than three years.

<sup>214</sup> American Optometric Association (SNPRM Comment #96).

Several commenters reiterated the idea—raised and discussed in some detail in the SNPRM<sup>215</sup>—that instead of requiring a patient acknowledgment or confirmation, the Commission ought simply to require that prescribers post signs informing consumers of their right to their prescriptions.<sup>216</sup> In its SNPRM, the Commission acknowledged that signage offers some of the benefits of a patient confirmation, but concluded that it had significant drawbacks: in the particular environment of a prescriber’s office, far fewer consumers would learn of their rights from a sign than from being asked to sign a receipt; signage would serve as less of a reminder to prescribers and their staff to release prescriptions; signage would do nothing to aid the Commission in monitoring and enforcing the prescription-release requirement; and relying on patients to notice a sign and ask for their prescriptions put the onus on consumers to enforce the Rule, and would effectively amend the FCLCA’s automatic-release provision to release-upon-request, a statutory revision only Congress can make.<sup>217</sup> The Commission also noted that relying on consumers to ask for their prescriptions is problematic since consumers might not see the sign, or might be uncomfortable asking their prescribers for their prescriptions.<sup>218</sup> Based on those reasons, the Commission declined to propose signage as an alternative to a Confirmation of Prescription Release.<sup>219</sup>

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<sup>215</sup> SNPRM, 84 FR at 24679.

<sup>216</sup> Letter from 20 U.S. Senators (SNPRM Comment #38); Letter from Sen. Lisa Murkowski (SNPRM Comment #49); Cutter (SNPRM Comment #81); American Optometric Association (SNPRM Comment #96); Gilbert (SNPRM Comment #119); Patel (SNPRM Comment #123); Letter from N.D. State Sen. Judy Lee (SNPRM Comment #161).

<sup>217</sup> SNPRM, 84 FR at 24682-83.

<sup>218</sup> *Id.* at 24682.

<sup>219</sup> *Id.* at 24682-83.

Some SNPRM commenters agreed with the Commission’s position, stating that “requiring prescribers to post signs doesn’t work,”<sup>220</sup> and asserting that in California, where a state law requires contact lens prescribers to post signs detailing patient rights, some optometrists fail to comply, or post the signs in locations consumers are unlikely to see them.<sup>221</sup> In contrast, other commenters contended that the Commission should reconsider the signage alternative, reiterating that it would be less burdensome and intrusive for prescribers and could address the FTC’s educational objectives without costly regulation.<sup>222</sup> The AOA also took issue with the fact that the Commission cited HHS’s implementation of a signed-acknowledgment for a prescriber’s HIPAA obligation instead of opting for signage.<sup>223</sup> According to the AOA, anything HHS concluded when it constructed the HIPAA signed-acknowledgment is no longer relevant since HHS is now considering eliminating the requirement and switching to signage in order to reduce the burden on health care practitioners.<sup>224</sup> Furthermore, according to the AOA, “the

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<sup>220</sup> Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101).

<sup>221</sup> Americans for Tax Reform (SNPRM Comment #72). As noted in the SNPRM, the Commission does not have empirical data about prescriber compliance with the state signage requirement, 16 CCR 1566, which has been in effect in California since 1994. However, an analysis of consumer survey evidence provided by Survey Sampling International indicates that regardless of signage, Californians do not automatically receive their prescriptions in substantially greater numbers than residents of states without a signage requirement. SNPRM, 84 FR at 24679.

<sup>222</sup> Kochik (SNPRM Comment #8) (stating that the real issue is that patients are unaware of the law, and so the solution is signage); Letter from 20 U.S. Senators (SNPRM Comment #38); Letter from Sen. Lisa Murkowski (SNPRM Comment #49).

<sup>223</sup> American Optometric Association (SNPRM Comment #96). The obligation in question is the HIPAA requirement that health care providers provide patients with a Notice of Privacy Practices (“NPP”) and obtain a patient’s signature acknowledging receipt of same. Notice of Privacy Practices for Protected Health Information, 14 CFR 164.520(c)(2)(ii).

<sup>224</sup> American Optometric Association (SNPRM Comment #96) (quoting Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 FR 64302,

physician community is united in its belief” that the HIPAA signed-acknowledgment should be eliminated, and this shows that such acknowledgment requirements constitute poor policy, and signage is a better option.<sup>225</sup>

While it is true that HHS is presently evaluating whether to eliminate the HIPAA Notice of Privacy Practices signed-acknowledgment requirement, the Commission’s Confirmation of Prescription Release proposal, and the decision not to allow signage as an alternative, does not rely on the HIPAA signed-acknowledgment requirement as precedent. In the SNPRM, the Commission merely referenced aspects of HIPAA’s signed-acknowledgment requirement and HHS’s evaluation of the regulatory burden as informative when considering whether to require some form of patient confirmation of

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64302-03 (2018), <https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf#page=1>.)

<sup>225</sup> American Optometric Association (SNPRM Comment #96). It is worth noting that a review of the comments submitted in response to the recent HHS proposal to eliminate HIPAA’s signed-acknowledgment requirement reveals that while many health care providers do consider it an unnecessary use of staff time and resources, other health care providers support the acknowledgment requirement, and several noted that the burden of obtaining a patient’s signed acknowledgment is relatively minimal. *See, e.g.*, Jackson Health System (Comment in Response to Request For Information, Office for Civil Rights, Department of Health and Human Services [hereinafter “HHS RFI Comment”] #467) (does not support modifying the requirement because signed NPP acknowledgment forms are “useful” to prove that the NPP was provided to the patient); Dr. Mitchell Strauss (HHS RFI Comment #851) (“The signature is the only way of confirming for posterity that the NPP was discussed. If this step is no longer required, it will be far too easy for practices to stop making the effort for acknowledgement of the NPP.”); Multnomah and Clackmas Counties (HHS RFI Comment #926) (foresees adverse consequences—potential complaints and misunderstandings—if signed acknowledgment requirement is removed); San Francisco Department of Public Health (HHS RFI Comment #1241) (“Having a written record assures patients and covered entities that patients are informed about privacy practices.”); American College of Osteopathic Family Physicians (HHS RFI Comment #1262) (strongly believes that there must be

prescription release.<sup>226</sup> Any other reliance on the HIPAA signed-acknowledgment requirement is generally inappropriate since that signed-acknowledgment requirement differs from the Commission’s confirmation proposal in important respects. The primary intent of the HIPAA signed-acknowledgment was to provide patients an opportunity to review the provider’s Notice of Privacy Practices, discuss concerns related to their private health information, and request additional confidentiality.<sup>227</sup> It was not to remedy a lack of compliance by doctors with HIPAA requirements. Unlike this Rule review, the HHS record does not contain empirical evidence showing that doctors are not fulfilling their obligations to provide Notices of Privacy Practices to patients, and only a handful of commenters to HHS’s recent Request for Information even suggested that this could occur should the HIPAA signed acknowledgment be removed.<sup>228</sup> This contrasts sharply with the circumstances of the Commission’s proposed Confirmation of Prescription Release, which is intended to remedy a documented compliance gap resulting, at least to some extent, from inherent incentives that may discourage prescribers from providing patients with their prescriptions.

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some level of accountability and responsibility for ensuring patients understand their privacy rights); Massachusetts Department of Mental Health (HHS RFI Comment #1003) (“The burden is negligible.”); Missouri Hospital Association (HHS RFI Comment #1175) (“MHA’s members do not find the requirement cumbersome.”); Cigna (HHS RFI Comment #1132) (“Obtaining acknowledgment of receipt is not an operational burden [and] the burden to maintain document of acknowledgment or declination is minimal.”). HHS RFI Comments are available at

<https://www.regulations.gov/docketBrowser?rpp=25&po=0&D=HHS-OCR-2018-0028>.

<sup>226</sup> SNPRM, 84 FR at 24682.

<sup>227</sup> Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, Office for Civil Rights, Department of Health and Human Services, 83 FR at 64308.

<sup>228</sup> *See generally* Comments in Response to Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, Office for Civil Rights, Department of Health and Human Services,

<https://www.regulations.gov/docketBrowser?rpp=25&po=0&D=HHS-OCR-2018-0028>.

The Commission continues to believe that for purposes of automatic prescription release, signage would be significantly less effective than the proposed Confirmation of Prescription Release. None of the comments to the SNPRM presented any data or evidence that would counter the Commission's prior conclusion. The AOA's argument that the HIPAA signed-acknowledgment experience should not be looked to as a model does not alter the Commission's determination that there is a compelling need for a verifiable method of ensuring that contact lens patients receive their prescriptions.

**b. Educational Programs as an Alternative to Confirmation of Prescription Release**

Some commenters opined that instead of having consumers confirm that they received their prescription, the best manner to inform consumers about their prescription rights was through an educational program.<sup>229</sup> According to one contact lens manufacturer, the FTC and sellers should continue to “communicate to patients through social media, websites, advertising, and other channels so that patients become even more aware that they can leave their final fitting with a copy of their right prescription.”<sup>230</sup> Others suggested that the Commission could partner with the Centers for Disease Control and the Food and Drug Administration (“FDA”) to produce public service announcements informing patients of their rights.<sup>231</sup> Another commenter suggested that instead of a signed confirmation, patients' rights to their prescriptions could be “spelled out in the entry forms a patient signs when they check in.”<sup>232</sup> Similarly, the AOA

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<sup>229</sup> Abert (SNPRM Comment #20); Tran (SNPRM Comment #94); CooperVision, Inc. (SNPRM Comment #130).

<sup>230</sup> CooperVision, Inc. (SNPRM Comment #130).

<sup>231</sup> American Optometric Association (SNPRM Comment #96); Tran (SNPRM Comment #94).

<sup>232</sup> Cutter (SNPRM Comment #81).

suggested that a “patient bill of rights for contact lens wearers” could be provided to patients that would include FDA information on considerations for buying lenses.<sup>233</sup> One commenter, the NAOO, said that even with a Confirmation of Prescription Release, the Commission should focus on educating the public about its rights to automatic release of a prescription.<sup>234</sup>

The Commission agrees that educating the public can aid in increasing the likelihood that contact lens users will receive their prescriptions after a fitting.<sup>235</sup> Consumer education in itself, however, whether provided via information entry forms, a patients’ bill of rights, advertising, or public service announcements, would not have a significant impact on prescriber compliance with automatic prescription release, and would not increase the Commission’s ability to monitor and enforce the Rule. The proposed education alternatives would also place a burden on consumers to enforce their own rights, an approach the Commission has rejected repeatedly in the past when considering whether to amend the Contact Lens Rule and Eyeglass Rule to release-upon-request.<sup>236</sup> Therefore, while the Commission believes education about the Rule and its

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<sup>233</sup> American Optometric Association (SNPRM Comment #96).

<sup>234</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>235</sup> The Commission educates consumers on their rights under the Contact Lens Rule through a variety of sources, including blog posts, Facebook, Twitter, and on the FTC’s website. *See, e.g.*, <https://www.consumer.ftc.gov/articles/0116-prescription-glasses-and-contact-lenses>.

<sup>236</sup> *See* Eyeglass I, 43 FR at 23998 (stating that relying upon release-upon-request is problematic because many consumers are unaware of their right to a prescription, and because the right should be “immunized from an evidentiary squabble over whether the consumer actually did or did not request the prescription”); Final Trade Regulation Rule, Ophthalmic Practice Rules 54 FR 10285, 10286-87 (Mar. 13, 1989) [hereinafter Eyeglass II] (rejecting a proposal to change the Rule to release-upon-request and finding a “continuing need” for automatic release). *See also* Contact Lens Rule, 69 FR at 40492 (discussing a commenter proposal to allow prescribers to not release the prescription or release it for “informational purposes only” if the patient has purchased a full year’s

automatic-prescription-release provision is important, the Commission does not believe education should be the sole means of improving Rule compliance.

## **7. Comments About the Burden and Benefits of the Confirmation of Prescription Release Proposal**

Many commenters stated that even with the proposed modifications to increase flexibility, the Confirmation of Prescription Release requirement is still overly burdensome for prescribers.<sup>237</sup> According to commenters, eye care practitioners are already overburdened by regulatory requirements, and the confirmation requirement would divert resources from patient care, increase health care costs, and might even drive some prescribers to cease prescribing contact lenses or close their practices.<sup>238</sup> More specifically, the AAO stated that many of the options for obtaining patient confirmation would require practices to change procedures and alter administrative forms.<sup>239</sup> Others noted that the requirement to dispense paper copies of the confirmation to patients runs counter to the trend towards electronic records, particularly for those who have already

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supply of contact lenses at the time of the examination, and rejecting it because “such an exception would be contrary to the Act’s express requirement that consumers receive a copy of their prescription at the completion of a contact lens fitting”).

<sup>237</sup> Warner (SNPRM Comment #9); Mass Mail Campaign (SNPRM Comment #25) (saying the requirement imposed “massive new costs and far-reaching new requirements on all contact lens prescribing”); Yokum (SNPRM Comment #53); Staup (SNPRM Comment #104); American Society of Cataract and Refractive Surgery (SNPRM Comment #127); Letter from Sen. Lisa Murkowski (SNPRM Comment #49).

<sup>238</sup> Goldstein (SNPRM Comment #14) (“The economic burdens of administrative compliance with these new regulations would except in rare cases encourage me not to fit or prescribe contact lenses.”); Pierce (SNPRM Comment #17) (will ultimately lead to higher health care costs, might have to raise fees); Mass Mail Campaign (SNPRM Comment #25); Shum (SNPRM Comment #80) (“Adding more paperwork and scanning work—and making it required on everyone—doesn’t sound like it would be a big deal, but to a small practice it’s huge.”); Cinalli (SNPRM Comment #93) (new regulation will close many practices); Klepfisz (SNPRM Comment #140) (burden has the potential to put some prescribers out of business).

<sup>239</sup> American Academy of Ophthalmology (SNPRM Comment #136).

invested in an electronic recordkeeping system.<sup>240</sup> One commenter opined that patients ought to bear more responsibility for their own health care.<sup>241</sup> Others noted that the proposal was “going against the tide” by adding a new regulation at a time when some government agencies are looking to reduce regulations.<sup>242</sup>

Some commenters believed the Commission was underestimating the burden to obtain confirmations and preserve the records, and provided their own estimates, including that it would cost \$10,000 per year,<sup>243</sup> or would require 10 minutes per patient for a total of “850 man-hours per year,”<sup>244</sup> the equivalent of about 21 additional weeks of work. The AOA, which had previously estimated the cost of the signed-acknowledgment requirement to be as high as \$18,795 per optometrist,<sup>245</sup> did not submit a new burden estimate for the Confirmation of Prescription Release proposal, but reiterated its belief that the Rule’s burden falls disproportionately on prescribers, and expressed concern that

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<sup>240</sup> Lowe (SNPRM Comment #40); Reeder (SNPRM Comment #55) (signature upon receipt of prescription is “burdensome and counter to other initiatives to reduce paper held by offices”); Boyer (SNPRM Comment #59) (“We try very hard to reduce paper waste . . . . [This] will undo our efficiency and distract our staff from our daily caseload, resulting in increased costs and reduced care.”).

<sup>241</sup> Steiner (SNPRM Comment #7).

<sup>242</sup> American Optometric Association (SNPRM Comment #96); American Society of Cataract and Refractive Surgery (SNPRM Comment #127).

<sup>243</sup> Pierce (SNPRM Comment #17).

<sup>244</sup> Steinemann (SNPRM Comment #65).

<sup>245</sup> American Optometric Association (NPRM Comment #3830). This estimate was cited again by some commenters to the SNPRM. Koerber (SNPRM Comment #41); American Society of Cataract and Refractive Surgery (SNPRM Comment #127). In the SNPRM, the Commission explained that it could not accord this estimate significant weight because it was based not on the cost of the Commission’s proposed Signed Acknowledgment but on the overall cost of government regulations (including those already in place), and because the survey had various methodological limitations. SNPRM, 84 FR at 24677.

the estimated financial burden for the Rule in the 2019 SNPRM is higher than the financial burden estimate cited for the NPRM’s signed-acknowledgment proposal.<sup>246</sup> Some commenters also stated that the use of option (D), electronic delivery, would not significantly reduce their burden, since it would require them to update their systems or invest in expensive technology.<sup>247</sup> According to the AOA, many prescribers would not be able to opt for electronic delivery because of limitations in electronic health records systems, privacy and data-security concerns, and state regulations that might not permit prescription posting to portals.<sup>248</sup>

Other commenters disputed that the burden would be significant, and stated that the confirmation requirement would not add significant costs or time.<sup>249</sup> According to the Information Technology & Innovation Foundation, prescriber claims that the proposal would require significant additional staff training are overstated.<sup>250</sup> Another commenter, a prescriber, stated, “In our office, we already have patients sign a contact lens agreement before the contact lens evaluation process. I don’t see a problem adding a document at the end of the process and having the patient sign an acknowledgment of rx receipt.”<sup>251</sup> One commenter contended that while there would be some burden on eye care providers, it represented just a “tiny fraction” of the industry’s overall revenue, and would be far

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<sup>246</sup> American Optometric Association (SNPRM Comment #96).

<sup>247</sup> American Society of Cataract and Refractive Surgery (SNPRM Comment #127).

<sup>248</sup> American Optometric Association (SNPRM Comment #96).

<sup>249</sup> Tobias (SNPRM Comment #45); Rawson (SNPRM Comment #68); (Citizen Outreach (SNPRM Comment #78); Consumer Action (SNPRM Comment #101); Information Technology and Innovation Foundation (SNPRM Comment #103); National Association of Optometrists and Opticians (SNPRM Comment #129); Consumer Reports (SNPRM Comment #133).

<sup>250</sup> Information Technology and Innovation Foundation (SNPRM Comment #103) (“A few minutes of instruction, coupled with reading a one- or two-page memo should more than suffice.”).

<sup>251</sup> Gilberg (SNPRM Comment #46).

outweighed by the benefits.<sup>252</sup> Others asserted that allowing prescribers to provide patients with digital copies would save both prescribers and patients time and money.<sup>253</sup> Some commenters suggested that the Commission was actually over-estimating the burden imposed by the confirmation requirement.<sup>254</sup> 1-800 CONTACTS, for example, submitted a new analysis from Stanford University Professor Laurence Baker, which called the assumptions used in the Commission’s burden analysis very “conservative,” and estimated that a reduction in verifications by just 15% would be sufficient to offset all of the costs of the confirmation requirement.<sup>255</sup> The NAOO also felt the burden would be “minimal,” and opined that with more patients in possession of their prescriptions, there would be fewer orders relying on the verification process, and thus fewer verifications for prescribers to have to take the time to respond to.<sup>256</sup> NAOO also opined that with more practitioners moving to practice management systems and electronic health records, digital delivery of contact lens prescriptions is a “very feasible” option for many prescribers, which would reduce the burden of the confirmation requirement.<sup>257</sup>

Some commenters also felt that the Commission should not give much weight to burden concerns raised by prescribers due to their history of not complying with their

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<sup>252</sup> Taxpayer Protection Alliance (SNPRM Comment #118) (overall burden of the new requirement would be minimal and outweighed by the substantial benefit of having significantly more patients in possession of their prescription).

<sup>253</sup> Grimm (SNPRM Comment #36) (proposal to allow new methods for providing prescriptions will help relieve paperwork burden); Coalition for Contact Lens Consumer Choice (SNPRM Comment #78); Liao (SNPRM Comment #2) (portal proposal will make automatic release more efficient).

<sup>254</sup> National Taxpayers Union (SNPRM Comment #149); 1-800 CONTACTS (SNPRM Comment #135, Ex. A).

<sup>255</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>256</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>257</sup> *Id.*

prescription-release obligations.<sup>258</sup> The National Hispanic Medical Association, for example, stated that the focus on the burden for prescribers was “upsetting when one remembers just how many patients are being robbed of their right to lower prices and more convenient shipping and being denied a copy of something that they worked hard to pay for, namely, their own prescription.”<sup>259</sup>

The Commission has considered the burden the Confirmation of Prescription Release requirement would place on prescribers. As stated in the SNPRM, the evidentiary record does not establish that the burden will be substantial.<sup>260</sup> Nothing received or revealed since the SNPRM alters that assessment. In fact, numerous health care providers—commenting on their experience with HIPAA—said that the burden of requiring that a patient sign a confirmation-type receipt is “minimal,”<sup>261</sup> “negligible,”<sup>262</sup> or “not significant.”<sup>263</sup> And while AOA is correct that the SNPRM’s estimated financial

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<sup>258</sup> Information Technology & Innovation Foundation (SNPRM Comment #103); 1-800 CONTACTS (SNPRM Comment #135); National Hispanic Medical Association (SNPRM Comment #146).

<sup>259</sup> National Hispanic Medical Association (SNPRM Comment #146).

<sup>260</sup> SNPRM, 84 FR at 24681.

<sup>261</sup> Multnomah and Clackamas Counties (HHS RFI Comment #926); Cigna (HHS RFI Comment #1132).

<sup>262</sup> Massachusetts Department of Mental Health (HHS RFI Comment #1003).

<sup>263</sup> San Francisco Department of Public Health (HHS RFI Comment #1238). *See also* Jackson Health System (HHS RFI Comment #467) (“The acknowledgment procedure takes less than one minute.”); UnityPoint Health (HHS RFI Comment #1122) (costs are relatively low, average of 60 seconds to explain NPP and obtain patient’s signature); UC Health (HHS RFI Comment #1155) (time spent to explain and obtain each signed acknowledgment is 40 seconds per patient); Missouri Hospital Association (HHS RFI Comment #1175); American Alliance of Orthopaedic Executives (HHS RFI Comment #1183). Other commenters to the HHS proposal disagreed, stating that the NPP signed acknowledgment requirement was an unnecessary burden, although much of their criticism was directed at the NPP itself rather than the acknowledgment. *See, e.g.,* American Physical Therapy Association (HHS RFI Comment #601) (“Providers currently undertake reasonable efforts to obtain the patient’s signature, and in most instances the patients ignore the language when signing the document.”); Highmark

burden for the Confirmation of Prescription Release was higher than that estimated for the Signed Acknowledgment, that was primarily due to an increase in the average hourly wages for prescribers and staff.<sup>264</sup> In terms of *time* required for prescribers and their staff to comply, the SNPRM burden from the confirmation proposal was 13% less than that of the NPRM’s signed-acknowledgment proposal.<sup>265</sup> The estimated burden of this modified Final Rule is also higher than the Signed Acknowledgment proposal, but a large part of the increase is due to higher wages and a substantial rise in the number of estimated contact lens wearers since publication of the NPRM.<sup>266</sup> Furthermore, while the Final Rule’s estimated financial burden for the Confirmation of Prescription Release requirement of \$20,428,750, is not insignificant, it amounts to approximately just \$342 in increased administrative costs per eye care provider.<sup>267</sup> In addition, while not every prescriber will be able to use option (D) to deliver a prescription electronically, the Commission is confident that this option will still reduce the burden for many, especially

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Health (HHS RFI Comment #1124) (“The effort to comply with this requirement is disproportionately onerous vis-à-vis the general lack of attention individuals afford the NPP.”).

<sup>264</sup> SNPRM, 84 FR at 24693-94.

<sup>265</sup> SNPRM, 84 FR at 24693-94.

<sup>266</sup> See Section XI, *infra*.

<sup>267</sup> This is based on an estimate from Wallace Lovejoy, a consultant for the National Association of Optometrists and Opticians, that there are approximately 43,000 optometrists and 16,700 ophthalmologists in the U.S. CLR Panel I Tr., *supra* note 100, at 6. Estimates vary as to the total number of eye care providers and contact lens prescribers in the United States, making it difficult to precisely calculate the burden on a per-provider or per-prescriber basis. The investment firm Harris Williams & Co., for instance, put the estimate at 46,000 optometrists and 18,000 ophthalmologists. Harris Williams & Co., Vision Industry Update, at 2 (Mar. 2017) [https://www.harriswilliams.com/system/files/industry\\_update/vision\\_industry\\_update\\_hcls\\_0.pdf](https://www.harriswilliams.com/system/files/industry_update/vision_industry_update_hcls_0.pdf). Meanwhile, the U.S. Bureau of Labor Statistics estimates there are 42,100 optometrists in the U.S., but does not provide an estimate for the number of ophthalmologists. <https://www.bls.gov/ooh/healthcare/optometrists.htm#tab-1>. It must be noted, however, that not all optometrists and ophthalmologists prescribe contact lenses.

as more prescribers move toward electronic recordkeeping.

#### **8. Comments About the Exemption for Prescribers Who Do Not Have a Direct or Indirect Financial Interest in the Sale of Contact Lenses**

In the SNPRM, the Commission proposed an exemption from the Confirmation of Prescription Release requirement for prescribers who do not have a direct or indirect financial interest in the sale of contact lenses, including, but not limited to, though an association, affiliation, or co-location with a contact lens seller.<sup>268</sup> The purpose of the proposed exemption was to reduce the burden on prescribers who do not sell lenses, and therefore, have no incentive to withhold prescriptions. The failure of the prescriber to provide the prescription under such circumstances would provide no benefit to the prescriber while likely alienating the patient. In fact, there is a strong incentive to provide patients with their prescriptions, since that is the only way they would be able to obtain contact lenses.

At least one commenter voiced support for the exemption,<sup>269</sup> but some were critical of the proposal.<sup>270</sup> Some commenters suggested removing it in order to “future proof” the prescription-release process in light of new and evolving business models—and intermingled financial interests—between prescribers and contact lens sellers.<sup>271</sup>

According to one commenter, the exception for those without a financial interest is

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<sup>268</sup> SNPRM, 84 FR at 24698.

<sup>269</sup> Consumer Reports (SNPRM Comment #133) (“Although getting and keeping a record of the patient confirmation will not pose any significant burden, by definition these prescribers would seem not to pose any risk of conflict of interest in releasing the prescription; indeed, they would have an inherent interest in releasing it.”).

<sup>270</sup> Contact Lens Institute (SNPRM Comment #79); Zerbinopoulos (SNPRM Comment #147); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>271</sup> See Contact Lens Institute (SNPRM Comment #79); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151); Alcon (SNPRM Comment #117).

“intentionally vague and leaves the barn door open for interpretation and abuse.”<sup>272</sup> The AOA also objected to the underlying premise that prescribers might consider their own interests above those of their patients.<sup>273</sup>

The Commission recognizes these concerns, but believes there is a significant benefit in more narrowly targeting only those with an incentive to withhold prescriptions, thereby further reducing the overall burden and avoiding unnecessarily impacting prescribers who are unlikely to violate the Rule. Moreover, the Commission believes that determination of whether a financial interest exists is feasible, and that prescribers are unlikely to arrange their financial interests and business structures solely to circumvent the Confirmation of Prescription Release requirement. The Commission also believes it has the investigative tools to examine whether there is a financial interest, should the need arise. And if the Commission determines upon later review that such financial manipulation is occurring to circumvent the Rule, the Commission can revisit whether to remove the exemption.

#### **D. Additional Discussion and Commission Determination Regarding the Confirmation of Prescription Release Proposal**

The Commission has carefully reviewed and analyzed the entire record developed with respect to the Confirmation of Prescription Release proposal. This record includes more than 8,000 comments submitted in response to its 2015 Request for Comment, 2016 NPRM, 2018 Contact Lens Workshop, and 2019 SNPRM, as well the original history and legislative record relating to enactment of the FCLCA and the Rule in 2004.

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<sup>272</sup> Zerbinopoulos (SNPRM Comment #147).

<sup>273</sup> American Optometric Association (SNPRM Comment #96).

The evidentiary record as set forth in the NPRM and the SNPRM, as well as the Commission’s enforcement and oversight experience, supports the view that compliance with the Rule’s automatic-prescription-release requirement is sub-optimal, and as a result, a substantial number of consumers—several million contact lens users every year—are not receiving their contact lens prescriptions as required by law. Many consumers are unaware they even have a right to receive them. Implementing a Confirmation of Prescription Release requirement will result in an increase in the number of patients in possession of their prescriptions; improved flexibility and choice for consumers; a reduced verification burden for prescribers and sellers; a reduced likelihood of medical errors associated with incorrect, invalid, and expired prescriptions; and a reduction in the number of attempts to verify with the wrong prescriber.<sup>274</sup> The ultimate result will be improved competition in the market, more efficient contact lens sales, improved patient safety, and lower prices for consumers. Furthermore, the requirement will increase the Commission’s ability to enforce and assess its Rule, and will accomplish this in a reasonable manner that takes into consideration the needs and burdens of prescribers and sellers.

In response to commenters’ concerns, the Commission has made three modifications to the proposal put forth in the SNPRM. The Commission concurs with the suggestion that requiring prescribers to identify the specific method or methods they would use for electronic delivery of prescriptions will increase awareness and allow patients to make a more informed decision. The Commission will therefore define “Provide to the patient a copy” in the Final Rule to require that prescribers who choose to

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<sup>274</sup> SNPRM, 84 FR at 24681.

offer an electronic method of delivery identify the specific method or methods used. The Commission also believes that evidence of consumer consent to electronic delivery of a prescription will aid in enforcing the Rule, and thus in its Final Rule, the Commission is requiring that prescribers keep records or evidence of a patient's affirmative consent to a digital copy for at least three years. Lastly, for instances where a consumer refuses to sign the confirmation, in the Final Rule, the Commission directs the prescriber to note the refusal and preserve this record as evidence of compliance. The Commission believes that the burden from these three changes will be minimal.

### **III. Additional Requirements for Sellers Using Verification Calls Containing Automated Messages**

In response to the Commission's NPRM, a number of commenters criticized the use of verification calls containing automated messages ("automated telephone messages"), which they often refer to as "robocalls,"<sup>275</sup> with some requesting an outright ban of these calls.<sup>276</sup> The Act and the Rule dictate that sellers that do not have a contact lens prescription presented to them directly or by facsimile verify the prescription by "direct communication."<sup>277</sup> That term, in the Act and Rule, is defined as "completed communication by telephone, facsimile, or electronic mail."<sup>278</sup> The Commission has stated that the Act expressly permits telephone communication for verification and

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<sup>275</sup> See SNPRM, 16 FR at 24684 and n.270.

<sup>276</sup> See SNPRM, 16 FR at 24685 and n.281.

<sup>277</sup> 15 U.S.C. 7603(a); 16 CFR 315.5(a)(2).

<sup>278</sup> Specifically, the Act defines direct communication to "include" a completed communication via one of these three methods, 15 U.S.C. 7603(g), whereas the Rule defines "direct communication" to "mean" a completed communication via one of these three methods, 16 CFR 315.2, a distinction discussed below.

believes that it would be contrary to congressional intent to prohibit use of automated telephone calls for the purpose of prescription verification.<sup>279</sup>

In response to the SNPRM, commenters continued to express criticism of automated telephone messages<sup>280</sup> with some continuing to urge the Commission to ban them.<sup>281</sup> The AOA indicated that issues surrounding automated telephone messages have increased in the past five years and that poor quality automated telephone messages are jeopardizing eye health and resulting in consumers wearing non-prescribed contact lenses. It reports an increase in the use of calls that are difficult to understand, do not include all of the necessary information to confirm the prescription, and create barriers for prescribers to communicate corrections.<sup>282</sup> Johnson & Johnson Vision Care and individual prescribers believe that automated telephone messages can ultimately lead to patients receiving incorrect lenses and suffering adverse health outcomes.<sup>283</sup>

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<sup>279</sup> SNPRM, 16 FR at 24684.

<sup>280</sup> Gilberg (SNPRM Comment #46); Armitage (SNPRM Comment #66); Contact Lens Institute (SNPRM Comment #79); American Optometric Association (SNPRM Comment #96); Health Care Alliance for Patient Safety (SNPRM Comment #128); CooperVision, Inc. (SNPRM Comment #130); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>281</sup> Gilberg (SNPRM Comment #46); Armitage (SNPRM Comment #66); Contact Lens Institute (SNPRM Comment #79); Health Care Alliance for Patient Safety (SNPRM Comment #128); CooperVision, Inc. (SNPRM Comment #130); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>282</sup> American Optometric Association (SNPRM Comment #96).

<sup>283</sup> Reeder (SNPRM Comment #55) (automated calls and passive verification can result in approval for patients who have never been seen and can lead to injury); Armitage (SNPRM Comment #66) (no way to safely and accurately ensure that a patient's prescription is correctly verified with a robocall-based system); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151). *See also* Alcon Vision, LLC (SNPRM Comment #117) (noting health and safety risks associated with robocalls).

Other commenters, however, indicated that automated telephone messages were not problematic and should not be prohibited.<sup>284</sup> Consumer Action stated that “automated call systems appear to be working in a majority of cases” and that prescribers should design more responsive systems for handling such requests.<sup>285</sup> The NAOO commented that from its members’ perspective, there are “no issues with the use of automated calls, which tend to be infrequent to any particular prescriber’s office” and that such calls are an efficient method of verification.<sup>286</sup>

**A. The Congressional Record Does Not Support Prohibiting Automated Telephone Messages**

Commenters in favor of a ban on such calls argue that the Commission lacks evidence that Congress intended to include automated calls in the definition of “direct communication”<sup>287</sup> and should eliminate the use of this antiquated technology in favor of methods that provide written documentation and the possibility of greater oversight in the verification process.<sup>288</sup> In support of a ban, commenters stated that the Act does not mention the use of automated telephone messages and that the Commission’s interpretation of such calls as a valid form of “direct communication” may be counter to

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<sup>284</sup> Consumer Action (SNPRM Comment #101); National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>285</sup> Consumer Action (SNPRM Comment #101).

<sup>286</sup> National Association of Optometrists and Opticians (SNPRM Comment #129); *see also* 1-800 CONTACTS (SNPRM Comment #135) (its records indicate that “on average, prescribers are asked to verify just one order from 1-800 a week”).

<sup>287</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); CooperVision, Inc. (SNPRM Comment #130); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>288</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); CooperVision, Inc. (SNPRM Comment #130); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151). CLR Panel IV Tr., *supra* note 121, at 9 (request of Steinemann for written requests only and not “robocalls”).

testimony provided during hearings that occurred prior to the Act's implementation.<sup>289</sup> These commenters stated that "congressional members and the then CEO of a major online contact lens seller made statements critical of automated telephone verification, stating explicitly that fax or another verifiable method were the preferred prescription verification methods for contact lens prescriptions."<sup>290</sup>

A closer analysis of the congressional testimony reveals a question to the CEO of the contact lens seller about earlier testimony by the AOA mentioning problems with both automated calls and continuous faxes.<sup>291</sup> The CEO's response merely recognized that there had been criticism of automated calls, and stated that at that time the company preferred fax verifications because they were written.<sup>292</sup> There is no other mention of issues with automated calls by congressional members or the CEO during that hearing.<sup>293</sup> Instead, such testimony arguably shows that Congress had been made aware of the criticisms of automated calls and, if it had wished to do so, could have banned their use

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<sup>289</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>290</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>291</sup> 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) (Rep. Shimkus: "Mr. Coon [CEO of 1-800 CONTACTS], there have been some questions [raised in earlier hearing testimony from the AOA] about the techniques companies like yours use to verify orders for contact lens prescriptions, and problems such as automated calls and continuous faxes inhibiting optometrists from verifying prescriptions. Could you just go through your procedures for me?").

<sup>292</sup> *Id.* (In response to Rep. Shimkus's request to go through the company's procedures, Rep. Burr: Mr. Coon, how does 1-800 currently request doctor verification? Mr. Coon: Well, the best system that we have found works the best, which we do in a majority of our orders--and there has been criticism of phone automated systems and other things. The system that works the best is in writing by fax. We know that there is a confirmation that it was received. And that's the system that we would recommend.").

<sup>293</sup> The Commission is also unaware of any other on-the-record discussions about automated calls during congressional consideration of the FCLCA.

explicitly. Yet, Congress specifically included telephone as a valid form of direct communication. The hearing also evidences a recognition that telephone communications, unlike faxes, would not be written. As a result, reference to this testimony does not change the Commission's view that automated telephone messages are a permissible form of direct communication.

The Health Care Alliance for Patient Safety referred to automated telephone messages as antiquated technology,<sup>294</sup> and stated that the Commission should ban such calls in favor of methods that provide verifiable written communication, including fax, emails, and electronic portals.<sup>295</sup> Such documentation, according to the Alliance, will allow for greater oversight and a safer environment allowing prescription verification through clearer, more concise and accurate communication between the prescriber and the seller.<sup>296</sup> As previously stated, Congress expressly permitted use of the telephone knowing that this method did not produce writings like the other delineated verification methods, facsimile and email, and thus, the Commission declines to prohibit the use of this medium for verification.

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<sup>294</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128).

<sup>295</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); CooperVision, Inc. (SNPRM Comment #130). The Commission declines to include portals as a method by which sellers can verify prescriptions. In considering the proposal, the Commission considered that the Act defines direct communication to include telephone, fax, or email. As stated in the 2004 SBP, Congress's use of the term "includes" contemplates that additional methods of communication could develop that could be used in the verification process. 69 FR 40490. However, there is no evidence that prescribers and sellers are using, or are likely to use, portals in the verification process.

<sup>296</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128). The Contact Lens Institute criticized the Commission for failing to address the fact that the information conveyed in a telephonic communication needs to be reduced to a writing by the prescriber's office so it can be compared to patient records, a process that must in virtually all cases be conducted separately from the call itself. SNPRM Comment #79. It follows, according to CLI, that written requests are more efficient and effective communication tools for both sellers and prescribers.

**B. Comments About, and Adoption of, Requirements Proposed in the SNPRM to Improve Quality of Automated Telephone Messages**

In the SNPRM, the Commission recognized that additional requirements for automated verification calls were necessary to relieve the burden on prescribers and reduce potential health risks to patients from incomplete or incomprehensible automated telephone messages. Specifically, the Commission noted that prescribers must be able to understand automated messages so they can, if necessary, respond to sellers to prevent improper sales.<sup>297</sup> As a result, the Commission proposed, via an amendment to § 315.5, requirements for sellers to improve verification calls that use, in whole or in part, an automated message. For these calls, sellers must: (1) record the entire call; (2) commence the call by identifying it as a request for prescription verification; (3) provide the information required by § 315.5(b) in a slow and deliberate manner and at a reasonably understandable volume; and (4) give the prescriber the option to repeat the information.<sup>298</sup>

Commenters were largely in favor of the Commission's proposals to: (1) commence the call by identifying it as a request for prescription verification; (2) provide the information required by § 315.5(b) in a slow and deliberate manner and at a reasonably understandable volume;<sup>299</sup> and (3) give the prescriber the option to repeat this information.<sup>300</sup> Seller 1-800 CONTACTS indicated that its verification messages already

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<sup>297</sup> SNPRM, 16 FR at 24685.

<sup>298</sup> SNPRM, 16 FR at 24685.

<sup>299</sup> The Commission notes that these criteria have always been part of the Rule, but it has determined that they should be expressly set forth in the Rule. *See* 81 FR 88540 (“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.”).

<sup>300</sup> American Optometric Association (SNPRM Comment #96) (stating support for these requirements, but expressing concern they are coming too late); National Association of

comply with these proposed requirements, and the NAOO indicated that its members have not identified any significant burdens in complying with these requirements.<sup>301</sup> CooperVision indicated that these proposals, along with some of the Commission's other proposals, helped address some of the more troubling issues with automated messages.<sup>302</sup> On the other hand, the Contact Lens Institute, comprised of the major contact lens manufacturers, indicated that the Commission's proposed measures demonstrate the impossibility of assuring that automated messages provide effective communication of required information and a reliable basis for passive verification.<sup>303</sup> For instance, it stated that the Commission's requirements to commence the call by identifying it as a request for prescription verification and to give prescribers an option to repeat assumes that prescribers will have live staff available 24 hours a day and will not need to rely on recording devices.<sup>304</sup>

The Commission does not find these criticisms compelling. The Commission recommended these proposals with an awareness that sometimes prescribers' offices take

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Optometrists & Opticians (SNPRM Comment #129); 1-800 CONTACTS (SNPRM Comment #135); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151) (expressing approval for these provisions should the Commission not prohibit these calls altogether).

<sup>301</sup> National Association of Optometrists & Opticians (SNPRM Comment #129); 1-800 CONTACTS (SNPRM Comment #135).

<sup>302</sup> CooperVision, Inc. (SNPRM Comment #130).

<sup>303</sup> Contact Lens Institute (SNPRM Comment #79). Members of the Contact Lens Institute are Alcon Vision, Bausch + Lomb, CooperVision and Johnson & Johnson Vision Care. The Commission notes that the opinions expressed in the CLI's comment do not always conform with the opinions of the manufacturers as expressed in their individually filed comments.

<sup>304</sup> It also described the Commission's requirement to deliver the message in a "slow and deliberate manner" and at a "reasonable volume" as so vague as to be potentially unenforceable. Contact Lens Institute (SNPRM Comment #79). The Commission disagrees with this assessment, finding that these conditions are met if, upon listening to a call, the required information is comprehensible to a reasonable person.

these calls live and, at other times, the calls are left on recording devices. An option to repeat the information is helpful if a person answers live. If not, the prescriber has the ability to replay the message from the recording device. Similarly, commencing the call by identifying it as a request for prescription verification should help ensure that the prescriber's office is ready to take the relevant information down, both when answering live and when playing the message from a recording device. As a result, the Commission is implementing these amendments in its Final Rule.

**C. The Commission's Proposal Requiring Sellers to Record Automated Telephone Messages**

In the SNPRM, the Commission also requested comments on its proposed amendment to § 315.5 to require sellers who verify prescriptions through automated telephone verification messages to record the entire call.<sup>305</sup> Some commenters opposed the proposal,<sup>306</sup> while others supported it.<sup>307</sup> 1-800 CONTACTS opposed the recording requirement, stating that it would impose a costly burden on sellers, is unnecessary because the Commission lacks evidence of a systematic problem with automated calls, and would not facilitate enforcement or improve compliance.<sup>308</sup> This seller also commented that the requirement combined with state wiretapping laws may cause sellers

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<sup>305</sup> SNPRM, 84 FR at 24685.

<sup>306</sup> Contact Lens Institute (SNPRM Comment #79); 1-800 CONTACTS (SNPRM Comment #135); Consumer Reports (Comment #133).

<sup>307</sup> The Health Care Alliance for Patient Safety (SNPRM Comment #128), CooperVision, Inc. (SNPRM Comment #130), and Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151), supported the recording requirement if the Commission did not ban automated telephone messages altogether. *See also* American Optometric Association (SNPRM Comment #96); National Association of Optometrists & Opticians (SNPRM Comment #129).

<sup>308</sup> 1-800 CONTACTS (SNPRM Comment #135).

to switch to other, perhaps less-reliable verification methods.<sup>309</sup> In favor of the proposal, the AOA indicated that the cost of compliance is justified given the widespread issues with robocalls that currently exist.<sup>310</sup>

In support of its position that the recording requirement is unnecessary, 1-800 CONTACTS pointed to the Commission's statement in the SNPRM that it does not have empirical data showing the frequency of verification calls that contain incomplete or incomprehensible automated messages.<sup>311</sup> The seller further commented that the number of sellers that use this particular technology is likely limited and the Commission can much more easily acquire the evidence necessary to investigate complaints and bring an enforcement action in appropriate circumstances.<sup>312</sup> It stated that "the same cost-benefit approach that justifies additional recordkeeping for prescription release, counsels against additional superfluous and costly regulation and in favor of targeted enforcement."<sup>313</sup>

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<sup>309</sup> *Id.*

<sup>310</sup> American Optometric Association (SNPRM Comment #96).

<sup>311</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>312</sup> 1-800 CONTACTS stated that the Commission lacked evidence about whether problems occur with automated calls of more than a limited number of sellers, and if it is a limited number of sellers, the Commission should consider education and enforcement efforts instead of rule changes. For instance, the Commission could obtain the recording itself from prescribers who assert that they have received an invalid or incomprehensible verification call. *Id.* Although the Commission could obtain such recordings from prescribers, the information would not be complete. Without the ability to obtain recordings from the seller, the Commission would be unable to assess if the call the seller relied on was compliant, was non-compliant (violating the Rule) but an anomaly, or was part of a widespread use of problematic calls. Moreover, as to its point about the limited number of sellers making these calls, new contact lens sellers are routinely entering the market and the Commission needs to ensure it can enforce against them if it receives complaints.

<sup>313</sup> 1-800 CONTACTS (SNPRM Comment #135).

Consumer Reports noted that it was not aware of noncompliance similar to that of prescribers' failure to release prescriptions.<sup>314</sup>

The Commission lacks empirical data on this issue, as noted in the SNPRM.<sup>315</sup> However, it is undisputed that automated telephone messages are a commonly used method of verification. Moreover, these calls impose a cost on prescribers, and there are potential health risks to patients from incomplete and incomprehensible automated telephone requests.<sup>316</sup> In fact, many commenters have indicated problems with the quality of automated telephone messages.<sup>317</sup> The AOA commented in response to the SNPRM that, in its survey of 629 doctors of optometry, 85% reported that automated calls for prescription verifications have increased in the past five years, and 88% indicated that the quality of such calls has decreased in the past five years.<sup>318</sup> These commenters have exposed an issue for enforcement: without a call recording,<sup>319</sup> the Commission cannot reliably assess whether that call was compliant and further whether the seller has a pattern of placing non-compliant calls (and selling after such calls).

1-800 CONTACTS commented that it is an unnecessary burden for sellers to record and retain copies of thousands of identical verification calls, the costs of which

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<sup>314</sup> Consumer Reports (SNPRM Comment #133).

<sup>315</sup> SNPRM, 84 FR at 24685.

<sup>316</sup> *Id.*

<sup>317</sup> NPRM, 81 FR at 88538 nn.152, 154, 155; SNPRM, 84 FR at 24684 n.270. *See also* CLR Panel IV Tr., *supra* note 121, at 8 (statement of David Cockrell that the office can't understand many of the robocalls); *id.* at 8 (statement of Tim Steinemann that many robocalls are unintelligible or cut off).

<sup>318</sup> American Optometric Association (SNPRM Comment #96). However, because the AOA did not provide the survey itself or the data from the survey, the Commission does not rely on it as more than anecdotal evidence.

<sup>319</sup> The Commission has received numerous comments from prescribers indicating that they have received non-compliant messages, some of which were left on their answering machines, yet has received very few actual recordings of these messages from prescribers.

would exceed the benefits.<sup>320</sup> Consumer Reports shared this sentiment and suggested that it would be more reasonable for the Commission to require sellers to retain a sample recording of the standard script, leaving blanks for prescription and patient details.<sup>321</sup> The Commission believes that seeing a script of information relayed or a sample recording has limited utility. A script or a sample recording would not reveal whether the required information was transmitted for any particular automated telephone message or if, for instance, required information was transmitted before a representative or machine answered, after an answering machine cut off, when a prescriber’s office put the call on hold, or over hold music, in which case the call could not be lawfully used as a basis for the sale.<sup>322</sup> Further, a script or sample recording would not permit the Commission to assess whether each call was delivered in a “slow and deliberate manner” and at a “reasonably understandable volume.” Without knowing this information, the Commission would be unable to determine conclusively whether any particular verification request was valid. Therefore, the Commission is not adopting this recommendation.

1-800 CONTACTS asserted that the requirement to record verification calls would not only impose additional regulatory burdens on sellers, but also expose sellers to

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<sup>320</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>321</sup> Consumer Reports (SNPRM Comment #133).

<sup>322</sup> One commenter requested a requirement for online sellers to maintain files of recordings of *each verification attempt* made by automated message for a period of no less than three years. Health Care Alliance for Patient Safety (SNPRM Comment #128). The Commission is only requiring sellers to maintain recordings of automated telephone calls that are the basis for the sale, and to maintain these recordings for three years. There is no need under the Rule for sellers to maintain recordings of unsuccessful verification attempts.

legal risk.<sup>323</sup> The seller argued that by recording telephone communications, sellers might risk violating two-party consent laws in the states that require all parties on the call to consent to recordings.<sup>324</sup> After reviewing the relevant statutes and applicable case law, the Commission does not believe sellers risk conducting illegal calls by recording them.<sup>325</sup>

For instance, though the California penal code prohibits eavesdropping on or recording confidential communications without two-party consent, the code excludes from the definition of “confidential communication” any circumstances “in which the parties to the communication may reasonably expect that the communication may be

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<sup>323</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>324</sup> Twelve states have such a requirement: California, Connecticut, Delaware, Florida, Illinois, Maryland, Massachusetts, Montana, Nevada, New Hampshire, Pennsylvania, and Washington. *See* Cal. Penal Code § 632(a), (c) (West 2019); Conn. Gen. Stat. § 52-570d(a) (West 2019); Del. Code Ann. tit. 11, § 2402(a), (c)(4) (West 2019); Fla. Stat. Ann. § 934.03(1), (3)(d) (West 2019); 720 Ill. Comp. Stat. Ann. 5/14-2(a) (West 2019); Md. Code Ann., Cts. & Jud. Proc. § 10-402(a), (c)(3) (West 2019); Mass. Gen. Laws Ann. ch. 272, § 99(C) (West 2019); Mont. Code Ann. § 45-8-213(1)(c), (2)(a)(iii) (West 2019); Nev. Rev. Stat. Ann. § 200.620 (West 2019); N.H. Rev. Stat. Ann. § 570-A:2 (2019); 18 Pa. Stat. and Cons. Stat. Ann. § 5703, 5704(4) (West 2019); Wash. Rev. Code Ann. § 9.73.030(1), (3) (West 2019). It is also possible that Michigan has a two-party consent law, although interpretations of the law differ, and the issue has not been firmly resolved. *See* Mich. Comp. Laws Ann. § 750.539c (“Any person. . . who willfully uses any device to eavesdrop. . . without the consent of all parties thereto. . . is guilty of a felony). *Compare AFT Mich. v. Project Veritas*, 378 F. Supp. 3d 614, 620 (E.D. Mich. 2019) (finding statute prohibits participants from recording private discourse of any other person involved in the conversation unless all persons consent); *with Sullivan v. Gray*, 324 N.W.2d 58, 60 (Mich. Ct. App. 1982) (finding statute does not require two-party

overheard or recorded.”<sup>326</sup> The California Supreme Court has stressed that § 632 of the California penal code does not preclude parties from ever recording conversations, but rather prohibits parties from doing so “secretly” or “surreptitiously,” declaring that a business would not violate the state’s wiretapping laws if it advised parties to a communication of its intent to record the call at the outset of the conversation.<sup>327</sup> Similarly, in Massachusetts, a person cannot willfully intercept any wire or oral communication, with “interception” defined in the statute as secretly hearing, secretly recording, or aiding another to do so without the parties’ consent.<sup>328</sup> The Massachusetts Supreme Court has ruled that a system that expressly notifies the parties that the call will be recorded does not commit an interception because the system does not record the

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consent because it only prohibits eavesdropping, which is defined as recording the “private discourse of others.” (emphasis added)).

<sup>325</sup> Of course, the Commission cannot predict precisely how different jurisdictions will apply state laws. However, the Commission is unaware of a party ever being held liable for violating two-party consent requirements in a situation where the call contained a disclosure message at its onset. The Commission further notes that jurisdictions take different approaches to deciding which state law applies for interstate or multi-state phone calls. *See, e.g., Ditech Fin. LLC v. Buckles*, 401 P.3d 215 (Nev. 2017). Therefore, when recording calls with prescribers located in other states, sellers should abide by the more stringent law that applies or obtain the consent of all parties to the communication. As the Commission stated in the SNPRM, 84 FR at 24685 n.288, sellers are responsible for determining compliance with state law taping requirements.

<sup>326</sup> Cal. Penal Code § 632(a), (c).

<sup>327</sup> *Kearney v. Salomon Smith Barney, Inc.*, 137 P.3d 914, 930 (Cal. 2006); *see also Hataishi v. First Am. Home Buyers Prot. Corp.*, 168 Cal. Rptr. 3d 262, 271 (Cal. Ct. App. 2014) (stating California consumers are accustomed to receiving notice of a business’s intention to record a call); *CS Wang & Assoc. v. Wells Fargo Bank, N.A.*, 305 F. Supp. 3d 864, 885 (N.D. Ill. 2018) (Under the California Invasion of Privacy Act, “the baseline assumption in situations where the recorded party does not initiate the call, does not have a prior relationship with the caller, and does not receive a warning at the outset of the

conversation in secrecy.<sup>329</sup> Thus, in California and Massachusetts, sellers who provide a standard notification at the beginning of the call, which has become customary in many business communications, are unlikely to risk violating state wiretapping laws. Moreover, after reviewing the plain language of other state statutes requiring two-party consent and case law, the Commission concludes that if sellers express their intentions to record the conversation at the outset of each call, sellers located in or contacting prescribers in two-party consent states will not risk violating a state’s respective wiretapping law. Announcements at the outset of the calls would prevent sellers from committing violations because prescribers can either provide or withhold consent. For instance, under Florida’s and Maryland’s statutes,<sup>330</sup> as long as a party has received notice of an intent to record, the notified party can expressly or impliedly consent by remaining on the line.<sup>331</sup> 1-800 CONTACTS notes that a prescriber could effectively

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*call*, is that it is reasonable for a party to expect that its conversation is not being recorded.”) (emphasis added).

<sup>328</sup> See Mass. Gen. Laws Ann. ch. 272, § 99(B)(4), (C)(1).

<sup>329</sup> See *Commonwealth v. Boyarsky*, 897 N.E.2d 574, 579 (Mass. 2008) (finding “there was no interception because there was no secret recording, and the inquiry is at an end”); see also *Marquis v. Google, Inc.*, No. SUCV2011-02808-BLS1, 2014 WL 4180400, at \*12 (Mass. Super. Ct. July 27, 2014) (“The core of the statute is . . . the prevention of the *secret* interception of wire communications . . . . In consequence, if a recording is ‘not made secretly,’ it does ‘not constitute an ‘interception’ and there has been no violation of the statute.”)

<sup>330</sup> Fla. Stat. Ann. § 934.03(2)(d); Md. Code. Ann., Cts. & Jud. Proc. § 10-402(a), (c)(3).

<sup>331</sup> See *Levin v. Red Rock Fin. Servs., LLC*, No. 70006, 2017 WL 519414, at \*1 (Nev. Ct. App. Jan. 30, 2017) (agreeing that summary judgment applying Nevada and Florida law had been properly granted because appellant “necessarily heard the pre-recorded announcement during every phone call . . . and consequently gave implied consent to be recorded during each call *by continuing with the call*”) (emphasis added); *Bridgell v. State*, No. 1220, 2016 WL 4698158, at \*3-4 (Md. Ct. Spec. App. Sept. 7, 2016) (finding plaintiff “was not forced to communicate . . . nor continue with the phone conversation after being notified that it would be recorded and monitored” and consented to recording “by continuing to speak *after* the [warning] message [had] played.”) (emphasis added). See also Wash. Rev. Code Ann. § 9.73.030(3) (“[C]onsent shall be considered obtained

reject a valid method of verification—verification by telephone—by declining to give consent.<sup>332</sup> In the event that a prescriber declines to consent to a recorded call containing an automated telephone verification message, sellers may make verification requests via email, live call, or fax. Sellers may also elect to leave automated telephone messages after hours on prescribers’ answering machines. Such calls would not implicate wiretapping laws since the prescriber is not on the line.<sup>333</sup>

Commenters also opined on whether the Commission should extend its recording requirement to verification calls that do not involve automated messages, *i.e.* live calls. 1-800 CONTACTS suggested that the requirement to record calls including automated messages should apply equally to live calls because sellers might otherwise have an incentive to outsource live verification calls to inexpensive call centers that can “game the system” by making it difficult for prescribers to understand or respond to live verification requests.<sup>334</sup> On the other hand, the NAOO, without explanation, supported the Commission’s recording requirement for automated calls as long as the Commission does not expand the requirement to apply to live calls.<sup>335</sup>

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whenever one party has announced to all other parties engaged in the communication or conversation, in any reasonably effective manner, that such communication or conversation is about to be recorded or transmitted.”).

<sup>332</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>333</sup> Some prescribers commenting on the Rule have expressed concern that verification calls placed during non-business hours violate the Rule. *See* NPRM, 81 FR at 88544 and n.232. Sellers who leave compliant verification messages after hours do not violate the Rule as long as they wait the required eight business hours before selling lenses (assuming there is no communication from the prescriber invalidating or approving the message before that time period concludes).

<sup>334</sup> 1-800 CONTACTS (SNPRM Comment #135). The seller also pointed to the Commission’s statement in the SNPRM that it does not know that a phone call with an automated message is necessarily less reliable than one with a live person. *Id.* (citing SNPRM, 84 FR at 24685).

<sup>335</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

For several reasons, the Commission declines to compel sellers to record live calls. Foremost, during live calls, a prescriber can ask a seller to repeat the message or to clarify unintelligible information, and can look up a patient's file in real time to verify the prescription.<sup>336</sup> In this setting, a seller is likely to limit any bad conduct. While bad actors could speak incoherently, exclude key information, or refuse to repeat the message when asked, the Commission has not received or seen evidence of such behavior, and the record does not reflect any other widespread issue involving the quality of live calls. Finally, the Commission considered mass merchandisers that verify prescriptions largely or exclusively by calling prescribers to obtain verification via a live call when a customer purchases lenses at the store. Because these sellers use their phone lines for a multitude of purposes unrelated to prescription verification, such as taking consumer orders or checking inventory for a consumer, it would be difficult to implement a recording system in compliance with this Rule. However, should the Commission receive complaints that show an issue with sellers' conduct on live calls, the Commission will reassess the need to require sellers to record live verification calls.

**D. The Final Rule Does Not Adopt Commenters' Additional Recommendations Regarding Automated Telephone Messages**

A number of additional recommendations were suggested by commenters regarding calls that contain, in full or in part, automated messages.<sup>337</sup> The Health Care Alliance for Patient Safety and Johnson & Johnson Vision Care requested that the FTC

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<sup>336</sup> CLR Panel IV Tr., *supra* note 121, at 15 (statement of David Cockrell referring to how live calls provide opportunity for two-way conversation).

<sup>337</sup> The Contact Lens Institute (SNPRM Comment #79), Health Care Alliance for Patient Safety (SNPRM Comment #128), and Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151) proposed these additional requirements in the event that the Commission declined to prohibit use of verification via automated telephone messages.

review and approve a transcript of sellers' automated telephone messages before sellers are permitted to use calls containing such messages.<sup>338</sup> The Contact Lens Institute urged the Commission to require sellers to follow a "specific script that includes standardized terms, a standardized order of presenting the required information, and a standardized pace,"<sup>339</sup> and to require sellers to document that they only use means of transmission that have been tested and shown to result in receipt of clear and unambiguous information at the receiving end of the call.<sup>340</sup>

The Commission is not implementing these recommendations. The information that sellers need to include to make a valid verification request is clearly delineated in § 315.5(b), (d)(2), and (d)(4) of the Final Rule.<sup>341</sup> The Commission does not believe that reviewing and approving a transcript would be an effective use of its resources because it is the call itself that ultimately determines whether there is a valid verification request. Further, while there is some utility in providing a script so prescribers receive the information in a predictable manner, the Commission is not convinced that there is only one effective way for a seller to comply with the Rule, or that this requirement is necessary.<sup>342</sup> The Rule already indicates what information needs to be included in the

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<sup>338</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>339</sup> Contact Lens Institute (SNPRM Comment #79). Alcon Vision made a similar recommendation. *See* SNPRM Comment #117.

<sup>340</sup> Contact Lens Institute (SNPRM Comment #79).

<sup>341</sup> Commission review of a script would not reveal whether the seller was complying with Section 315.5(d)(3) and (4) of the Final Rule (the requirements as to cadence, volume, and the ability to repeat the information).

<sup>342</sup> Similarly, 1-800 CONTACTS requested a requirement that a pre-recorded message be limited to providing only the information required under the Rule and not include extraneous information that could make the call confusing or more burdensome. SNPRM Comment #135. Although the Commission cautions sellers against including extraneous

message, and the additional requirements the Commission is implementing should make it easier for prescribers to obtain the information. Should seller verification messages be deficient in providing all the required information, prescribers should notify the seller. Moreover, assuming a seller is complying with the Rule by recording calls that contain these messages, the Commission can ascertain whether the call included all the required information (and whether the seller ultimately sold lenses pursuant to an invalid verification call). A review of the recording will provide better information on compliance than would knowing that the seller used a transcript—including an FTC-approved transcript—or a means of transmission that the seller has tested and documented as effective.

The Health Care Alliance for Patient Safety and Johnson & Johnson Vision Care also requested a requirement that online sellers confirm that automated calls are answered by a person at the prescriber's office, as opposed to a recording device, before initiating an automated message.<sup>343</sup> In essence, they are asking for a requirement that all verification calls be placed during a prescriber's business hours, presumably the time when prescribers' phone lines are staffed.<sup>344</sup> These commenters also requested that the Commission require online sellers who use automated telephone messages to provide, for prescriber's use, a centralized call-back number and have the call-back number staffed by

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information, it has not seen evidence of a widespread use of calls including such information and thus is not implementing this recommendation.

<sup>343</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>344</sup> It is not clear that this option would be desired by prescribers, some of whom have indicated that they do not have time during business hours to respond to these requests or that such calls tie up their phone lines. *See* NPRM, 81 FR 88539 n.158.

a person from the seller.<sup>345</sup> In the same vein, CooperVision commented that the Commission should require sellers to provide the means for the prescriber to disrupt a verification call that uses, in whole or in part, an automated message, in order to connect with a person at the seller to provide correct information.<sup>346</sup> Without this requirement, according to CooperVision, eye care professionals are limited in their ability to correct information that is important for the patient's eye health or that could prevent improper substitution of lenses.<sup>347</sup>

The Rule does not require sellers' communication via telephone, email, or fax to occur during business hours. The Rule requires, instead, that sellers wait eight business hours after a valid verification call to sell the lenses. Moreover, the Rule already requires the seller to provide the name of a contact person at the seller's company, including facsimile and telephone numbers.<sup>348</sup> Should a prescriber inform the seller within eight business hours that the prescription was inaccurate, expired, or otherwise invalid, the seller cannot lawfully sell those contact lenses. If a prescriber informs a seller that the verification request itself was non-compliant, the seller is on notice that it may need to provide another verification request prior to selling the lenses. The prescriber need not relay that information to a person at the seller, whether during the verification call or at

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<sup>345</sup> *Id.*; see also CLR Panel IV Tr., *supra* note 121, at 10 (statement of David Cockrell that the office needs to be able to contact the seller immediately and it "can't even leave a message").

<sup>346</sup> CooperVision, Inc. (SNPRM Comment #130).

<sup>347</sup> CooperVision also stated confusion as to whether the Commission's requirement for sellers to provide an option to repeat the verification information included a requirement for sellers to provide the means for the prescriber to immediately disrupt an automatic call in order to connect with a live person. SNPRM Comment #130. It does not.

<sup>348</sup> 16 CFR 315.5(b)(6).

other times.<sup>349</sup> Instead, it is sufficient notice for a prescriber to leave a voicemail, or send a facsimile, that provides the seller with enough information so as to identify the consumer or order being called about (a consumer name, reference number, or even the prescriber's name with the date of the verification call could be adequate), and that the prescription is inaccurate, expired, or otherwise invalid.<sup>350</sup> In addition, requiring sellers to reach a person (and not a machine) at the prescriber's office, or to provide a call-back number that is answered by a person (and not a machine), would mean either that sellers would need to have agents available at all times, or else only contact prescribers during business hours for both the seller and prescriber, which may be difficult if they are located in different time zones. Requiring that sellers have someone available at all times to respond to prescriber inquiries would also be costly for sellers, with no readily apparent countervailing benefit. For these reasons, the Commission declines to implement a requirement that sellers ensure that automated telephone messages are answered by a person at the prescriber's office, as opposed to a recording device, or that prescribers be able to reach a live person at the seller.<sup>351</sup>

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<sup>349</sup> If a seller does not maintain a person to answer the phone number it provides, it must provide an opportunity for the prescriber to leave a message. A seller that does not check its voicemail runs the risk of selling lenses after a prescriber has timely invalidated or corrected the prescription, thereby violating the Rule.

<sup>350</sup> Final Rule § 315.5(e) requires the prescriber to specify the basis for the inaccuracy or invalidity of the prescription, and if the prescription is inaccurate, the prescriber shall correct it. Final Rule 16 CFR 315.5(e). Even if the prescriber violates the Rule by failing to specify the basis for the inaccuracy or invalidity, or by failing to correct the prescription, the seller is still prohibited from selling if a prescriber informs the seller that the prescription is inaccurate, expired, or otherwise invalid within the eight-business-hour time period.

<sup>351</sup> The Commission notes that some sellers have agents who stay on the line to ensure that, before commencing the automated message, an individual at the prescriber's office has answered the phone, or that the answering machine has picked up before leaving the

The Health Care Alliance for Patient Safety and Johnson & Johnson Vision Care further requested a requirement that online sellers verify that they are making verification calls to the office of a legitimate eye care professional. The Commission is aware of allegations of sellers making verification calls to numbers clearly not affiliated with eye care prescribers. The Rule requires a seller to sell contact lenses in accordance with a contact lens prescription for the patient that, if not presented to the seller, is verified by direct communication.<sup>352</sup> Of course, for prescription verification to be meaningful, that verification must go to the consumer's eye care prescriber. Although the seller does not know whether the prescriber contact information provided by the consumer is that of the consumer's own eye care prescriber, to ensure that its verification request complies with the Rule, it is incumbent upon the seller to ascertain whether the number provided by the consumer is for *an eye care prescriber*. If it is apparent from the consumer's entry itself,<sup>353</sup> or from the seller's research on the internet or otherwise, that the number provided is not affiliated with a prescriber, or if it cannot be determined whether it is, the seller should either reach out to the consumer to obtain better contact information or cancel the order. Calls to numbers clearly not associated with eye care prescribers are not compliant verification requests, and any sales made pursuant to such requests violate the Rule. The Commission intends for this notice to provide sufficient guidance for sellers and does not see a need to amend the Rule to address this issue.

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message. Such a practice helps ensure that the beginning of the message is not cutoff or played over hold music.

<sup>352</sup> 16 CFR 315.5(a).

<sup>353</sup> For instance, sellers should not verify a prescription when the consumer identifies the prescriber as "Santa Claus." Similarly, sellers should not place verification calls to phone numbers that consumers list as the prescriber phone number when that phone number is the same number a consumer lists as her own contact number.

The Commission is implementing the recommendations outlined in the SNPRM for automated telephone messages in the Final Rule, without modification. CooperVision requested guidance on how the Commission intends to interpret and enforce these provisions.<sup>354</sup> This notice should provide sellers with information to assist them in complying with the new rule requirements. The Commission also plans to publish education on these Final Rule requirements. As to enforcement, should the Commission receive complaints about the quality of automated calls, it can request that the seller produce the recording of the call in question.

#### **IV. Prescribers' Selection of Communication Mechanism**

In the NPRM, the Commission pointed out that the Act does not permit prescribers to limit the communication mechanism sellers may use to submit requests for verifying prescriptions, and that sellers are able to use any or all of the three delineated methods, telephone, facsimile, or electronic mail.<sup>355</sup>

In response, prescribers continued to request that they be able to select the method of communication used to submit verification requests from among telephone, facsimile, or electronic mail.<sup>356</sup> Johnson & Johnson Vision Care commented that it wished to work with the Commission and Congress to improve prescriber-seller communications, such as by allowing a prescriber to select her preferred method for verification requests.<sup>357</sup> The AOA commented that the Commission took a step in the right direction when it

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<sup>354</sup> CooperVision, Inc. (SNPRM Comment #130).

<sup>355</sup> NPRM, 81 FR at 88542.

<sup>356</sup> O'Daniel (NPRM Comment #179); Krattli (NPRM Comment #1976).

<sup>357</sup> Johnson & Johnson Vision Care, Inc. (NPRM Comment #4327). The manufacturer also requested that sellers be required to provide an option, as part of a verification message, for the prescriber's office to elect an alternate means to receive the request, and an alternate time frame after which the window to respond to verification requests must be completed. Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

suggested that sellers evaluate whether honoring prescriber preferences with regard to communication method would increase the speed and efficiency of the verification process.<sup>358</sup> It nevertheless urged the Commission to provide more instruction to sellers, and to outline the verification-related complaints that the Commission has received, so prescribers and sellers can work together to ensure patients receive the contact lenses that were prescribed.<sup>359</sup>

The Commission reiterates its suggestion that sellers and prescribers work together to ensure that patients receive their prescribed lenses. As stated in the NPRM, the Commission requests sellers to consider whether the speed and efficiency of the verification process would be increased by accommodating prescribers' requests to contact them with verification requests via a certain method.<sup>360</sup> However, 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.<sup>361</sup> The Commission is therefore not making any changes to the Rule in this area.

## **V. Miscellaneous Passive Verification Issues**

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<sup>358</sup> American Optometric Association (NPRM Comment #3830).

<sup>359</sup> *Id.*

<sup>360</sup> NPRM, 81 FR at 88542. Similarly, the seller should consider whether to accommodate prescribers' requests to contact them during specified time-periods (*i.e.*, business hours, or after business hours).

<sup>361</sup> *See* 15 U.S.C. 7603(g). The Commission came to the same conclusion in its initial rulemaking. 69 FR at 40497. The Commission recognizes that in practice, sellers' options may be limited. For instance, should a prescriber's office not have facsimile, a seller would be unable to complete a verification request via fax.

### A. Active Verification Is Not Required

In the NPRM, the Commission declined to propose replacing passive verification with active verification, despite concerns from many commenters.<sup>362</sup> Commenters expressed concern that the passive verification system could easily be manipulated, for example, by a patient who provides false or incorrect prescriber information to a seller, or by a seller who sends the same verification request over and over again in the hope that the prescriber will fail to reply and deny one of them.<sup>363</sup> However, because Congress decided to include a passive verification system in the Act, and the issues commenters raised were identical to those raised during the initial 2004 rulemaking, the Commission chose not to revisit the decision to include passive verification.<sup>364</sup>

Following the NPRM, many commenters reiterated the same concerns with respect to passive verification, including that sellers could abuse the system or that consumers might obtain lenses without a prescription or receive incorrect lenses, and they advocated for a switch to active verification.<sup>365</sup> Because these concerns are similar to those raised during the initial rulemaking in 2004 and because Congress mandated passive verification in the FCLCA, the Commission again declines to modify the Rule to

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<sup>362</sup> NPRM, 81 FR at 88543.

<sup>363</sup> *Id.*

<sup>364</sup> *Id.*

<sup>365</sup> *See, e.g.*, Golden (WS Comment #1353); Weidel (WS Comment #2333); Gray (WS Comment #2730); Audia (NPRM Comment #698); Bazan (NPRM Comment #706); Dewart (NPRM Comment #897); Nixon (NPRM Comment #1510); Weissman (NPRM Comment #1676); Goshe (NPRM Comment #2597); Fritsch (NPRM Comment #2683); Garr (NPRM Comment #2858); Phan (NPRM Comment #3350). Some commenters continued to support passive verification. *See* 1-800 CONTACTS (WS Comment #3207); National Association of Optometrist and Opticians (WS Comment #3208) (“No changes are needed to the passive verification system.”).

require active verification.<sup>366</sup> However, the Commission has made several changes to the Rule aimed at improving the quality of automated verification calls, which will allow prescribers to more effectively prevent the sale of contact lenses when the prescription is inaccurate, expired, or otherwise invalid.<sup>367</sup> The Commission has also improved patients' access to their prescriptions by implementing requirements enabling patients to obtain electronic copies and additional copies of their prescriptions, and to present their prescriptions directly to sellers, which should reduce the need for passive verification requests.<sup>368</sup> The Commission recognizes that some sellers may engage in verification practices that violate the Rule's requirements<sup>369</sup> and, for that reason, will continue to monitor the marketplace and investigate potential violations when appropriate.

#### **B. Concerns About Patient Manipulation**

In the NPRM, the Commission declined to propose any changes to the Rule to address concerns that patients were manipulating the passive verification system by deliberately providing inaccurate prescriber information to the seller.<sup>370</sup> The Commission noted that if prescribers received a verification request for an individual who was not their patient, they have the ability to respond that such request is invalid, which would prevent the sale under § 315.5 of the Rule. Some commenters provided anecdotal evidence of instances where consumers have intentionally provided inaccurate information, but the Commission did not have any empirical evidence showing the

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<sup>366</sup> The Commission also notes that nothing in the Rule prevents active verification by a seller. If it prefers, a seller can choose to actively verify a prescription. CLR Panel IV Tr., *supra* note 121, at 5 (statement of Jennifer Sommer) (stating that Walmart often actively verifies prescriptions by calling the prescriber's office).

<sup>367</sup> See Section III, *supra*; 16 CFR 315.5(c)(2), (d).

<sup>368</sup> See Section II.C.5, *supra*, and Sections VII and VIII, *infra*.

<sup>369</sup> 16 CFR 315.5(a)-(d).

<sup>370</sup> NPRM, 81 FR at 88543.

frequency of this problem.<sup>371</sup> Moreover, Congress was aware that passive verification was not a foolproof method to prevent verification of invalid prescriptions, but nonetheless mandated passive verification to balance the interests of consumer health and prescription portability.

In response to the NPRM, commenters continued to express concerns with patients being able to obtain contact lenses without a valid prescription, especially with only eight business hours to respond to a verification request, and with the potential health consequences.<sup>372</sup> To address concerns with patient manipulation of passive verification, commenters advocated using an active verification system, requiring that a prescription be presented, changing the method used to send verification requests, or increasing the amount of time for a prescriber to respond.<sup>373</sup>

The Commission recognizes prescribers' concerns about the potential health effects on patients who wear non-prescribed lenses. However, as noted in the NPRM, Congress chose the passive verification framework as a way to balance consumer health

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<sup>371</sup> *Id.*

<sup>372</sup> *See, e.g.,* Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151); Lem (WS Comment #470); Dillehay (WS Comment #822); Baird (WS Comment #1918); Hemler (WS Comment #2312); Patel (WS Comment #2691); Gray (WS Comment #2730); Bottjer (WS Comment #3378); Tuttle (NPRM Comment #161); Gilberg (NPRM Comment #198); Moy (NPRM Comment #382); Engler (NPRM Comment #453); Francis (NPRM Comment #588); Stott (NPRM Comment #687); Kempf (NPRM Comment #915); McPherson (NPRM Comment #3397); Schlater (NPRM Comment #3504); Bengoa (NPRM Comment #3600); Jackson (NPRM Comment #3736).

<sup>373</sup> *See, e.g.,* Contact Lens Association of Ophthalmologists, Inc. (WS Comment #770); Northsight Vision Care Center (WS Comment #1196); Golden (WS Comment #1353); Begeny-Mahan (WS Comment #1702) (requesting that the eight-business-hour period be changed to forty-eight hours); Kirkconnell (WS Comment #1754) (requesting two business days to respond and stating that requests should be faxed); American Society of Cataract and Refractive Surgery (WS Comment #3142) (advocating for extending the eight-business-hour time-period for passive verification to five business days); Bazan (NPRM Comment #706); Garr (NPRM Comment #2858); Greitzer (NPRM Comment #3388).

and prescription portability.<sup>374</sup> Congress also allowed verifications by direct communication, which it defined as including telephone, facsimile, and electronic mail.<sup>375</sup> Congress was aware that passive verification was not a perfect method to prevent patients from deliberately providing incorrect information.<sup>376</sup> The Commission does not have any evidence, aside from anecdotal reports, showing the extent to which patients are intentionally providing incorrect information to a seller in order to obtain contact lenses. Thus, the Commission does not believe that significant modifications to the Rule to address the concern about consumers submitting inaccurate prescriber information are warranted.

However, in its Final Rule, the Commission has implemented several changes to improve verification calls that use an automated telephone system, which will make it easier for prescribers to deny requests based on inaccurate prescriber information. These changes include identifying at the start of the call that it is a prescription verification request, delivering the information in a slow and deliberate manner and at a reasonably understandable volume, and giving the prescriber the option to repeat the call.<sup>377</sup> Prescribers will be better able to identify the relevant patient information and inform sellers during the eight-business-hour period that the request is invalid.<sup>378</sup> The Commission will also continue to monitor the marketplace, investigate any sellers encouraging patients to provide false information, and continue its consumer education

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<sup>374</sup> NPRM, 81 FR at 88543.

<sup>375</sup> 15 U.S.C. 7603.

<sup>376</sup> NPRM, 81 FR at 88543.

<sup>377</sup> See Section III.

<sup>378</sup> 16 CFR 315.5(d).

efforts communicating the importance of having a prescription when purchasing contact lenses.<sup>379</sup>

### **C. Eight-Business-Hour Time Frame Is Appropriate**

In the NPRM, the Commission considered commenters' concerns that the eight-business-hour time frame was too short and that verification calls were being placed outside of business hours or when the prescriber's office was closed.<sup>380</sup> The Commission declined to lengthen or otherwise modify the eight-business-hour time frame during which a prescriber must respond to a verification request.<sup>381</sup> The Commission did not find sufficient evidence quantifying how the eight-business-hour time frame imposed a significant burden or showing that a significant number of prescribers were unable to respond to the verification requests within the allotted time. The Commission further noted that there have been no compelling changes to the marketplace since the Rule was implemented in 2004 that would justify extending the period beyond eight business hours.

In response to the NPRM, some commenters indicated that eight business hours constituted a sufficient period for a prescriber to respond to a verification request.<sup>382</sup>

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<sup>379</sup> See, e.g., Federal Trade Commission, *Halloween know-how: Cosmetic contacts require an Rx*, <https://www.consumer.ftc.gov/blog/2019/10/halloween-know-how-cosmetic-contacts-require-rx>; Federal Trade Commission, *Prescription Glasses and Contact Lenses*, <https://www.consumer.ftc.gov/articles/0116-prescription-glasses-and-contact-lenses> (“All contact lenses—even ones just meant to change your appearance—require a prescription.”).

<sup>380</sup> NPRM, 81 FR at 88544-5. Other concerns about passive verification, unrelated to the length of time a prescriber has to respond to a verification request, are addressed in Sections III, IV, and V.A and B.

<sup>381</sup> *Id.*

<sup>382</sup> Coalition for Contact Lens Consumer Choice (WS Comment #3239); Consumer Action (NPRM Comment #3721); Consumers Union (NPRM Comment 3969) (stating that eight business hours “was generally sufficient and has proven workable,” but

However, other commenters continued to express concerns with the limited time frame,<sup>383</sup> particularly due to the potential negative health consequences for patients wearing non-prescribed lenses, should a prescriber fail to deny an invalid verification request in time.<sup>384</sup> Many prescribers wrote that eight business hours was just not a sufficient amount of time to respond due to, for example, busy offices, limited staff, high volume of requests, and regular office closures on business days.<sup>385</sup>

The Commission considered these comments and, for the reasons stated in the NPRM, declines to change the eight-business-hour period, including by lengthening the period or changing how the period is calculated. Congress mandated the verification system and that a prescriber respond within “8 business hours, or a similar time as

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suggesting that the period could be changed to twenty-four hours with weekends and holidays excluded); *see also* CLR Panel IV Tr., *supra* note 121, at 16 (statement of Cindy Williams) (stating that eight hours is sufficient time to respond).

<sup>383</sup> *See, e.g.*, Becker (WS Comment #571); Contact Lens Association of Ophthalmologists, Inc. (WS Comment #770); Begeny-Mahan (WS Comment #1702) (requesting that the eight-business-hour period be changed to forty-eight hours); Kirkconnell (WS Comment #1754) (requesting two business days to respond and stating that requests should be faxed); American Society of Cataract and Refractive Surgery (WS Comment #3142) (advocating for extending the eight-business-hour time-period for passive verification to five business days); Hanen-Smith (NPRM Comment #154); Cade (NPRM Comment #2163) (suggesting that sellers should exclude a weekday from the eight-business-hour calculation if they become aware that the prescriber’s office is closed); American Academy of Ophthalmology (NPRM Comment #3657) (proposing lengthening the response period to two business days); Coalition for Patient Vision Care Safety (NPRM Comment #3883); Contact Lens Association of Ophthalmologists (NPRM Comment #4259) (asking that the period be extended to two days).

<sup>384</sup> *See, e.g.*, Rhee (WS Comment #3468); Meyers (NPRM Comment #173); Gilberg (NPRM Comment #198); Engler (NPRM Comment #453); Kempf (NPRM Comment #915); McPherson (NPRM Comment #3397); American Society of Cataract and Refractive Surgery (NPRM Comment #3820); Tesinsky (NPRM Comment #4012).

defined by the Federal Trade Commission.”<sup>386</sup> In determining this time period, Congress balanced the harm to consumers if they were unduly delayed in receiving their contact lenses against the harm from receiving contact lenses based on an invalid prescription.<sup>387</sup> The Commission does not find any compelling changes to the marketplace since the Rule’s promulgation in 2004 that support extending the eight business hour period.<sup>388</sup>

## **VI. Seller Alteration of Contact Lens Prescriptions and Private Label Concerns**

The current Rule states that a “seller may not alter a contact lens prescription.” The only exception applies to private label contact lenses and allows the seller, when a patient has a prescription for private label contact lenses, to substitute identical contact lenses that the same company manufactures and sells under a different name.<sup>389</sup>

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<sup>385</sup> Boyer (SNPRM Comment #59); Becker (WS Comment #571) (recommending two business days); Contact Lens Association of Ophthalmologists, Inc. (WS Comment #770); Begeny-Mahan (WS Comment 1702) (stating that the eight-hour period is a problem because the office is closed on Wednesdays); Huynh (WS Comment #1940); Dhaliwal (WS Comment #2684); American Society of Cataract and Refractive Surgery (WS Comment #3142); Morales (WS Comment #3404); Yu-Davis (WS Comment #3410), Rhee (WS Comment #3468); Meyers (NPRM Comment #173); Pierce (NPRM Comment #187) (estimating that the office spends approximately twelve minutes responding to a verification request); Kempf (NPRM Comment #915) (stating that the office is closed on Wednesdays and incorrect prescriptions received late on Tuesday will be filled); Goodman (NPRM Comment #1340) (stating that the prescriber is unable to respond to requests within the eight-hour period because the office is closed on Mondays); Speiser (NPRM Comment #2233) (stating that eight hours are not enough time because the doctor spends time at the hospital and is not in the office every day); Weingeist (NPRM Comment #2496) (stating that the practice is small and the requests are burdensome); American Society of Cataract and Refractive Surgery (NPRM Comment #3820); McPherson (NPRM Comment #3397) (stating that the office is very busy with patients and verification requests can be forgotten).

<sup>386</sup> NPRM, 81 FR at 88544. Some prescribers or sellers may be confused about when the eight-business-hour period starts following a verification request and the applicable time zone. *See, e.g.*, Goodman (WS Comment #599); Palmer (WS Comment #2215); Wang (WS Comment #3448); Gilberg (NPRM Comment #198); Huff (NPRM Comment #1964); Osterholzer (NPRM Comment #2085) (stating that the office is not open during the same hours as the seller and in a different time zone). Under the Rule, when a request is received after 5 p.m., the eight-business-hour period would not start until 9 a.m. the

In the SNPRM, the Commission expressed its concern about the emergence of sellers' business models that rely exclusively on passive verification as a means to substitute their own brand of contact lenses for the prescribed lens.<sup>390</sup> As noted in the SNPRM, many prescribers detailed harm that resulted from wearing unapproved lenses, such as headaches, corneal neovascularization, corneal ulcers, and other irreversible and vision-threatening diagnoses.<sup>391</sup> As a result, the Commission proposed two modifications to the Rule.

The first modification proposed in the SNPRM, adding a paragraph (g) to § 315.5, would require sellers to provide a clear and prominent method for the patient to present

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next weekday that is not a federal holiday, or if applicable, on Saturday at the beginning of the prescriber's actual business hours. A business hour is determined based on the time zone of the prescriber. 16 CFR 315.2, 315.5.

<sup>387</sup> NPRM, 81 FR at 88544.

<sup>388</sup> The Commission recognizes a need for clarification with respect to whether a seller can ship lenses to a consumer after receiving notification from a prescriber that the submitted prescription is inaccurate, invalid, or expired but when such notification occurs after the eight-business-hour period has passed. In its initial rulemaking, the Commission declined to expressly prohibit sellers from shipping lenses in such an instance, but noted that nothing in the Rule prohibits a prescriber from submitting late notifications to the seller or the seller from acting upon them, and that it would likely be in the best interest of their mutual consumer for them to do so. Contact Lens Rule, 69 FR 40050. However, the Commission is aware that the marketplace for contact lens sales now includes subscription models, in which sellers provide a quantity of lenses to consumers, not in a single-delivery supply, but rather in periodic installments (usually every month, although sometimes quarterly or semi-annually). In such a circumstance, the seller would have plenty of time to halt a subsequent installment shipment after being informed that the consumer's prescription was invalid, inaccurate, or expired. Therefore, the Commission clarifies that while the Rule does not prohibit an initial shipment to a consumer in instances where the seller received such notification after the eight-business-hour period has passed, any subsequent shipments based on the initial verification request would violate the Rule. A seller who has been notified that the patient does not have a valid prescription cannot ignore such notification and continue to sell and ship lenses every month simply because the notification came in after the eight-business-hour deadline.

<sup>389</sup> 16 CFR 315.5(e).

<sup>390</sup> SNPRM, 84 FR at 24687-88.

<sup>391</sup> *Id.* at 24686.

the seller with a copy of the patient's prescription. Such method might include, without limitation, electronic mail, text message, file upload, or facsimile. The Commission stated that this proposal would address prescriber and manufacturer concerns by increasing the number of patients who present online sellers with their prescriptions rather than relying on verification.<sup>392</sup>

The second modification proposed in the SNPRM targeted concerns about prescription verification more directly. The proposed modification of § 315.5(f) would define alteration to include a seller's providing, as part of a verification request, a prescriber with a manufacturer or brand other than that specified on a patient's prescription. The proposal included an exception, however, for sellers when they provide a manufacturer or brand that a patient provided to the seller, either on the order form or orally in response to a request for the manufacturer or brand listed on the prescription. In other words, to avail themselves of the exception, sellers must ask consumers to provide the manufacturer or brand listed on their prescription. The SNPRM further provided that a seller would not be able to avail itself of the exception by relying on a prepopulated or preselected box, or on consumers' online searches for a particular manufacturer or brand, as an indication that they were prescribed that manufacturer or brand.<sup>393</sup> A seller not covered under the exception discussed above who made a verification request containing a manufacturer or brand other than, and not identical to, the one written on the consumer's prescription by their prescriber, would violate the Rule, even if a prescriber subsequently invalidated the request and the lenses were never sold.<sup>394</sup>

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<sup>392</sup> *Id.* at 24688.

<sup>393</sup> *Id.* at 24689.

<sup>394</sup> *Id.*

**A. The Final Rule Includes a Requirement for Sellers to Accept Prescription Presentation**

Commenters who discussed the Commission’s proposal to require sellers to provide a clear and prominent method to present prescriptions were unanimous in their support, although some suggested revisions that they believed would make it more effective.<sup>395</sup> A number of commenters asserted that this amendment would help decrease the number of verification requests<sup>396</sup> and eliminate errors stemming from incorrect verification requests.<sup>397</sup> In addition, the NAOO pointed out that such presentation benefits the consumer and the seller by reducing the time needed to fill the order and providing additional assurance of the prescription’s validity.<sup>398</sup> 1-800 CONTACTS also supported—and says that it already complies with—the prescription presentation proposal.<sup>399</sup> Simple Contacts commented that the proposed requirement is fair, and opined that “any seller who does not support prescription presentation has not made a good faith attempt to accurately verify all patient prescriptions.”<sup>400</sup> Simple Contacts,

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<sup>395</sup> Simple Contacts (SNPRM Comment #87); American Optometric Association (SNPRM Comment #96); Health Care Alliance for Patient Safety (SNPRM Comment #128); National Association of Optometrists and Opticians (SNPRM Comment #129); 1-800 CONTACTS (SNPRM Comment #135); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>396</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); National Association of Optometrists and Opticians (SNPRM Comment #129); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>397</sup> Health Care Alliance for Patient Safety (SNPRM Comment #128); National Association of Optometrists and Opticians (SNPRM Comment #129); 1-800 CONTACTS (SNPRM Comment #135); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

<sup>398</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>399</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>400</sup> Simple Contacts (SNPRM Comment #87). *See also* National Association of Optometrists and Opticians (SNPRM Comment #129) (“Contact lens sellers that do not provide a method to upload the prescription may be trying to avoid getting the patient’s

however, expressed skepticism that the amendment would significantly reduce the number of alterations by sellers abusing the passive verification system.<sup>401</sup>

Because the Commission did not receive any comments opposing this proposal, the Commission is incorporating the requirement in its Final Rule. The Commission believes the proposal will help reduce the number of verifications, reduce errors associated with incorrect verification attempts, and make it more difficult for ill-intentioned sellers to abuse the passive verification framework and take advantage of consumers who might not realize that the seller intends to verify a different lens than the one written on their prescription.

In the Final Rule, the Commission has changed the “clear and prominent” requirement to pertain to a disclosure of the method of prescription presentation (*e.g.*, a disclosure that the method is available to provide the prescription). In so doing, the Commission makes clear that sellers cannot provide a method of prescription presentation without also providing a clear and prominent disclosure thereof.<sup>402</sup> The Commission has retained the requirement that the method (*e.g.*, email address, phone number to receive text messages, or upload link) be prominent.<sup>403</sup> The Commission has

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specific brand information, so that they can switch the patient into a different proprietary brand.”).

<sup>401</sup> Simple Contacts (SNPRM Comment #87). The Health Care Alliance for Patient Safety stated that “it is unclear whether the proposed amendment would have any effect on the incidence of alteration[s]” since the Commission is not also prohibiting calls containing automated verification messages. SNPRM Comment #128.

<sup>402</sup> For telephone orders, sellers would comply by making a prominent method available and giving clear and prominent notice of the method.

<sup>403</sup> The Commission finds its proposed SNPRM requirement that the method be clear unnecessary given the new language requiring the disclosure of the method to be clear and prominent.

also determined that it is unnecessary to include prescribers in this section of the Rule since it pertains to the ordering process between a seller and a consumer.<sup>404</sup>

Commenters suggested three additional requirements for the prescription presentation proposal. First, the NAOO suggested the Commission require that the method to present prescriptions be in close proximity to the option to provide the parameters of the contact lens for verification, so as to increase the likelihood that consumers would understand they have a choice between providing a prescription or having one verified with their prescriber.<sup>405</sup> As drafted, the language did not specify at what point in the process a seller must make the method for prescription presentation available. The Commission believes that the NAOO's suggestion of close proximity would be helpful, but notes that if the method, and a disclosure thereof, are provided in close proximity but *after* the collection of all information required for verification is provided, the prescription presentation benefit may be diminished. In other words, if a consumer enters all the information required for verification (contact lens brand, powers, prescriber name and phone number) before learning about prescription presentation, and having an opportunity to present the prescription, the consumer may choose not to also provide the prescription. As a result, the Commission is amending the language of § 315.5(g) in the Final Rule to require that the method and the disclosure of the method for the patient to present the seller with a copy of the patient's prescription must be *prior to*

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<sup>404</sup> The Rule anticipates prescription presentation by prescribers to sellers. Section 315.5(a)(1) indicates that one way sellers can sell contact lenses is if they receive a prescription from a prescriber directly or by facsimile. 16 CFR 315.5(a)(1).

<sup>405</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

requesting a prescriber's contact information, which is necessary to verify a contact lens prescription.<sup>406</sup>

Two commenters opined on whether consumers should be able to choose the method for providing their prescriptions. Consumer Reports stated its belief that, when offering prescription presentation, sellers should be required to provide consumers all four methods listed in the proposed Rule—electronic mail, text message, file upload, and facsimile—in lieu of giving sellers the option to choose from those methods.<sup>407</sup> It indicated that requiring all four would not burden the seller, and there may be reasons that patients prefer one option over the others.<sup>408</sup> On the other hand, the NAOO supported the Commission's proposal to let the seller decide the method.<sup>409</sup> The Commission has decided to require sellers to offer prescription presentation by the same medium through which the order is placed, or by electronic mail, text message, or file upload.<sup>410</sup> When orders are placed via telephone, sellers are required to offer prescription presentation via electronic mail, text message, or file upload. Because faxes are not commonly used by consumers, sellers can offer fax presentation as the sole option only when the orders are placed by fax. This framework gives consumers and prescribers an opportunity to present prescriptions, while limiting the burden on sellers, some of whom

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<sup>406</sup> In the case of orders placed by telephone, the Rule requires sellers to provide clear and prominent disclosure of the method for prescription presentation (*e.g.*, a seller's email address) prior to requesting a prescriber's contact information.

<sup>407</sup> Consumer Reports (SNPRM Comment #133).

<sup>408</sup> *Id.*

<sup>409</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>410</sup> A seller who chooses to offer all methods will likely benefit by having more consumers provide prescriptions than if it offered only one or even two methods. Benefits to sellers from having prescriptions on file include avoiding the costs involved in verification, and having the ability to provide contact lenses more quickly than relying on verification.

are small.<sup>411</sup> The Commission believes that these changes from the SNPRM proposal are not significant, are consistent with the stated purpose of the proposal as outlined in the SNPRM,<sup>412</sup> and will help ensure the maximum benefit from the Rule change.

Consumer Reports also recommended that sellers be required not just to accept prescription presentation, but also to specifically request and encourage patients to provide prescriptions.<sup>413</sup> The Commission declines to adopt this suggestion. The Commission's Final Rule requires sellers to accept prescriptions. The Final Rule also requires that sellers clearly and prominently disclose how consumers can provide them with prescriptions. Sellers that more overtly request or encourage the submission of prescriptions (*e.g.*, through price cuts and faster delivery times) will likely further increase the number of prescriptions presented, allowing both sellers and consumers to reap the benefits. However, the Commission has determined that beyond providing a method for consumers to present their prescriptions and notice of such method prior to requesting their prescriber's contact information, sellers should have discretion whether to promote or incentivize that practice.

**B. Alteration Includes a Seller Providing a Prescriber with a Verification Request for a Non-Prescribed Manufacturer or Brand, but Includes an Exception for Verifying a Manufacturer or Brand that a Consumer Indicates Is on Her Prescription**

In the SNPRM, the Commission proposed a modification of § 315.5(f) to define alteration to include a seller's providing, as part of a verification request, a prescriber with a manufacturer or brand other than that specified on a patient's prescription. The

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<sup>411</sup> For all orders, sellers can meet the requirement by accepting prescriptions via email. There should not be a significant burden on business to obtain and maintain an email address and process and store prescriptions received through email.

<sup>412</sup> SNPRM, 84 FR at 24688-89.

<sup>413</sup> Consumer Reports (SNPRM Comment #133).

proposal included an exception, however, for sellers when they provide in a verification request a manufacturer or brand that a patient provided to the seller, either on the order form or orally in response to a request for the manufacturer or brand listed on the prescription.<sup>414</sup> As discussed below, in the Final Rule, the Commission has determined to adopt this definition of alteration along with a modified version of the accompanying exception.

**1. The Final Rule Modifications Regarding Alteration Are Beneficial and Address Abuses of the Verification System**

1-800 CONTACTS expressed its belief that the proposed alteration modification was unnecessary and requested that the Commission carefully evaluate any new regulations that could interfere with the convenience and competitive pricing of legitimate sellers.<sup>415</sup> Although the seller recognized the presence of single-brand sellers in the market, and the problems some cause, 1-800 CONTACTS stated that the addition of quality standards for verification calls, along with targeted enforcement against sellers with a business model based solely on noncompliant verification methods, would reduce the ability of these sellers to profit from abusing the passive verification system.<sup>416</sup> Specifically, it felt that “enforcement against one such business [] would likely be sufficient to chill or completely eliminate replication of this business model.”<sup>417</sup> The Commission agrees that the requirement to provide a method for prescription presentation, and a disclosure thereof, should reduce the number of verification requests, and that the addition of quality standards for verification calls should reduce the

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<sup>414</sup> SNPRM, 84 FR at 24698.

<sup>415</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>416</sup> *Id.*

<sup>417</sup> *Id.*

incidence of non-compliant verification calls and increase the ability of prescribers to deny invalid requests or correct inaccurate ones. However, based on comments from prescribers as well as its own investigations and experience, the Commission believes those amendments on their own are inadequate to curb the practice of substitution to non-prescribed brands through abuse of the verification system. The Commission has previously stated that, under the existing Rule, a verification request is not valid and does not commence the eight-business-hour verification period if a seller knows or should know that the verification request includes a different brand and manufacturer than that prescribed.<sup>418</sup> Any sales after such requests violate the Rule, even if a prescriber has not responded. In these instances, the seller is not selling in accordance with a prescription. Despite clearly articulating this position, the FTC continues to receive reports about the proliferation of passive verification abuses. Furthermore, sellers may argue that they are technically compliant with the Rule because they submitted verification requests and prescribers had an opportunity to respond to the requests. They may also argue that they did not have knowledge that a consumer did not have a prescription for that manufacturer or brand of lens.

Additionally, this is not an issue of one bad actor. As noted in the SNPRM, the Commission has seen the emergence of businesses that rely exclusively, or almost exclusively, on passive verification as a means to substitute their own brand of contact lenses.<sup>419</sup> Simple Contacts' comment notes that, within the last two years, several new companies have entered the U.S. market and that their abuse of the verification system

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<sup>418</sup> SNPRM, 84 FR at 24687-88.

<sup>419</sup> SNPRM, 84 FR at 24687.

appears willful.<sup>420</sup> The AOA similarly noted an increase of direct-to-consumer brands and named three new market entrants that reportedly replace their own brand of lenses for the prescribed brand.<sup>421</sup> The Commission therefore sees benefits to defining alteration to include a seller's providing a prescriber, as part of a verification request, with a manufacturer or brand other than that specified on a patient's prescription.

## **2. Comments Related to the Exception to Alteration When a Seller Provides the Manufacturer or Brand of Lenses that a Consumer Provides in Response to a Seller's Request for that Information**

The SNPRM proposed that sellers receive an exception from alteration when they provide, in a verification request, a manufacturer or brand that a patient provided to them, either on the order form or orally in response to a request for the manufacturer or brand listed on the prescription.<sup>422</sup> If the seller seeks to verify a manufacturer or brand other than that indicated by the consumer, even if a prescriber ultimately denies the request, the seller has committed a violation. The implementation of the alteration definition, including the exception, should serve as an effective deterrent against sellers that try to game the verification system to sell non-prescribed contact lenses.

In response to the SNPRM, commenters expressed concerns that some sellers might take advantage of the exception by inducing, suggesting, advertising, or otherwise causing consumers to provide a name other than that on their prescription so as to allow the seller to seek verification of a brand that had not been prescribed for the consumer.<sup>423</sup>

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<sup>420</sup> Simple Contacts (SNRPM Comment #87).

<sup>421</sup> American Optometric Association (SNPRM Comment #96).

<sup>422</sup> SNPRM, 84 FR at 24686.

<sup>423</sup> National Association of Optometrists and Opticians (SNPRM Comment #129); CooperVision, Inc. (SNPRM Comment #130); Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

The NAOO was specifically concerned that “less scrupulous sellers” would attempt to take advantage of this exception, and noted that currently some sellers only request the power of the lenses from the customer and then ask prescribers to verify a prescription with a private label brand.<sup>424</sup> Commenters proffered different recommendations as to how to address this issue. CooperVision requested that the Commission state in a guidance document that sellers cannot induce, suggest, advertise, or otherwise cause patients to provide the wrong name, and to provide examples of improper statements.<sup>425</sup> Johnson & Johnson Vision Care suggested that, should the Commission retain the exception, it should add the following clarifying language to the preamble section of the Rule: “This exception is intended to provide explicit direction for sellers as to when they are responsible for instances of prescription alteration. Under no circumstances may a seller, wishing to avail themselves of this exception, direct, encourage, motivate, or suggest, either implicitly or explicitly, that a patient enter any manufacturer or brand other than that listed on the patient’s prescription.”<sup>426</sup> The NAOO recommended that the Rule itself be further amended to provide more specific direction as to what the seller must, may, and cannot do when asking patients for the information the FCLCA requires in a verification request. Specifically, it recommended adding a requirement that to avail

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<sup>424</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>425</sup> CooperVision, Inc. (SNPRM Comment #130).

<sup>426</sup> Johnson & Johnson Vision Care recognized that the exception could serve as guidance for sellers to determine whether they are responsible for an illegal prescription alteration. However, it believes the exception should not be added to the Rule because a patient may not be able to correctly enter their information given the nuances of a contact lens prescription and the meaning of the different elements therein. Ultimately, Johnson & Johnson Vision Care is concerned that the exception may contribute to passive verification of an inaccurate prescription, and thus, illegal substitution. SNPRM Comment #151. The Commission does not believe that this concern is relevant to the exception, which relates to a consumer only providing her manufacturer or brand.

itself of the exception, a seller must have had no reason to believe that the name provided by the consumer was not the manufacturer or brand listed on that consumer's prescription.<sup>427</sup>

The Commission agrees that sellers must not induce, suggest, advertise, or otherwise lead consumers to provide a manufacturer or brand different from that listed on their prescriptions. The Commission believes, however, that the recommended change is unnecessary because, should a seller attempt to induce or trick the consumer into providing the seller with a manufacturer or brand different from that listed on the consumer's prescription, it would not be able to avail itself of the exception. Any such conduct by the seller would call into question whether the consumer had *provided* the seller with the manufacturer or brand listed *on her prescription* in response to a clear request for such information, as required by the Rule.

Commenters expressed concern that the exception for patient prescription entry would allow consumers to override their prescriptions by providing a manufacturer or brand of contact lenses other than that prescribed to them by their prescriber.<sup>428</sup> Similarly, one commenter stated that sellers should ensure that consumers understand that they need to request the lens specified on their prescription and, if consumers want a different lens, sellers shall state prominently that consumers must discuss the request with, and make the change through, their prescribers.<sup>429</sup> The concern that this amendment gives consumers permission to override their prescriptions, including choosing a new brand, is unfounded. The exception in no way gives consumers the ability to override prescribers'

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<sup>427</sup> National Association of Optometrists and Opticians (SNPRM Comment #129).

<sup>428</sup> American Optometric Association (SNPRM Comment #96); Health Care Alliance for Patient Safety (SNPRM Comment #128).

<sup>429</sup> CooperVision, Inc. (SNPRM Comment #130).

prescriptions, and it does not change the prescriber’s ability to inform a seller that the prescription submitted for verification is inaccurate, expired, or otherwise invalid.<sup>430</sup> In fact, by requiring sellers to ask consumers their manufacturer or brand to meet the exception, the proposal is encouraging just the opposite—inviting consumers to choose the brand prescribed for them. And, once the seller receives a communication from the prescriber that the prescription is invalid, it cannot sell the lenses without violating the Rule. The Commission therefore does not see a need to require sellers to inform consumers that if they want a different lens, they must go to their prescribers. Asking consumers for the manufacturer or brand listed on their prescriptions, and clarifying that sellers may not induce, suggest, or otherwise cause consumers to select or provide a manufacturer or brand other than that prescribed, should be adequate to curtail much of the illegal alterations occurring through abuse of the verification system. Moreover, the Commission has issued consumer notices that indicate that if consumers wish to switch their brand of lens, they need to contact their prescribers.<sup>431</sup> The Commission will continue its educational efforts in this area.

### **3. Comments Regarding and Commission Guidance on Acceptable Methods for Obtaining the Brand or Manufacturer Listed on Consumers’ Prescriptions**

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<sup>430</sup> Final Rule 16 CFR 315.5(e). Despite this prohibition, substitution to another brand of lenses was always a risk with passive verification, but it was a risk Congress considered before instituting the verification framework set forth in the Act. *See, e.g.*, FCLCA Subcomm. Hearing, *supra* note 17 (statements of Howard Beales, Federal Trade Commission); *id.* (statements of J. Pat Cummings, American Optometric Association) (“And the problem with passive verification is that people will get contact lenses without a prescription.”).

<sup>431</sup> *See, e.g.*, Federal Trade Commission, *Prescription Glasses and Contact Lenses*, <https://www.consumer.ftc.gov/articles/0116-prescription-glasses-and-contact-lenses> (last visited Nov. 19, 2019).

1-800 CONTACTS expressed concern that the Commission's amendment might interfere with its ability to improve the user experience. It indicated that it sells hundreds of brands of lenses and offers consumers a variety of methods to identify their brand, including drop-down menus, a search box, and filters that display lenses by brand, modality, and other parameters and that some consumers do not enter their brand information on an order form.<sup>432</sup>

Simple Contacts asked for greater specificity on the acceptable mechanisms for soliciting the contact lens brand or manufacturer, as a way to prevent bad actors from finding mechanisms to circumvent the intent of the Rule. Simple Contacts recommended limiting such mechanisms to five: providing verbal confirmation of the brand or manufacturer; providing a copy of a prior prescription indicating the brand or manufacturer; typing a selection into a free entry text or search field; selecting a brand or manufacturer from a list or database containing the majority of commercially available brands (*e.g.*, a drop-down menu), or providing a photo of a contact lens box.<sup>433</sup>

Johnson & Johnson Vision Care opined that should the Commission proceed with the exception, a seller should not be able to avail itself of the exception by relying on a prepopulated or preselected box, or on consumers' online searches for a particular brand or manufacturer, as a representation by consumers that they do, in fact, have a prescription for that brand or manufacturer. In contrast to the view expressed by 1-800 CONTACTS and Simple Contacts, Johnson & Johnson Vision Care requested the

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<sup>432</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>433</sup> Simple Contacts (SNPRM Comment #87). The NAOO also stated that a seller should be able to rely on a customer-provided photograph of packaging of contact lenses for a current prescription. SNPRM Comment #129.

Commission prohibit drop-down menus and similar tools as methods by which a seller could avail itself of the exception.<sup>434</sup>

The Commission agrees that greater specificity surrounding acceptable methods would benefit sellers trying to comply with the Rule, but recognizes the myriad of ways consumers can interact with sellers to purchase lenses. Specifically, the Commission agrees that the requirement to provide the manufacturer or brand if not orally, then on an order form, imposes unnecessary limits for a consumer to select her manufacturer or brand. As a result, it is removing the term “order form” from the Final Rule. However, while sensitive to sellers’ needs to create the best and most convenient consumer experience, the Commission believes requiring that they ask for the name of the manufacturer or brand listed on consumers’ prescriptions can still be done while providing a positive purchasing experience for their customers.

At a minimum, in order for sellers to consider the consumer’s indication of manufacturer or brand as adequate to qualify for the exception, the manufacturer or brand must be: (1) provided in response to a seller’s request for the manufacturer or brand listed on the consumer’s prescription, and (2) an affirmative statement or selection by the consumer, not a preselected or prefilled entry (collectively “the minimum criteria”). As to the first minimum criterion, a seller cannot assume that a consumer who searches on the internet for a specific manufacturer or brand of lens has a prescription for that manufacturer or brand of lens. Similarly, a consumer’s selection next to a request for the manufacturer or brand the consumer wears or wishes to purchase would be insufficient because a consumer may be wearing or attempting to order a non-prescribed lens. In

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<sup>434</sup> Johnson & Johnson Vision Care, Inc. (SNPRM Comment #151).

contrast, a seller can reasonably rely on a consumer's entry of a manufacturer or brand in response to a request for the "manufacturer or brand listed on your prescription."

The second minimum criterion for sellers to qualify for the exception is that they must elicit from the consumer an affirmative statement or selection of the manufacturer or brand. A seller that relies on a preselected, prechecked box stating "I agree I have a prescription for this brand," or something similar, would not qualify for the exception to alteration. For telephone orders, the consumer must state the name of the manufacturer or brand in response to a seller's request for the manufacturer or brand listed on her prescription.<sup>435</sup> A seller can rely on a consumer-provided photograph of a contact lens box or a copy of a prior prescription so long as the seller meets the two minimum criteria listed above and obtains additional information from the consumer or prescriber that the consumer has a current prescription for that brand.<sup>436</sup>

The Commission is not limiting the permissible methods for obtaining manufacturer or brand to meet the exception to only those discussed above. The Commission instead is leaving sellers the option of deriving other ways to elicit the prescribed manufacturer or brand, within the guidelines discussed in this section. The Commission also declines to add a preamble further explaining the ways for sellers to meet the exception, but instead relies on this notice as guidance.

1-800 CONTACTS opined that the Commission should not refer to "brand" in the amendment to the Rule as that language does not appear elsewhere in the Rule. It points

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<sup>435</sup> A seller receiving an affirmative response to its request "Do you have a prescription for this brand?" would be unable to meet the exception.

<sup>436</sup> The information from the prescriber or consumer would provide the seller with a basis for the verification other than the expired prescription. *See* Section X.B., *supra* and NPRM, 81 FR at 88546-67 (a seller may not use an expired prescription as the basis for a verification request).

out that the Rule defines a prescription as including a “material or manufacturer or both” and that the Commission’s inclusion of the reference to brand imposes an additional limit on consumer choice that the Act does not require. 1-800 CONTACTS requested instead that the exception to the Rule be applicable to “providing the prescriber with the name of a manufacturer or material other than that specified by the patient’s prescriber . . . .” The reference to brand in the definition of alteration and in the exception would indeed be the only references to brand in the Rule. However, in practice, it appears many, if not most, prescriptions list the manufacturer’s brand, not the manufacturer or material, and the brand is viewed as shorthand for the entire device.<sup>437</sup> Furthermore, very few consumers know the manufacturer or material of contact lens that they wear, and typically refer to their lenses by brand name. Amending the exception in the way 1-800 CONTACTS recommended would be unworkable since many consumers would be unable to provide the manufacturer or material in response to a seller’s request, and might even have to ask their prescribers. Should prescribers’ practices change from listing a brand on a prescription to listing a manufacturer or material, the Commission will reevaluate its decision.

#### **4. The Commission Is Not Imposing a Recordkeeping Requirement for Sellers Related to the Exception**

Lastly, CooperVision strongly recommended that the Commission reconsider its decision not to require sellers to keep records related to the exception and noted that the Rule relies heavily on requiring written evidence. CooperVision claimed that the lack of

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<sup>437</sup> SNPRM, 84 FR at 24686 n.299. *See also* National Association of Optometrists and Opticians (SNPRM Comment #129) (noting as an example that many, if not most, prescriptions for My Day lenses manufactured by CooperVision get written as “My Day,” not as “CooperVision” or “CooperVision My Day”).

a recordkeeping requirement would leave a gap that could be exploited, and would make it difficult for the Commission to pursue enforcement against sellers who violate the Rule.<sup>438</sup> The Commission disagrees with this assessment. Since the exception to alteration would be a defense for a seller, the seller would have the burden of proof to show it met the exception. Should the Commission believe that the seller has altered a contact lens prescription and submitted a verification request for a manufacturer or brand other than that indicated by a consumer, the seller would need evidence that it meets the exception. Sellers who determine not to maintain records do so at their own peril.

### **C. Private Label Issues**

Although most contact lenses in the United States are sold under national brand names (such as Acuvue Oasys, or Dailies Aquacomfort Plus), some manufacturers distribute their lenses to prescribers and retail sellers under private labels (such as Costco's Kirkland Signature contact lens brand or LensCrafters 1-Day Premium contact lenses). Private label contact lenses can be unique to one seller, or the private label brand may be available at multiple unaffiliated sellers.<sup>439</sup> Despite the label, however, the lenses inside the packaging are exactly the same as lenses sold under a national brand.<sup>440</sup>

#### **1. The Commission Adopts a Technical Amendment and Clarifies that the Only Permissible Substitution Involves Private Label Lenses**

In § 315.2, the Rule defines private label lenses as “contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the

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<sup>438</sup> CooperVision, Inc. (SNPRM Comment #130).

<sup>439</sup> 2005 Contact Lens Report, *supra* note 14, at 14-15.

<sup>440</sup> For example, Costco's Kirkland Signature Premium Daily Disposable lenses are the same as CooperVision MyDay disposable lenses.

same manufacturer but sold under the labels of other sellers.”<sup>441</sup> The Rule also provides that a prescription for private label contact lenses must include, in addition to other required information, the name of the manufacturer, trade name of the private label brand, and if applicable, the trade name of equivalent brand name.<sup>442</sup> The Rule’s definition for a private label lens prescription tracks the language of the Act.<sup>443</sup> With respect to how sellers treat and substitute private label lenses, however, the Commission recognized in the NPRM that the construction of § 315.5(e) of the Rule does not presently conform to the language or intent of the Act.<sup>444</sup> The clear language of the Act allows sellers to substitute national brand name lenses for private label lenses, and vice versa, so long as it is “the same contact lens manufactured by the same company and sold under multiple labels to individual providers.”<sup>445</sup> The Rule, meanwhile, states that 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.”<sup>446</sup> The different language of the Act thus allows sellers to substitute brand names for identical private labels, and private labels for identical brand names, while the Rule, as currently drafted, could be read to proscribe the latter.

To conform the Rule to the Act, the Commission proposed in the NPRM to strike the words “private label” from § 315.5(e), so it would state that a seller may “substitute for contact lenses specified on a prescription identical contact lenses that the same

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<sup>441</sup> 16 CFR 315.2.

<sup>442</sup> *Id.*

<sup>443</sup> *See* 15 U.S.C. 7610(3)(H).

<sup>444</sup> NPRM, 81 FR at 88552.

<sup>445</sup> 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 so long as the lenses are identical.

<sup>446</sup> 16 CFR 315.5(e).

company manufactures and sells under different labels.”<sup>447</sup> The Rule’s definitions of a “contact lens prescription” and of a “private label contact lens” would remain unchanged. The Commission made this proposal after becoming aware that, in addition to prescribers, some other sellers (such as Costco) now 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.

While the Commission’s proposal was intended to clarify the Rule and align it with the Act’s intent, some commenters opposed the change because they believed it could be interpreted as allowing substitution beyond that of private label lenses.<sup>448</sup> According to Johnson & Johnson Vision Care, the “private label” modifier is necessary to provide guidance that the only instance in which a seller can lawfully substitute lenses for those written on a prescription is for identical private label lenses, and that removing the words “private label” from the command section of the Rule (leaving it only in the definitions section), will render the term meaningless.<sup>449</sup> The removal of this term is especially problematic, according to the manufacturer, because illegal substitution is a problem in the marketplace, and it could ultimately cause undue, avoidable harm to

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<sup>447</sup> NPRM, 81 FR at 88552.

<sup>448</sup> Johnson & Johnson Vision Care, Inc. (NPRM Comment #4327); *see also* Tesinsky (NPRM Comment #4012) (fearing change may be interpreted as the “ability to substitute a different contact by the same manufacturer (for example substituting Acuvue Oasys for Acuvue Vita), rather than just a private label substitute”).

<sup>449</sup> Johnson & Johnson Vision Care, Inc. (NPRM Comment #4327); *see also* American Optometric Association (NPRM Comment #3830) (opposing Commission’s proposal and finding the term “private label” provides necessary clarity to ensure inappropriate substitutions do not occur).

patient eye health and vision safety.<sup>450</sup> Should the Commission choose to proceed with its removal of the term “private label” from § 315.5(e), Johnson & Johnson Vision Care requested that the Commission explicitly clarify that such removal does not allow for substitution beyond the scope of private label lenses or identical contact lenses that the same company manufactures and sells under different labels. It further suggested that the most appropriate and effective place to clarify how the Commission interprets this Rule provision would be in the preamble of the Rule, rather than the regulatory language itself.<sup>451</sup>

Costco, in contrast, supported the Commission’s proposed change, because it would make clear that sellers can substitute their own private label contact lenses for prescribed lenses that are identical to lenses made by the same manufacturer and sold under the manufacturer’s brand.<sup>452</sup> Although Costco believes that the existing Rule allows it, when presented with a valid prescription for the manufacturer’s brand, to substitute Kirkland Signature lenses, it believed that modifications to the language of § 315.5(e) would clarify and eliminate any doubt about the lawfulness of this practice. Costco also opined that without such a change, the legality of such substitution might be in question, and, as a result, some sellers, particularly those without an established relationship with prescribers, would likely be unwilling to invest in a private label lens

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<sup>450</sup> Johnson & Johnson Vision Care, Inc. (NPRM Comment #4327).

<sup>451</sup> Johnson & Johnson Vision Care, Inc. also supported its position that the clarification should be made in the preamble by reference to the fact that there were not specific reports of sellers encountering issues with the original Rule language. NPRM Comment #4327.

<sup>452</sup> Costco Wholesale Corporation (NPRM Comment #4281).

line.<sup>453</sup> Consumers Union also supported the change, indicating that it increases the choices available to consumers, including potentially more affordable options, without in any way undermining patient safety.<sup>454</sup>

The Commission did not intend for the removal of the words “private label” in the Rule to make substitution more widely permissible beyond that of a seller being able to provide a private label lens when the *identical* lens (made by the same manufacturer but sold under a different label) is written on the prescription. However, in order to allay concerns, the Commission has retained the term “private label,” but reordered the provision to clarify that permissible substitution only involves private label contact lenses. Thus, the Final Rule allows private label and brand name lenses, when they are identical lenses made by the same manufacturer listed on the prescription, to be substituted for each other.<sup>455</sup>

## **2. The Commission Is Not Imposing Additional Requirements on Prescriptions for Private Label Lenses**

As mentioned above, the Act and the Rule require prescriptions for private label contact lenses to include “the name of the manufacturer, trade name of the private label brand, and if applicable, trade name of equivalent brand name.”<sup>456</sup> LD Vision Group (LensDiscounters.com), in response to the NPRM, provided the Commission with

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<sup>453</sup> *Id.* Costco also commented that bringing a private label lens to market can significantly benefit consumers in terms of introducing lower prices. NPRM Comment #4281.

<sup>454</sup> Consumers Union (NPRM Comment #3969).

<sup>455</sup> Section 315.5(f) of the Final Rule reads: “Notwithstanding the preceding sentences, for private label contact lenses, a seller may substitute for contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.” The Commission revised the provision to refer to the “preceding sentences” to make it clear that the phrase beginning with “[n]otwithstanding” does not apply to anything other than § 315.5(f).

<sup>456</sup> 15 U.S.C. 7610; 16 CFR 315.2 (in definition of contact lens prescription).

instances of alleged rule violations involving private label prescriptions improperly written or written without equivalents.<sup>457</sup> It also requested that the Commission reconsider LD Vision Group's previous recommendations to: (1) require prescribers to annotate private label lens prescriptions with the brand-name equivalent and if the name-brand equivalent is unavailable, the private-label prescription must be medically necessary for that particular patient; (2) require manufacturers of contact lenses to make brand information available to all sellers, consumers, and the FTC; or (3) require manufacturers and sellers to make brand equivalency information available and easily accessible for private labels on their brand label packaging and online.

Although the Commission appreciates the additional information provided by LD Vision Group, the information has not altered the fact, as stated in the SNPRM, that the Act does 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.<sup>458</sup> The Act also does not expressly contemplate the imposition of disclosure requirements on manufacturers. Therefore, the Commission is not implementing the recommendations of LD Vision Group.

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<sup>457</sup> This commenter also disagreed with what it stated was the "Commission's diminishment of private label concerns." LD Vision Group, Inc. (NPRM Comment #3958).

<sup>458</sup> SNPRM, 81 FR 88551. In the SNPRM, the Commission also referenced the initial rulemaking, where sellers recommended that prescribers be required, when prescribing private label contact lenses, to identify on the prescription the name of a brand that a consumer could purchase from a seller other than the prescribing office. 69 FR 40503. The Act does not limit, in any way, the brand that a prescriber must select, and the current record does not have sufficient evidence indicating that this is a problem. *Id.* Therefore, LD Vision Group's proposal to limit prescribers from prescribing private label brands without a brand-equivalent is not adopted.

The Act and the Rule expressly require that, for private label contact lens prescriptions, prescribers include “trade name of equivalent brand name.”<sup>459</sup> Prescribers violate the Rule if they provide a script that omits this information because the script does not meet the definition of a contact lens prescription. With that in mind and given the additional information provided by LD Vision Group, the Commission will consider whether enforcement action is appropriate.

#### **VII. “Directly or by Facsimile” Language Includes Use of Online Patient Portals to Present Prescriptions**

Section 315.5(a)(1) of the Rule provides that a seller may sell contact lenses in accordance with a prescription that is presented to the seller “directly or by facsimile.” In the NPRM, the Commission initially determined 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.<sup>460</sup> The Commission noted that use of a patient portal “necessarily involves ‘an exact copy of the prescription within the scope of acceptable direct presentation mechanisms.’”<sup>461</sup> The Commission observed in the NPRM that technology had evolved since the Rule’s implementation in 2004 and that patient portals offered several potential benefits, including reducing: the chance of an inaccurate or expired prescription being presented to a seller; the costs for prescribers, patients, and sellers by making it easier and more efficient for patients to share and present

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<sup>459</sup> 15 U.S.C. 7610, 16 CFR 315.2 (contact lens prescription defined to include, in the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name).

<sup>460</sup> NPRM, 81 FR at 88537-38.

<sup>461</sup> *Id.* at 88538.

prescriptions; and the number of verification requests to prescribers.<sup>462</sup> The Commission sought comments on whether the use of online portals complies with the Rule and requested information about whether the Commission should consider any other issues related to the presentation of prescriptions to sellers.

Although the Commission received many comments indicating that patients are able to receive their prescriptions electronically, including through patient portals, and interact with their prescribers electronically,<sup>463</sup> few comments addressed the use of portals to present prescriptions directly to sellers. Commenters agreed that such technology could offer benefits, including reducing the number of requests for verification and additional copies, and giving patients greater access to their prescriptions.<sup>464</sup> However, it is unclear how often, if at all, prescribers send prescriptions

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<sup>462</sup> *Id.*

<sup>463</sup> *See, e.g.*, Eklund (WS Comment #502); Reed (WS Comment #749); Gitchell (WS Comment #759); Andrews (WS Comment #1014); Carvell (WS Comment #1021); Cecil (WS Comment #1892); Kuryan (WS Comment #3472); Hopkins (NPRM Comment #184); Wilson (NPRM Comment #1310); Grove (NPRM Comment #1702); MacDonald (NPRM Comment #2118); Andrus (NPRM Comment #3345); American Academy of Ophthalmology (NPRM Comment #3657) (“For practices that utilize electronic medical record systems, patients can request a copy of their prescription and [be] issued one electronically.”); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89).

<sup>464</sup> National Association of Optometrists and Opticians (NPRM Comment #3851) (noting that the option to provide a prescription through a portal should be available because technology will continue to advance); 1-800 CONTACTS (NPRM Comment #3898); Costco Wholesale Corp. (NPRM Comment #4281) (supporting the FTC’s determination regarding presentation of prescriptions directly or by facsimile for the reasons cited in the NPRM); NPRM, 81 FR at 88538 (identifying the potential benefits of using a portal to present a prescription to a seller). Other commenters have expressed the potential benefits of portals or electronic health records generally. *See, e.g.*, Information Technology & Innovation Foundation (SNPRM Comment #103); Opticians Association of Americas (WS Comment #482); Marshall (WS Comment #518) (suggesting the benefit of electronic medical records in allowing easier access to the prescription); McCarty (WS Comment #1898); CooperVision, Inc. (WS Comment #3077); Coalition for Contact Lens Consumer Choice (WS Comment #3239) (stating that new technologies like electronic health records have benefits for consumers).

to sellers through a portal. Use of portals to transmit prescriptions to sellers could face barriers, including technology issues between the parties caused by using different software and platforms, and privacy restrictions preventing sellers from accessing patients' portal accounts.<sup>465</sup>

The Act and Rule clearly envision and support the use of electronic means to provide prescriptions. Section 7601(a)(2) of the Act requires prescribers to “provide or verify the contact lens prescription by electronic or other means” to patients' agents.<sup>466</sup> As discussed in the NPRM, it would be inconsistent for the Rule to permit prescribers to provide prescriptions electronically to patients, but not allow prescribers to provide a prescription electronically to a seller.<sup>467</sup>

Use of electronic medical records has increased in the health field generally,<sup>468</sup> and many prescribers already use electronic methods to communicate with patients,

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<sup>465</sup> Hill (WS Comment #1361); McCarty (WS Comment #1898); Shum (WS Comment #543) (stating that “[t]he use of patient portals to send Rx would be unreliable due to inconsistent EHR [(electronic health records)] software and that some doctors do not have EHR”); National Hispanic Medical Association (SNPRM Comment #146) (stating that creating a portal to share prescription information could be a burden on prescribers and patients); 1-800 CONTACTS (NPRM Comment #3898) (stating that “to the extent prescribers use portals to provide sellers with prescriptions, their portal should have the ability to send the prescription to the seller directly by email, text, or facsimile, and a seller should not be required to develop direct communication links to the portal”); CLR Panel V Tr., *supra* note 191, at 19-20.

<sup>466</sup> 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2).

<sup>467</sup> NPRM, 81 FR at 88538.

<sup>468</sup> One survey from 2017 found that 52% of individuals were offered online access to their medical records by a health provider or insurer, an increase from 42% in 2014. Of those patients who were offered online access, more than half actually viewed their online medical records at least once in the past year. U.S. Dep't of Health & Human Servs., The Office of the National Coordinator for Health Information Technology, “Individuals' Use of Online Medical Records & Technology for Health Needs” 1-2 (2018). Furthermore, in 2013, 57% of prescriptions nationally were sent electronically from physicians to pharmacies, with the rate in some states over 80%. U.S. Dep't of Health & Human Servs., The Office of the National Coordinator for Health Information Technology, “E-Prescribing Trends in the United States” 8 (2014).

including through patient portals.<sup>469</sup> Given the potential benefits, prescribers and patients should have the option to present a prescription to sellers through a patient portal when this method is available. Therefore, the Commission affirms its initial determination that the “directly or by facsimile” language includes the use of online patient portals by patients and prescribers to present contact lens prescriptions to sellers.

### **VIII. Requests for an Additional Copy of a Prescription**

In the SNPRM, the Commission proposed requiring that prescribers who receive requests for additional copies of prescriptions from patients or their agents respond within forty business hours.<sup>470</sup> The Commission believed that the forty-business-hour requirement was necessary to ensure that patients or their agents could receive additional copies of their prescription in a timely manner while recognizing that a shorter time period was unnecessary because patients would have already received a copy of their prescription after the contact lens fittings were completed and sellers could always submit a verification request.<sup>471</sup> Additionally, prescribers would be required to note in the patient’s file the name of the requester and the date and time the prescription was provided. The Commission sought comment on whether prescribers should be required to respond within a certain time period, whether forty business hours was the appropriate

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<sup>469</sup> American Optometric Association (SNPRM Comment #96) (stating that approximately 47.5% of optometrists used electronic health records with a patient portal in their practice); National Association of Optometrists and Opticians (SNPRM Comment #129) (“Practice management systems and electronic health records (EHRs) with the capacity to allow patient portals, email, and text communication are easily available at reasonable prices to optometrists . . .”); National Hispanic Medical Association (SNPRM Comment #146); 1-800 CONTACTS (NPRM Comment #3898). *But see* CLR Panel V Tr., *supra* note 191, at 17 (comment by a panelist that only 8% of his office’s patients used the portal).

<sup>470</sup> SNPRM, 84 FR at 24684.

<sup>471</sup> *Id.*

time period, and what records, if any, prescribers should be required to keep to document the request and response.<sup>472</sup>

**A. Benefits of an Additional Copy and the Time Period to Respond to a Request**

The AOA contends that Congress did not intend for sellers to be given authorization to serve as the patient’s agent.<sup>473</sup> Rather, the AOA “assume[s] that Congress implemented this provision to account for cases in which a family member or caregiver needed authorization to obtain a patient’s prescription.”<sup>474</sup> As noted in the NPRM, the Commission relied on the plain language of the Act and Rule to determine that sellers could serve as agents for patients,<sup>475</sup> and the AOA does not point to any contrary evidence.<sup>476</sup> Additionally, the AOA believes that no deadline to respond to requests for additional copies is necessary because prescribers take their responsibilities to their patients seriously.<sup>477</sup>

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<sup>472</sup> *Id.*

<sup>473</sup> American Optometric Association (SNPRM Comment #96).

<sup>474</sup> *Id.*

<sup>475</sup> NPRM, 81 FR at 88536. In addition to sellers, the SNPRM noted that patients themselves could request an additional copy of the prescription. Although a commenter requested that the Commission modify the Rule to clarify that patients can request their own additional copy (National Association of Optometrists and Opticians (SNPRM Comment #129)), the Commission believes that the Rule’s language is sufficient and declines to make such change. SNPRM, 84 FR at 24684 n.259.

<sup>476</sup> American Optometric Association (SNPRM Comment #96).

<sup>477</sup> *Id.* The AOA also urged the Commission not to rely on 1-800 CONTACTS data indicating that only 46% of its requests for an additional copy of a prescription received a response because 1-800 CONTACTS may not have the patients’ consent to act as an agent. Although the Commission considered the 1-800 CONTACTS data, the Commission did not rely solely on this information when issuing its proposed Rule. SNPRM, 84 FR at 24669.

Other commenters supported the Commission’s proposal regarding requests for additional copies.<sup>478</sup> Commenters noted that a deadline to respond would: (1) make the process more predictable for patients and sellers, especially when involving a prescriber who has not responded to such requests in the past;<sup>479</sup> (2) potentially reduce the number of verification requests, which would benefit prescribers, sellers, and patients; and (3) improve the accuracy of information provided to sellers ensuring that patients receive the correct lenses.<sup>480</sup> In addition to anecdotal accounts of prescribers not responding to requests for additional copies, 1-800 CONTACTS commented that, in 2019 to date, it had received a response to approximately 52% of its requests for an additional copy with 82% of the responses being received within forty-eight hours of the request.<sup>481</sup> This 2019 data is similar to 1-800 CONTACTS’ 2016 data, which showed that 46% of the requests received a response and 90% of those responses were received within two days.<sup>482</sup> In response, the AOA questions 1-800 CONTACTS’ 2016 data because patients, who gave

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<sup>478</sup> Citizen Outreach (SNPRM Comment #78); Lens.com (SNPRM Comment #85); Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); Consumer Action (SNPRM Comment #101); Information Technology and Innovation Foundation (SNPRM Comment #103); National Association of Optometrists and Opticians (SNPRM Comment #129); Consumer Reports (SNPRM Comment #133); 1-800 CONTACTS (SNPRM Comment #135); American Academy of Ophthalmology (SNPRM Comment #136); Attorneys General of 27 States (SNPRM Comment #139).

<sup>479</sup> Although not always the case, some sellers expressed difficulties with obtaining responses from prescribers. *See* National Association of Optometrists and Opticians (SNPRM Comment #129) (stating that at least one NAOO member reported receiving timely responses while other members found that it was “difficult, if not impossible, to get any form of a timely response”).

<sup>480</sup> Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); National Association of Optometrists and Opticians (SNPRM Comment #129); Consumer Reports (SNPRM Comment #133); 1-800 CONTACTS (SNPRM Comment #135); Attorneys General of 27 States (SNPRM Comment #139); Contact Lens Association of Ophthalmologists (NPRM Comment #4259).

<sup>481</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>482</sup> 1-800 CONTACTS (NPRM Comment #3898).

consent through a prechecked box, may not have intended for 1-800 CONTACTS to act as their agent in requesting the prescription.<sup>483</sup> The AOA posits that prescriber concern over patients' consent "may have impacted responses to [1-800 CONTACTS'] requests," but offers no evidence to support this argument.<sup>484</sup> Likewise, the AOA did not provide any data showing the extent to which prescribers have responded to requests for additional copies. Given the potential benefits and the aforementioned data, the Commission does not believe it is sufficient to rely simply on the expectation that all prescribers would fulfill their responsibilities to their patients. Rather, the Commission believes that the Rule should be amended to add a deadline to respond to a request for an additional copy.

Although some commenters agreed that the Commission's proposed deadline of forty business hours was a reasonable length of time,<sup>485</sup> other commenters urged the Commission to use a shorter period, such as one business day<sup>486</sup> or twenty-four business hours,<sup>487</sup> because (1) patients would want a quicker response, (2) the longer time period could undercut a benefit of using a prescription—reducing the number of verification requests, and (3) prescribers could be confused between forty business hours for an

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<sup>483</sup> American Optometric Association (SNPRM Comment #96).

<sup>484</sup> *Id.*

<sup>485</sup> Coalition for Contact Lens Consumer Choice (SNPRM Comment #89); American Optometric Association (SNPRM Comment #96) (noting that if a deadline were added, forty business hours would be reasonable); Information Technology and Innovation Foundation (SNPRM Comment #103); 1-800 CONTACTS (SNPRM Comment #135); American Academy of Ophthalmology (SNPRM Comment #136).

<sup>486</sup> Consumer Reports (SNPRM Comment #133).

<sup>487</sup> National Association of Optometrists and Opticians (SNPRM Comment #129) (supporting a shorter time limit, in part, because the burden of complying could be lower due to portal, text, or email use).

additional copy request and eight business hours for a verification request.<sup>488</sup>

Additionally, the work involved for a prescriber's office to respond to a request would not increase with a shorter deadline.<sup>489</sup> Although patients would benefit from a shorter response period, the Commission recognizes the additional stress on prescribers of having less time to respond, even if the work involved to complete a response remains the same. Because patients should have already received a copy of their prescription after the fitting,<sup>490</sup> sellers can submit a verification request to complete the sale more quickly,<sup>491</sup> and prescribers have an obligation to respond to a request for an additional copy, unlike a verification request, the Commission declines to make any further changes and will adopt the proposed forty-business-hour period.

#### **B. Requirement to Maintain Records**

Finally, as to what records, if any, a prescriber should be required to maintain regarding the request for an additional copy, the AOA believes that sellers, not prescribers, should shoulder this burden because sellers are “leveraging the patient agent provision to obtain patient prescriptions.”<sup>492</sup> Records of the request and the response would allow the Commission to monitor compliance.<sup>493</sup> However, the Commission does not believe requiring the requestor to maintain such information would be appropriate because the obligation under the Rule to respond to prescription requests rests with

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<sup>488</sup> National Association of Optometrists and Opticians (SNPRM Comment #129); Consumer Reports (SNPRM Comment #133).

<sup>489</sup> Consumer Reports (SNPRM Comment #133).

<sup>490</sup> 16 CFR 315.3(a)(1).

<sup>491</sup> 16 CFR 315.5(a)(2).

<sup>492</sup> American Optometric Association (SNPRM Comment #96).

<sup>493</sup> The proposed Rule would mandate that prescribers make notations of the required information in their records, but would not require that they keep specific documentation. SNPRM, 84 FR at 24698. However, prescribers could choose to keep documentation of the request and response if they preferred.

prescribers and they would be in the best position to maintain records.<sup>494</sup> Importantly, the Rule allows “any person designated to act on behalf of the patient[,]” including the patients themselves, family members, or caregivers, to request a copy of a prescription, not just sellers.<sup>495</sup> A shift of the recordkeeping burden to any designated agent making a request would not allow for effective monitoring because the Commission might need to obtain records from a wide variety of agents in order to determine whether a particular prescriber is complying with the Rule. Thus, the Commission declines to change the recordkeeping requirement.

In conclusion, the Commission adopts the changes proposed in the SNPRM to require that prescribers respond to requests for an additional copy of a prescription within forty business hours and note in the patient’s record the name of the requestor and the date and time that the prescription was provided in response.

## **IX. Excessive Quantity**

In the NPRM, the Commission declined to make any changes regarding the number of lenses that a consumer can purchase with a prescription.<sup>496</sup> Several commenters had expressed concerns that consumers were able to obtain more than a year’s supply of contact lenses, often by purchasing more than a year’s worth at one time or by refilling their prescription just before the expiration date.<sup>497</sup> However, the Commission determined that there was insufficient evidence on the record to support a

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<sup>494</sup> See also National Association of Optometrists and Opticians (SNPRM Comment #129) (“We believe it will be straight-forward and simple for the prescriber to keep a record of receiving the request for a copy and noting how and when the prescriber responded.”).

<sup>495</sup> SNPRM, 84 FR at 24684 n.259, 24698.

<sup>496</sup> NPRM, 81 FR at 88549.

<sup>497</sup> *Id.* at 88547-48.

limit on the maximum quantity of lenses that consumers can purchase prior to the prescription's expiration.<sup>498</sup> Although there was some evidence that patients purchased contact lenses just before their prescriptions expired, this evidence did not show that the quantity of lenses being purchased was excessive or that consumers were skipping eye exams.<sup>499</sup> Furthermore, the Commission believed that a maximum quantity limit would be difficult to administer and could have a more significant negative effect on consumers who, instead of following the recommended replacement schedule, opt to wear their lenses longer until they see a prescriber.<sup>500</sup>

In response to the NPRM, some commenters supported the Commission's decision not to impose quantity limits<sup>501</sup> while others expressed concerns about the purchase of excessive quantities and advocated for limits.<sup>502</sup> The commenters who support quantity limits are concerned that patients who purchase excessive quantities of

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<sup>498</sup> *Id.* at 88548-49. The Commission also declined to modify the Rule to state that contact lens prescriptions are valid for an unlimited quantity of lenses regardless of any prescriber-imposed limitation. The Commission found no evidence that prescribers were using quantity limits to undercut the prescription length and recognized that some state laws or regulations mandated that quantity information be included on a prescription, or that a prescriber may choose to do so. NPRM, 81 FR at 88549-50. However, prescribers cannot use quantity limits as a way to frustrate the Rule's prescription expiration requirements. *Id.* at 88550.

<sup>499</sup> *Id.*

<sup>500</sup> *Id.*

<sup>501</sup> Coalition for Contact Lens Consumer Choice (NPRM Comment #3718); Consumer Action (NPRM Comment #3721); 1-800 CONTACTS (NPRM Comment #3898).

<sup>502</sup> *See, e.g.*, Contact Lens Institute (SNPRM Comment #79); Goodman (WS Comment 599); Hanen (WS Comment #712); Dillehay (WS Comment #822); Rosenblatt (WS Comment #841); Hooven (WS Comment #1366); Henry (WS Comment #2194); Robson (WS Comment #2210); Wiechmann (WS Comment #2823); Health Alliance for Patient Safety (WS Comment #3206); Alcon Laboratories, Inc. (WS Comment #3339); Ellenbecker (WS Comment #3353); Jeun (NPRM Comment #1774); Daza (NPRM Comment #2002); Silva (NPRM Comment #3072); CooperVision, Inc. (NPRM Comment #3841); Coalition for Patient Vision Care Safety (NPRM Comment #3883); *see* CLR Panel IV Tr., *supra* note 121, at 19 (statement of David Cockrell).

lenses face increased health risks because they do not see their prescriber as often.<sup>503</sup>

Contrary to the Commission's position in the NPRM, they believe that there is evidence in the record that consumers are purchasing an excessive number of lenses close to the end of their prescription and that a quantity limit can be implemented.<sup>504</sup> These commenters point to survey evidence by Johnson & Johnson Vision Care showing that consumers, in response to reminders that their prescriptions would be expiring soon, ordered more lenses.<sup>505</sup>

However, the concern is not whether consumers are purchasing lenses near the end of their prescription, but whether they are purchasing excessive quantities. As noted in the NPRM, the Johnson & Johnson Vision Care survey did not ask about the quantity of lenses purchased by consumers.<sup>506</sup> The Commission had previously found that consumers typically do not purchase a year's supply of lenses at one time.<sup>507</sup>

Additionally, 1-800 CONTACTS stated that it was aware of survey evidence it believed showed that six months is the average size of an order made during the last thirty days of a prescription, which is similar to, based on 1-800 CONTACTS internal data, the average

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<sup>503</sup> Jeun (NPRM Comment #1774); Daza (NPRM Comment #2002); CooperVision, Inc. (NPRM Comment #3841); Coalition for Patient Vision Care Safety (NPRM Comment #3883).

<sup>504</sup> CooperVision, Inc. (NPRM Comment #3841); Coalition for Patient Vision Care Safety (NPRM Comment #3883).

<sup>505</sup> CooperVision, Inc. (NPRM Comment #3841) (stating that evidence of the high number of patients being contacted in the last days of their prescription "provides a powerful inference that sales in many situations are excessive"); Coalition for Patient Vision Care Safety (NPRM Comment #3883).

<sup>506</sup> NPRM, 81 FR at 88549-50; *see also* Johnson & Johnson Vision Care, Inc. (RFC Comment #582) (asking consumers whether a seller notified them that their prescription was expiring and whether they have ever ordered lenses within a month of their prescription's expiration).

<sup>507</sup> NPRM, 81 FR at 88549.

quantity ordered throughout the duration of the prescription.<sup>508</sup> Thus, the Commission does not have sufficient basis to conclude, despite anecdotal reports and alleged practices by some sellers, that consumers are purchasing lenses in excessive quantities near the end of their prescription.<sup>509</sup> Neither does the Commission have sufficient evidence showing that consumers are going to eye care providers less frequently because they previously purchased large quantities of contact lenses. In fact, evidence suggests that a majority of consumers are seeing their eye care provider regularly. One survey found that contact lens wearers have an eye exam every thirteen months on average while another survey showed that about 56% of respondents received an eye exam every twelve months or less, with an overall average of approximately sixteen months.<sup>510</sup> These surveys appear consistent with a prior survey by the Coalition for Patient Vision Care Safety, which found that 87% of contact lens wearers had an eye exam last year.<sup>511</sup>

Some commenters also believe that a quantity limitation would not be difficult to implement when the seller has the prescription because sales could be limited to the amount of lenses necessary for the remaining period of the prescription or based on typical usage.<sup>512</sup> However, it would be impractical for sellers to determine whether the

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<sup>508</sup> 1-800 CONTACTS (NPRM Comment #3898) (stating that for a monthly contact lens the standard package size is six months, which is the minimum quantity available).

<sup>509</sup> NPRM, 81 FR at 88549.

<sup>510</sup> 1-800 CONTACTS (NPRM Comment #3898).

<sup>511</sup> NPRM, 81 FR at 88549 n.308.

<sup>512</sup> Contact Lens Institute (SNPRM Comment #79) (stating that the “health and safety of patients requires limits on the sale of quantities of contact lenses beyond those reasonably required for patient use during the remaining term of a prescription” and urging that a verification request for a prescription that is close to expiration be treated as an alteration because it seeks to dispense excessive quantities of lenses); Coalition for Patient Vision Care Safety (NPRM Comment #3883) (stating that “when the seller has the prescription, no sale should exceed a supply of lenses necessary to last the remaining period of the prescription”); CooperVision, Inc. (NPRM Comment #3841).

quantity of lenses being purchased is necessary or typical because such amounts may not be the same for all consumers. Additionally, as noted in the NPRM, there are legitimate reasons why a consumer may want to purchase a supply of lenses that exceeds the remaining period of the prescription, including having enough lenses until the next scheduled appointment, having replacements for lost or torn lenses, or replacing lenses more frequently.<sup>513</sup> Additionally, quantity limitations could encourage some consumers to stretch out their lens supply by wearing them longer than recommended, which is a well-documented health issue that outweighs the potential harm of patients purchasing a quantity of lenses that exceeds what is strictly anticipated by the remaining length of the prescription.<sup>514</sup> Although it is possible that patients could purchase large quantities of lenses by presenting their prescription to multiple sellers, the Commission does not have evidence about the extent of such practice.<sup>515</sup> Finally, when verification is used, a prescriber can determine whether the quantity ordered is excessive, and, if it is, inform the seller within the eight-business-hour period that the request is inaccurate and specify the appropriate amount of lenses.<sup>516</sup> In conclusion, the Commission declines to modify the Rule to limit the quantity of lenses that consumers can purchase.

## **X. Expiration of Contact Lens Prescriptions**

Section 315.6(a) of the Rule requires that a prescription expire on the date specified by the law of the state in which the prescription was written, if that date is one

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<sup>513</sup> NPRM, 81 FR at 88549; 1-800 CONTACTS (NPRM Comment #3898).

<sup>514</sup> NPRM, 81 FR at 88549. *See also* 1-800 CONTACTS (NPRM Comment #3898) (citing survey data showing that 65% of participants tended to wear their last pair of contact lenses longer than when they have a supply of lenses).

<sup>515</sup> NPRM, 81 FR at 88550.

<sup>516</sup> 16 CFR 315.5(d); Contact Lens Rule, 69 FR at 40501; NPRM, 81 FR at 88550 n.313.

year or more after the issue date of the prescription.<sup>517</sup> The Rule also provides that a prescription shall not expire less than one year after the issue date of the prescription, unless the prescriber specifies a shorter period that is “based on the medical judgment of the prescriber with respect to the ocular health of the patient” and documents the reasoning for the shorter expiration period in the patient’s medical record.<sup>518</sup>

The NPRM addressed comments requesting that the Commission set a longer minimum length for prescriptions, prohibit expirations on certain prescriptions, or leave prescription length to the sole discretion of the provider.<sup>519</sup> However, because the Rule’s provisions closely track the Act, which sets a minimum expiration date “to prevent prescribers from selecting a short expiration date . . . that unduly limits the ability of consumers to purchase contact lenses” and because the Commission concluded that, in drafting the Act, Congress intended to defer to state law except where such law establishes a period of less than one year, the Commission stated that the current framework is appropriate and declined to make changes.<sup>520</sup> The NPRM also addressed prescriber reports of patients obtaining contact lenses through sellers, especially online sellers, with expired contact lens prescriptions.<sup>521</sup> Commenters requested a Rule change or greater enforcement of the Rule to deal with this problem.<sup>522</sup> However, finding that the Rule sufficiently prohibited the use of expired prescriptions, the Commission declines to amend the Rule.<sup>523</sup>

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<sup>517</sup> 16 CFR 315.6(a)(1).

<sup>518</sup> 16 CFR 315.6(a)(2)-(3); 16 CFR 315.6(b)(1).

<sup>519</sup> NPRM, 81 FR at 88546.

<sup>520</sup> *Id.*; *see also* 15 U.S.C. 7604.

<sup>521</sup> NPRM, 81 FR at 88546-47.

<sup>522</sup> *Id.*

<sup>523</sup> *Id.* at 88547.

### A. Length of Contact Lens Prescriptions

Following the NPRM's discussion of expiration length, the Commission received additional comments that favored making prescriptions valid for more than one year.<sup>524</sup> Some commenters advocated for such change because they believed that prescriptions rarely change<sup>525</sup> or that consumers would save money if they needed to obtain exams less often.<sup>526</sup> Other commenters expressed concern that shorter prescription expirations may have the undesirable result of encouraging consumers to wear contacts for longer than recommended<sup>527</sup> or that there should not be a standard minimum expiration in the Rule due to variations in patient needs.<sup>528</sup>

However, some manufacturer and prescriber organizations favored maintaining the Rule's current expiration provisions. Johnson & Johnson Vision Care stated that the current Rule "ensures that patients continue to receive the vital professional oversight to decrease avoidable risks and increases patient access to the latest technologies to best meet their vision care needs."<sup>529</sup> Likewise, the AOA and the Contact Lens Institute supported the Commission maintaining the Rule's current prescription length provisions.<sup>530</sup>

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<sup>524</sup> Radcliffe (WS Comment #2); Williams (WS Comment #1036); Yenovkian (WS Comment #1362); Yuen (NPRM Comment #1854); Susswein (NPRM Comment #3759).

<sup>525</sup> Radcliffe (WS Comment #2); Williams (WS Comment #1036).

<sup>526</sup> Williams (WS Comment #1036); Yuen (NPRM Comment #1854).

<sup>527</sup> Berenguer (WS Comment #111).

<sup>528</sup> Moss (WS Comment #837).

<sup>529</sup> Johnson & Johnson Vision Care, Inc. (NPRM Comment #4327). Peter Menziuso, President of JJVCI, also echoed this sentiment at the workshop, stating that the company feels strongly about maintaining the one-year expiration to assure patients are seeing their prescriber regularly and prioritizing health. *See* CLR Panel IV Tr., *supra* note 121, at 16.

<sup>530</sup> Contact Lens Institute (SNPRM Comment #79); American Optometric Association (NPRM Comment #3830).

After reviewing the comments, the Commission again declines to modify or remove the Rule’s prescription length provisions. The current Rule closely tracks the Act, which Congress mandated, and already contains provisions that allow for prescriptions longer than one year, dependent upon state law, and shorter than one year, when those are appropriate based on the medical judgment of the prescriber, ensuring flexibility.<sup>531</sup> The Commission does not find the record adequately supports lengthening the Rule’s prescription expiration provisions. Therefore, the Commission declines to alter the Rule’s provisions relating to prescription length.

#### **B. Sales Using Expired Contact Lens Prescriptions**

After the NPRM, commenters again raised the issue of sellers selling contact lenses past the prescription expiration dates,<sup>532</sup> and some argued that additional regulation is needed.<sup>533</sup> The Rule already makes clear that expired prescriptions are invalid and

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<sup>531</sup> 16 CFR 315.6(a)(2)-(3); 16 CFR 315.6(b)(1).

<sup>532</sup> *See, e.g.*, Hanian (SNPRM Comment #27); Pirozzolo (SNPRM Comment #33); Wilkes (SNPRM Comment #86); AOA (SNPRM Comment #96); Parikh (SNPRM Comment #152); Fuller (WS Comment #531); McBride (WS Comment #630); Swindell (WS Comment #682); Hamilton (WS Comment #781); Caywood (WS Comment #788); Matus (WS Comment #1534); Malaski (WS Comment #3160); DiGirolamo (NPRM Comment #23); Endry (NPRM Comment #29); Ross (NPRM Comment #48); Hanen-Smith (NPRM Comment #154); Weisz (NPRM Comment #963); Helwig (NPRM Comment #2349); Simpson (NPRM Comment #2896); Holle (NPRM Comment #3214); Gordon (NPRM Comment #3544); Reinstein (NPRM Comment #3560); Sheffer (NPRM Comment #3577).

<sup>533</sup> Kepley (SNPRM Comment #76); Radford (NPRM Comment #59); Rodriguez (NPRM Comment #3896) (“I was disappointed to learn that the FTC will not, under its existing authority, seek to more-fully address the many unscrupulous business practices of online contact lens sellers that have been putting the health and safety of patients at risk for more than a decade. Expired contact lens prescriptions are regularly processed and filled by these online business.”); Huang (NPRM Comment #2203); Avila (NPRM Comment #52); Hanen-Smith (NPRM Comment #154); Letter from Senator Heidi Heitkamp to Acting Chairwoman Maureen Ohlhausen (Jan. 5, 2018); Letter from Congressman Jeff Denham et al. to Chairman Joseph Simons (July 27, 2018).

prohibits sales with such prescriptions.<sup>534</sup> If a consumer presents the seller with an expired prescription, the seller cannot use it as the basis for the sale. Not only is the seller unable to base a sale on that expired prescription, but as the Commission clarified in the NPRM, a seller may not use an expired prescription as the basis for a verification request.<sup>535</sup> If, however, a seller is presented with a prescription that lacks an expiration date,<sup>536</sup> and that seller does not have knowledge as to whether the prescription is expired, the seller must verify the prescription with the prescriber prior to dispensing lenses. In this instance, the seller may rely on the prescriber to inform the seller if the prescription is expired.<sup>537</sup>

CooperVision requested that the Commission require that sellers, when not in possession of an unexpired prescription, ask consumers if their prescriptions have expired.<sup>538</sup> In the NPRM, the Commission addressed a similar request by AOA to require sellers to include the expiration and issue dates, both required elements of a prescription, in verification requests.<sup>539</sup> According to the AOA, this requirement would incentivize sellers to make sure patients know their prescription expiration date. However, as explained in the NPRM, the seller would not necessarily have the expiration or issue dates, and neither would the patient.<sup>540</sup> A better source for this information is the

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<sup>534</sup> 16 CFR 315.5(d).

<sup>535</sup> NPRM, 81 FR at 88546-47.

<sup>536</sup> 16 CFR 315.2.

<sup>537</sup> NPRM, 81 FR at 88547.

<sup>538</sup> CooperVision, Inc. (SNPRM Comment #130).

<sup>539</sup> NPRM, 81 FR at 88547 (citing AOA Comment #644).

<sup>540</sup> NPRM, 81 FR at 88547.

prescriber, who has the ability to invalidate a prescription request because it is expired.<sup>541</sup>

For this reason, the Commission will not implement CooperVision’s proposal.

Additionally, a number of prescriber organizations expressed concerns that consumers are able to buy lenses on expired prescriptions because of passive verification.<sup>542</sup>

Further, to lessen the chances of the sale of lenses after the expiration of a prescription, some commenters requested that the Commission require that prescriptions be presented at the time of the sale of lenses.<sup>543</sup> As stated in Section V, Congress mandated passive verification, and requiring prescription presentation would be inconsistent with Congress’s intent. The Final Rule also includes several changes to automated verification calls that will improve passive verification by allowing prescribers to better identify requests based on expired prescriptions.<sup>544</sup>

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<sup>541</sup> As explained in the Alteration section, Section VI, *supra*, if a seller wishes to avail itself of the exception to alteration, it may use an expired prescription as an indication of manufacturer or brand if the minimum criteria discussed in that Section are met, and the seller obtains additional information, from the consumer or the prescriber, that the consumer has a current prescription for that brand. In so doing, the seller obtains a basis for the verification request other than the expired prescription.

<sup>542</sup> Contact Lens Institute (SNPRM Comment #79) (“Indeed, CLI remains concerned about the contribution of passive verification via robocalls to filling expired or invalid prescriptions . . .”); American Society of Cataract and Refractive Surgery (SNPRM Comment #127) (“Significant concerns with patient safety, as the current eight-hour validation window allows inaccurate, falsified, and expired contact lens prescriptions to be filled. Subsequently, patients’ ocular health is put at risk because of a restricted validation period.”); American Society of Cataract and Refractive Surgery (NPRM Comment #3820) (“Many of our members practice in solo or small practices that often do not have the resources to respond to verification requests within the eight-hour time frame. This rule allows a seller to fill a prescription that is inaccurate, expired, or falsified simply because the prescriber has been unable to respond within eight hours. As a result, patients suffer serious eye injuries by wearing ill-fitted contacts.”); Massachusetts Society of Eye Physicians and Surgeons (NPRM Comment #4270).

<sup>543</sup> Sanders (SNPRM Comment #61); Wisniewski (NPRM Comment #1769); Hanian (NPRM Comment #153).

<sup>544</sup> *See* Section III, *supra*.

Finally, commenters again requested that the Commission bring enforcement actions against sellers that sell lenses after the expiration of the prescription.<sup>545</sup> As stated in the NPRM, if the Commission receives credible evidence that sellers are selling contact lenses when they have actual knowledge that the prescriptions are expired (either because they were presented with a copy of an expired prescription or received a response from a prescriber within the time frame specified in the Rule telling the seller that the prescription is expired), the Commission will take appropriate steps to investigate the allegations.<sup>546</sup>

## **XI. Paperwork Reduction Act**

The existing Rule contains recordkeeping and disclosure requirements that constitute “collection[s] of information” 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.*<sup>547</sup> On May 28, 2019, the Commission issued a SNPRM proposing amendments that would contain new information collection requirements subject to OMB review and approval. Specifically, the SNPRM estimated an additional recordkeeping burden for prescribers resulting from the proposed Rule

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<sup>545</sup> Cooper Vision, Inc. (SNPRM Comment #130); Stout (WS Comment #450); Stolicker (NPRM Comment #10); Osetek (NPRM Comment #22); Bass (NPRM Comment #55); Coalition for Patient Vision Care Safety (NPRM Comment #3883); Letter from Congressman David Roe to Chairman Joseph Simons (Nov. 29, 2018).

<sup>546</sup> NPRM, 81 FR at 88547.

<sup>547</sup> On October 2, 2019, the Commission requested permission from OMB to continue these pre-existing information collections, which were estimated to be 2,104,050 annual hours of burden (which were derived by adding 1,045,650 disclosure hours for contact lens prescribers to 1,058,400 recordkeeping hours for contact lens sellers). See 84 FR 51162 (Sept. 27, 2019); Agency Information Collection Activities; Submission for OMB. On December 9, 2019, OMB approved the Rule’s existing information collection requirements through December 31, 2022. OMB Control No. 3804-0127. See 84 FR 51162 (Sept. 27, 2019); Agency Information Collection Activities; Submission for OMB Review; Comment Request.

modifications to 597,917 hours (85,417 hours regarding signatures + 512,500 hours regarding their retention) and the associated estimated annual labor cost burden of \$13,244,727.<sup>548</sup> On the same date, the Commission also submitted a request to OMB seeking approval for the new information collections associated with the proposed rulemaking. On September 20, 2019, the OMB directed the Commission to examine public comments relating to the proposed rulemaking and describe any public comments received regarding the collection, as well as why the Commission did or did not incorporate the commenter's recommendation.<sup>549</sup> Below, the Commission describes and discusses the amendments to the Final Rule, the public comments received relating to the collection of information burden associated with the SNPRM, and the Commission's ultimate determination of the burden generated by the final amendments.

The Commission has made a number of modifications to the Rule that contain recordkeeping requirements that are collections of information as defined by 5 CFR 1320.3(c). First, the Rule has been modified to require that prescribers either: (A) obtain from patients, and maintain for a period of not less than three years, a signed confirmation of prescription release on a separate stand-alone document; (B) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's prescription; (C) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's contact lens fitting sales receipt; or (D) provide each patient with a copy of the

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<sup>548</sup> See 84 FR at 24693-94 (May 28, 2019); Supplemental notice of proposed rulemaking; request for public comment.

<sup>549</sup> OMB Control No. 3804-0127, ICR Reference No. 201910-3084-001, Notice of Office of Management and Budget Action (Sept. 10, 2019).

prescription via online portal, electronic mail, or text message, and for three years retain evidence that such prescription was sent, received, or, if provided via an online-patient portal, made accessible, downloadable, and printable by the patient.<sup>550</sup> For prescribers who choose to offer an electronic method of prescription delivery, the Final Rule requires that such prescribers identify the specific method or methods to be used, and maintain records or evidence of affirmative consent by patients to such digital delivery for three years.<sup>551</sup> For instances where a consumer refuses to sign the confirmation or accept digital delivery of their prescription, the Final Rule directs the prescriber to note the refusal and preserve this record as evidence of compliance.<sup>552</sup> None of these new requirements, however, would apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses.<sup>553</sup>

Additional modifications to the Rule that constitute collections of information as defined by 5 CFR 1320.3(c) require that sellers who use calls containing automated verification messages: (1) record the entire call; (2) commence the call by identifying it as a request for prescription verification; (3) provide the information required by § 315.5(b) in a slow and deliberate manner and at a reasonably understandable volume; and (4) give the prescriber the option to repeat the information.<sup>554</sup> The call recordings must be preserved for at least three years.<sup>555</sup>

The Commission hereby provides PRA burden estimates, analysis, and discussion for the requirements to collect patient signatures as confirmation of prescription release

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<sup>550</sup> 16 CFR 315.3(c)(1).

<sup>551</sup> 16 CFR 315.2.

<sup>552</sup> 16 CFR 315.3(c)(1)(iii).

<sup>553</sup> 16 CFR 315.3(c)(3).

<sup>554</sup> 16 CFR 315.5(d).

<sup>555</sup> 16 CFR 315.5(h)(4).

and as consent to electronic prescription delivery; and the requirement to record automated verification messages; and associated recordkeeping obligations.

**A. Confirmation of Prescription Release and Affirmative Consent to Digital Delivery of a Prescription**

**1. SNPRM Burden Estimate for the Confirmation of Prescription Release**

In its SNPRM, the Commission put forth estimates for the additional burden on individual prescribers' offices to generate and present to patients the confirmations of prescription release, and to collect and maintain the confirmations of prescription release for a period of not less than three years.<sup>556</sup> As set out in the PRA section's introductory paragraph above, the Commission previously calculated this burden to be 597,917 hours (85,417 hours for prescribers to collect patient signatures and 512,500 hours for prescribers' office staff to store them).<sup>557</sup> Based on average hourly wage rates, the Commission calculated the aggregate labor cost burden (totaling prescribers and prescribers' office staff) at \$13,244,727.<sup>558</sup> The Commission noted, however, that arguably, the overall burden of the Rule—including verification costs previously approved by the Office of Management and Budget<sup>559</sup>—could be lower (or not increase) given the proposed modification's potential offsetting effects of more patients being in possession of their prescriptions and consequently fewer verifications.<sup>560</sup>

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<sup>556</sup> SNPRM, 84 FR at 24692.

<sup>557</sup> *Id.* at 24693.

<sup>558</sup> *Id.* at 24694. This estimate was based on a mean hourly wage of \$57.26 for optometrists and \$16.30 for office clerks. Economic News Release, U.S. Dep't of Labor, Bureau of Labor Statistics, Table 1. National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2017.

<sup>559</sup> *See* note 549, *supra*.

<sup>560</sup> SNPRM, 84 FR at 24693-94.

The Commission requested comment on the accuracy of the FTC’s burden estimates, including whether the methodology and assumptions used are valid (such as whether prescribers or office staff are more likely to collect patient signatures and retain associated recordkeeping), and a quantification of the reduction in verifications resulting from the confirmation of prescription proposal.<sup>561</sup>

## **2. Comments Regarding the SNPRM Estimate for the Confirmation of Prescription Release Requirement**

In response to the Commission’s SNPRM proposal, several commenters reiterated that obtaining and storing the Confirmations of Prescription Release would create “onerous” administrative and financial burdens, but most commenters did not supply financial estimates for this burden.<sup>562</sup> The AOA, which had previously estimated the cost of the NPRM’s signed-acknowledgment proposal to be as high as \$18,795 per optometrist,<sup>563</sup> did not submit a new burden estimate for the Confirmation of Prescription Release proposal, but did opine that the increased flexibility of the new proposal would not reduce the overall burden on prescribers.<sup>564</sup> One commenter estimated that it would cost his practice \$10,000 per year in “paperwork, storage, and time spent by secretaries

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<sup>561</sup> *Id.*

<sup>562</sup> *See* Section II.C.7, *supra*.

<sup>563</sup> American Optometric Association (SNPRM Comment #3830). As noted in note 247, *supra*, the Commission explained in the SNPRM that it could not accord this estimate significant weight because it was based not on the cost of the proposed Signed Acknowledgment but on the overall cost of government regulations (including those already in place), and because the survey had numerous methodological limitations. SNPRM, 84 FR at 24677.

<sup>564</sup> American Optometric Association (SNPRM Comment #96). A few SNPRM commenters reiterated the AOA’s \$18,000 estimate (which the Commission previously determined it could not rely on, for reasons explained in the SNPRM), 84 FR at 24677, but did not provide additional information or empirical support for this figure. Koerber (SNPRM Comment #110); American Society of Cataract and Refractive Surgery (SNPRM Comment #127).

handling paperwork,” but did not provide details about his practice (the number of patients and prescribers, for instance) or how the estimate was derived, and what the cost amounted to on a per-patient or per-prescription basis.<sup>565</sup> Another commenter, Dr. Thomas Steinemann, wrote, “I dispute the FTC contention that each documentation will only take ‘one minute.’ Additional documentation can actually take several minutes when there are discrepancies in verification.”<sup>566</sup> Dr. Steinemann commented that according to his office manager, the “additional steps of verification and documentation” would add 10 minutes of administrative time per patient.<sup>567</sup> The comment, however, does not articulate how the Confirmation of Prescription Release requirement can create discrepancies in verification, or what “additional steps of verification” Dr. Steinemann or his office manager are referring to. The Confirmation of Prescription Release requirement does not directly impact the requirement that prescribers verify prescriptions upon request, other than to potentially make such requests less common if more patients have possession of their prescriptions and can present them to sellers when ordering.

In contrast to those critical of the burden and the Commission’s SNPRM PRA analysis, other commenters contended that the burden of the new requirement would be minimal or offset by a reduced burden in other respects of the Rule.<sup>568</sup> One commenter, the ITIF, asserted that evidence that the new requirement would increase prescriber costs “appears to be significantly overstated,” and noted that storing confirmation signatures in paper takes up “very little room and cost,” and, if stored electronically, storage costs are

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<sup>565</sup> Pierce (SNPRM Comment #17).

<sup>566</sup> Steinemann (SNPRM Comment #65); Steinemann (SNPRM Comment #138).

<sup>567</sup> *Id.*

<sup>568</sup> *See* Section II.C.7, *supra*.

“essentially zero.”<sup>569</sup> The ITIF also stated allowing prescribers to deliver prescriptions digitally would reduce the “already small” burden on prescribers of the confirmation of release requirement, and at the same time reduce the number of verification calls from third party lens sellers, thus further reducing the overall burden on both sellers and prescribers.<sup>570</sup>

Another commenter, the National Taxpayers Union (“NTU”), felt the SNPRM burden-estimates were “plausible,” and noted that the FTC’s estimates were based on underlying assumptions that may be overly cautious, and thus lead to overcounting.<sup>571</sup> In particular, the NTU noted that the Commission, in calculating the SNPRM’s PRA burden: (1) assumed that only optometrists would obtain patient signatures, when, in fact, support staff—who are paid less per hour—are permitted to do so; (2) provided sample confirmation language so prescribers wouldn’t have to formulate their own; (3) assumed that every provider would spend a minute per confirmation even though states already impose recordkeeping requirements, and electronic storage might take seconds; and (4) did not account for potentially offsetting reductions in burden hours for eye care providers due to reduced time and effort spent responding to verification requests (since

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<sup>569</sup> Information Technology & Innovation Foundation (SNPRM Comment #103).

<sup>570</sup> *Id.* See also National Association of Optometrists and Opticians (SNPRM Comment #129) (stating that with more practitioners moving to practice management systems and electronic health records, digital delivery of contact lens prescriptions is a “very feasible” option for many prescribers, which will further reduce the burden of the confirmation requirement).

<sup>571</sup> National Taxpayers Union (SNPRM Comment #149).

more patients would have possession of their prescriptions and be able to present them to third-party contact lens sellers).<sup>572</sup>

Likewise, 1-800 CONTACTS submitted a new analysis from Stanford Health Research Professor Laurence Baker that called the Commission's burden analysis "conservative," and estimated that a reduction in verification requests by 13-15% would be sufficient to offset all of the costs of the confirmation requirement.<sup>573</sup>

None of the SNPRM commenters offered detailed suggestions for reducing the burden resulting from the Confirmation of Prescription Release proposal, other than to suggest that the Commission withdraw its proposal completely or choose a substantially different alternative, such as signage or public education.<sup>574</sup> For reasons discussed in Section II.C.6., *supra*, the Commission does not believe such alternatives would effectively serve the purpose of the Rule.

### **3. Estimated Additional Burden Hours for the Confirmation of Prescription Release Requirement**

Commission staff estimates the PRA burden of the Confirmation of Prescription Release requirement based on comments received and its long-standing knowledge and experience with the eye care industry.<sup>575</sup> Staff continues to believe there will be an additional burden on individual prescribers' offices to satisfy the confirmations of

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<sup>572</sup> *Id.* See also National Association of Optometrists and Opticians (SNPRM Comment #129) (stating that with more patients in possession of their prescriptions, there would be fewer orders relying on the verification process).

<sup>573</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>574</sup> See Section II.C.6, *supra*.

<sup>575</sup> See Section I.B., *supra*, discussing the Commission's three decades of experience with the optical goods industry.

prescription release requirements, but that this burden will be relatively small in the context of the overall market for contact lenses and examinations.<sup>576</sup>

The number of contact lens wearers in the United States is currently estimated to be approximately 45 million.<sup>577</sup> Therefore, assuming an annual contact lens exam for each contact lens wearer, the Confirmation of Prescription Release requirement would require that 45 million people either read and sign a Confirmation of Prescription Release or agree to receive their prescription electronically.

Nothing in the comments to the SNPRM alters the Commission's belief that generating and presenting the Confirmation of Prescription Release will not require significant time or effort. The comments describing the burden as crippling and onerous do not contain empirical facts or data regarding the amount of time and cost of the Commission's proposal, and some estimates appear overstated.

The Commission continues to believe that creating the Confirmation of Prescription Release should not be difficult to implement since the requirement is flexible in that it allows any one of several different modalities and delivery methods, including adding the confirmation to existing documentation that prescribers routinely provide (sales receipts) or are already required to provide (prescriptions) to patients. The

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<sup>576</sup> One survey estimated that the U.S. contact lens market totaled approximately \$5,012,800,000 (not counting examination revenue) in 2017. "Vision Markets See Continued Growth in 2017, VisionWatch Says," Vision Monday, March 20, 2018, <http://www.visionmonday.com/business/research-and-stats/article/vision-markets-see-continued-growth-in-2017-visionwatch-says/>. See also note 609 and accompanying text, *infra*.

<sup>577</sup> Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, <https://www.cdc.gov/contactlenses/fast-facts.html>. This is an updated figure that represents an increase of four million wearers since the NPRM and SNPRM estimates were prepared.

requirement is also flexible in that it does not prescribe other details such as the precise content or language of the patient confirmation, but merely requires that, if provided to the patient pursuant to options specified in § 315.3(c)(1)(i)(A), (B), and (C), the confirmation from the patient must be in writing. At the same time, it is not required that prescribers spend time formulating their own content for the confirmation, since the Rule provides draft language that prescribers are free to use, should they so desire.

Furthermore, the confirmation requirement is flexible enough to cover situations where a contact lens fitting is completed remotely, since a prescriber can readily satisfy the confirmation and prescription-release requirements by various methods, including email, text, or uploading the prescription to a patient portal, so long as the patient consents to such delivery.

The four options for a prescriber to confirm a prescription release to a patient are set out in § 315.3(c)(1)(i)(A), (B), (C), and (D). The requirement in options (A), (B), and (C) to provide the patient with a Confirmation of Prescription Release statement are not disclosures constituting an information collection under the PRA because the FTC, in § 315.3(c)(1)(ii), has supplied the prescriber with draft language the prescriber can use to satisfy this requirement.<sup>578</sup> As noted above, however, the requirement in (A), (B), and (C) to collect a patient's signature on the Confirmation of Prescription Release and preserve it constitutes an information collection as defined by OMB regulations that implement the PRA. Nonetheless, the Commission believes it will require minimal time for a patient to read the confirmation and provide a signature. The Commission

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<sup>578</sup> “The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within” the definition of “collection of information.” 5 CFR 1320.3(c)(2).

estimated in the SNPRM that it would take patients ten seconds to read the one-sentence Confirmation of Prescription Release and provide a signature,<sup>579</sup> and the Commission believes that ten seconds remains an appropriate estimate.

The fourth option, § 315.3(c)(1)(i)(D), does not, in and of itself, constitute an information collection under the PRA, since no new information that would not otherwise be provided under the Rule is provided to or requested from the patient.<sup>580</sup> Excluding that option from consideration, and assuming the remaining three options are exercised with equal frequency, 75% of approximately 45 million annual prescription releases will entail reading and signing a confirmation statement. Thus, assuming ten seconds for each release, prescribers and their office staff would devote 93,750 hours, cumulatively (75% × 45 million prescriptions yearly × 10 seconds each) to obtaining patient signatures as confirmations of prescription release.<sup>581</sup>

Maintaining those signed confirmations for a period of not less than three years should also not impose substantial new burdens on individual prescribers and office staff. The majority of states already require that optometrists keep records of eye examinations

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<sup>579</sup> SNPRM, 84 FR at 24693. This estimate was based on responses to a consumer survey regarding how long it would take consumers to read the Signed Acknowledgment, and a prior PRA estimate for consumers to complete a similar signed acknowledgment.

<sup>580</sup> In order to utilize § 315.3(c)(1)(i)(D), however, a prescriber must obtain and maintain records or evidence of affirmative consent by patients to electronic delivery of their prescriptions. 16 CFR 315.2. The burden to do so is included in the recordkeeping burden calculation of this PRA Section.

<sup>581</sup> Section 315.3(c)(1)(iii) also requires that in the event that a patient declines to sign a confirmation requested under paragraphs (c)(1)(i)(A), (B), or (C), the prescriber must note the patient's refusal on the document and sign it. However, the Commission has no reason to believe that such notation should take any longer than for the patient to read and sign the document, so the Commission will maintain its calculation as if all confirmations requested under (c)(1)(i)(A), (B), or (C) require the same amount of time.

for at least three years,<sup>582</sup> and thus many prescribers who opt to include the confirmation of prescription release on the prescription itself would be preserving that document, regardless. Similarly, most prescribers already retain customer sales receipts for financial accounting and recordkeeping purposes, and thus prescribers who opt to include the confirmation of prescription release on the sales receipt also could be retaining that document, regardless. Moreover, storing a one-page document per patient per year should not require more than a few seconds, and an inconsequential, or *de minimis*, amount of record space. Some prescribers might also present the Confirmation of Prescription Release in electronic form, enabling patients to sign a computer screen or tablet directly and have their confirmation immediately stored as an electronic document. For other prescribers, the new recordkeeping requirement would likely require that office staff either preserve the confirmation in paper format, or electronically scan the signed confirmation and save it as an electronic document. For prescribers who preserve the confirmation electronically by scanning it, Commission staff estimates that saving such a document would consume approximately one minute of staff time. Commission staff does not possess detailed information on the percentage of prescribers' offices that currently use and maintain paper forms, electronic forms, or that scan paper files and maintain them electronically. Thus, for purposes of this PRA analysis, Commission staff will assume that *all* prescriber offices who opt for § 315.3(c)(1)(i) (A), (B), or (C) require a full minute per confirmation for recordkeeping arising from the modifications.

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<sup>582</sup> 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).

Excluding from PRA consideration the fourth option, § 315.3(c)(1)(i)(D), as there is no signature to obtain or retain, and assuming that prescribers elect the other options three-fourths or 75% of the time, the recordkeeping burden for all prescribers to scan and save such confirmations would amount to 562,500 hours (75% × 45 million prescriptions yearly × one minute for scanning and storing) per year.

As noted previously, the fourth option for satisfying the Confirmation of Prescription Release requirement does not necessitate that prescribers obtain or maintain a record of the patient's signature confirming receipt of her prescription. However, as explained in § 315.2, under the Rule's now-modified definition of *Provide to the patient a copy*, in order to avail themselves of the fourth option, prescribers must obtain and maintain records or evidence of the patients' affirmative consent to electronic delivery for three years. In order to remain as cautious as possible in estimating the burden, the Commission will use the assumption that consumers sign such consents for electronic delivery pursuant to § 315.3(c)(1)(i)(D) for one quarter of the 45 million prescriptions released per year,<sup>583</sup> and that this task would take the same amount of time as to obtain and maintain a signature of the patient's Confirmation of Prescription Release. Thus, the Commission will allot 218,750 hours<sup>584</sup> for the time required for prescribers to obtain affirmative consents and maintain records of same.

Therefore, the estimated incremental PRA recordkeeping burden for prescribers and their staff resulting from the Confirmation of Prescription Release modifications to the Rule amounts to 906,250 total hours ((93,750 and 31,250 hours, respectively, to

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<sup>583</sup> 11,250,000 (45 million prescriptions × 25%).

<sup>584</sup> 31,250 hours (11,250,000 prescriptions yearly × 10 seconds) for obtaining the signature plus 187,500 hours (11,250,000 affirmative consents × one minute) for storing such records.

obtain signatures confirming release and consenting to electronic delivery) plus (562,500 and 218,750 hours, respectively, to maintain such records for three years)).

As some commenters noted, the overall burden of the Rule—particularly verification costs previously approved by the Office of Management and Budget<sup>585</sup>—could lessen (or not increase by as much as the incremental burden from the proposed Rule modifications), given potentially offsetting effects presented by the Commission’s Rule modifications.<sup>586</sup> With more patients in possession of their prescriptions (due to increased prescription release), and a greater ability to present them to sellers (due to the modification requiring sellers to provide a method for patients to present prescriptions) fewer time-consuming verifications would be necessary.<sup>587</sup>

Based on new projections from 1-800 CONTACTS<sup>588</sup> and a previous analysis by the Commission,<sup>589</sup> a decrease of between 13%-23% in verifications could be sufficient to offset the entire cost of the Confirmation of Prescription Release requirement. In the SNPRM, however, the Commission noted that these estimates rely on a number of assumptions, not all of which are confirmed as accurate.<sup>590</sup> Furthermore, neither 1-800

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<sup>585</sup> See note 549, *supra*.

<sup>586</sup> See Information Technology & Innovation Foundation (SNPRM Comment #103); 1-800 CONTACTS (SNPRM Comment #135); National Taxpayers Union (SNPRM Comment #149).

<sup>587</sup> *Id.*

<sup>588</sup> 1-800 CONTACTS (SNPRM Comment #135) (estimating that a reduction of 13%-15% in verifications would offset the estimated costs of the proposal).

<sup>589</sup> SNPRM, 84 FR at 24693-94.

<sup>590</sup> *Id.* at 24678. The calculation also does not take into account any of the benefit to consumers from having their prescriptions and being able to choose from among competing sellers; the savings consumers might achieve by purchasing lower-priced lenses; the improvements to health and safety due to a reduction in errors associated with invalid prescriptions currently verified through passive verification; and the Commission’s ability to assess and verify compliance with the Rule.

CONTACTS, nor any other commenter, provided empirical data or projections as to how much the number of verifications will decline due to the Rule modifications. The Commission continues to lack this data, and thus cannot predict whether the verification decrease—should it occur—would be sufficient to offset any or all of the burden. Therefore, the Commission will not make an adjustment for offsetting effects and benefits at this time.

For this specific reason, and the various cautious assumptions described above, the Commission's estimate of 906,250 total hours for prescribers and their staff resulting from the Confirmation of Prescription Release requirement may well overstate the burden of the modification. Furthermore, the actual burden should be even lower because none of the Confirmation of Prescription Release requirements apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses. The Commission requested but did not receive comment on the percentage of prescribers who might be exempt, and does not currently possess sufficient information to determine what percentage of prescribers do not have a financial interest in the sale of contact lenses. The Commission thus has not reduced the estimated PRA burden accordingly at this time.

#### **4. Estimated Total Labor Cost Burden for the Confirmation of Prescription Release Modification**

Commission staff derives labor costs by applying appropriate hourly-cost figures to the burden hours described above. The task to obtain patient confirmations and consent to electronic delivery could theoretically be performed by medical professionals (*e.g.*, optometrists, ophthalmologists) or their support staff (*e.g.*, dispensing opticians, medical technicians, office clerks). In the SNPRM, the Commission requested comment as to whether prescribers or office staff are more likely to collect patient signatures and

retain associated recordkeeping, but did not receive significant guidance on this. Therefore, staff will continue to assume that optometrists will perform the task of collecting patient signatures, and staff will perform the labor pertaining to printing, scanning, and storing of documents, even though this may lead to some overcounting of the burden.

According to the Bureau of Labor Statistics, salaried optometrists earn an average wage of \$57.68 per hour, and general office clerks earn an average wage of \$16.92 per hour.<sup>591</sup> Using the aforementioned estimate of 125,000 total prescriber labor hours for obtaining patient signatures, the resultant aggregate labor costs to obtain patient signatures is \$7,210,000 (125,000 hours × \$57.68).

As previously noted, Commission staff assumes that office clerks will typically perform the labor pertaining to the printing, scanning and storing of prescription release confirmations. Applying a mean hourly wage for office clerks of \$16.92 per hour to the aforementioned estimate of 781,250 hours, cumulative labor costs for those tasks would total \$13,218,750.

Therefore, combining the aggregate labor costs for both prescribers and office staff to obtain signed patient confirmations and consent to electronic delivery and preserve the associated records, the Commission estimates the total labor burden of the Confirmation of Prescription Release modification to be \$20,428,750. This represents an increase from the SNPRM's estimated burden for the Confirmation of Prescription Release proposal due to a relatively large increase in the number of contact lens wearers

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<sup>591</sup> Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics – May 2018, <https://www.bls.gov/news.release/ocwage.t01.htm>.

now estimated by the Centers for Disease Control,<sup>592</sup> increases in the estimated wages of optometrists and office staff by the Bureau of Labor Statistics,<sup>593</sup> and the additional Rule modification requiring prescribers to collect and preserve patients' affirmative consent to electronic delivery of their prescriptions.

## **5. Capital and Other Non-Labor Costs for the Confirmation of Prescription Release Requirement**

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

### **B. Recording of Automated Telephone Messages**

As noted above, the Commission has further modified the Rule to require that sellers who use automated verification messages record the calls and preserve the recordings for three years. In the SNPRM, the Commission staff did not put forth a specific burden estimate for this requirement, but rather sought comments to help inform such estimated burden, to the extent applicable.<sup>594</sup>

The Commission received a few comments stating that the requirement presented a burden for sellers.<sup>595</sup> 1-800 CONTACTS, for instance, commented that the requirement to store the recorded calls would impose a costly new burden while providing relatively

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<sup>592</sup> Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, <https://www.cdc.gov/contactlenses/fast-facts.html>.

<sup>593</sup> Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics — May 2018, <https://www.bls.gov/news.release/ocwage.t01.htm>.

<sup>594</sup> SNPRM, 84 FR at 24694.

<sup>595</sup> See Sections III.B., C. and D, *supra*.

few associated benefits.<sup>596</sup> Consumer Reports essentially reiterated this view.<sup>597</sup> None of the commenters, however, provided data or cost figures that would help inform the Commission's estimated burden.

The Commission does not believe that requiring sellers who use automated telephone messages for verification to record the calls and preserve the recordings will create a substantial burden. The requirement will not require additional labor time for sellers, since the verification calls will be for the same duration that they are now (the length of time required to submit the information required for verification under § 315.5 (b)). However, the new requirement will likely require capital and other non-labor costs to record the calls and store them electronically. But sellers who utilize automated telephone messages for verification are already availing themselves of sophisticated communication technology, and thus should not find it daunting to implement technology to record such calls. Meanwhile the growth of digital recording technology, and the capital investment required for recording equipment and record storage, is rapidly declining and has been for some time.<sup>598</sup> A phone service provider used by at least one online contact lens seller, for example, advertises that it charges a quarter of one cent (\$.0025) for each minute recorded, plus a storage fee of \$.0005-per-month for each minute of recorded storage over 10,000.<sup>599</sup> In other words, assuming each verification call requires three minutes of recording, the first 3333 verification calls recorded and

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<sup>596</sup> 1-800 CONTACTS (SNPRM Comment #135).

<sup>597</sup> Consumer Reports (SNPRM Comment #133).

<sup>598</sup> See Final Rule, Telemarketing Sales Rule, 68 FR 4622 (Jan. 29, 2003) (discussing the cost for recording calls, and determining it was not a significant obstacle for telemarketers).

<sup>599</sup> Twilio Support, <https://support.twilio.com/hc/en-us/articles/223132527-How-much-does-it-cost-to-record-a-call->.

stored would cost \$25 (three-fourths of one cent per call),<sup>600</sup> and each additional verification call would cost approximately six cents apiece to record and store for three years.<sup>601</sup> Other phone service providers surveyed advertise call-recording options such as \$4.99 per gigabyte (about 5000 minutes) of recorded calls (about 4/10<sup>th</sup> of a cent per verification call),<sup>602</sup> and 1000 minutes of call recording for \$14.95 (approximately 4.5 cents per verification call).<sup>603</sup> Some services also advertise unlimited call-recording plans ranging anywhere from \$20-70 a month, depending on how many lines, and how much storage is required.<sup>604</sup> The costs of these services would vary depending on what other options are selected, how long storage is required, and the size of the order, among other things, and the Commission does not vouch for the sufficiency of any of these services. Rather, the Commission mentions these advertised promotions to demonstrate that the cost of recording calls does not appear to be burdensome. Moreover, the Commission believes, as stated in Section III, *supra*, that any incremental costs to sellers for recording calls is outweighed by the benefit to consumers and prescribers from curtailing invalid verification calls. For purposes of calculating the PRA burden, however, the Commission will estimate that each three-minute verification call costs five cents to record.

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<sup>600</sup>  $(10,000 \text{ minutes} \times \$0.0025) \div 3333 \text{ three-minute calls} = \$0.0075 \text{ per call.}$

<sup>601</sup> *Id.* For each additional three-minute verification call, it would cost three-quarters of a cent to record and .15 of a cent per month to store the recording (5.4 cents for 36 months), for a total of 6.15 cents per call.

<sup>602</sup> <https://getvoip.com/blog/2017/11/16/call-recording/>; *see also* <https://jive.com/features/call-recording> (estimating that one gigabyte typically stores about 5,000 minutes of recorded calls).

<sup>603</sup> <https://www.phone.com/pricing-all/>.

<sup>604</sup> <https://www.avoxi.com/blog/best-call-recording-service/>.

According to recent survey data, approximately 36% of contact lens purchases are from a source other than the prescriber.<sup>605</sup> Assuming that each of the 45 million contact lens wearers in the U.S. makes one purchase per year, this would mean that approximately 16,200,000 contact lens purchases (45 million x 36%) are made annually from sellers other than the prescriber. Based on prior discussions with industry, approximately 73% of sales by non-prescriber sellers require verification, meaning that approximately 11,826,000 purchases would require verification calls, faxes, or emails (16,200,000 × 73%). The Commission does not possess information as to the percentage of verifications completed by telephone versus fax or email. Thus for purposes of this analysis, the Commission will assume that all verifications are performed via telephone. Furthermore, the Commission does not have information as to the percentage of telephone verifications that are automated as opposed to live calls, and thus will assume that all telephone verifications are automated calls and subject to the new call-recording requirement.

Based on the aforementioned assumptions, the Commission estimates that the requirement to record automated telephone messages will require recording 11,826,000 calls<sup>606</sup> at an annual cost to third-party sellers, in the aggregate, of \$591,300 (11,826,000 × \$.05).

### **C. Total Burden for the Modifications to the Rule**

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<sup>605</sup> Jason J. Nichols & Deborah Fisher, “2018 Annual Report,” Contact Lens Spectrum, Jan. 1, 2019, <https://www.clspectrum.com/issues/2019/january-2019>; VisionWatch, Contact Lenses, September 2019.

<sup>606</sup> In some instances, sellers may have to call more than once to verify an order. In those instances, however, only the recording of the successful verification would need be preserved.

Combining the marginal cost of the Rule modifications for both sellers and prescribers, the Commission estimates that the amendments will impose an additional burden of \$21,020,050 (\$20,428,750 for prescribers + \$591,300 for third-party sellers). Adding these estimated costs to the OMB's already approved existing cost burden (\$84,548,448) results in a total PRA burden from the Rule of \$105,568,498. While not insubstantial, this represents just two percent of the overall \$5,012,800,000 contact lens market in the United States.<sup>607</sup> Moreover, as noted previously, the estimated burden is calculated using several cautious assumptions that may overstate the actual cost; in all likelihood, the actual burden will be significantly less.

## **XII. Regulatory Flexibility Act**

The Regulatory Flexibility Act ("RFA")<sup>608</sup> requires that the Commission provide an Initial Regulatory Flexibility Analysis ("IRFA") with a Proposed Rule, and a Final Regulatory Flexibility Analysis ("FRFA") with the Final Rule, unless the Commission certifies that the Rule will not have a significant economic impact on a substantial number of small entities.<sup>609</sup> The purpose of the regulatory flexibility analysis is to ensure that the agency considers the impact on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities.

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<sup>607</sup> "Vision Markets See Continued Growth in 2017, VisionWatch Says," Vision Monday, March 20, 2018, <http://www.visionmonday.com/business/research-and-stats/article/vision-markets-see-continued-growth-in-2017-visionwatch-says/>. *See also*, Steve Kodey, US Optical Market Eyewear Overview, 4, [https://www.ftc.gov/sites/default/files/filefield\\_paths/steve\\_kodey\\_ppt\\_presentation.pdf](https://www.ftc.gov/sites/default/files/filefield_paths/steve_kodey_ppt_presentation.pdf).

<sup>608</sup> 5 U.S.C. 601-612.

<sup>609</sup> 5 U.S.C. 603-605.

Although the Commission believed that the amendments it proposed would not have a significant economic impact on small entities, it included an IRFA in the SNPRM and solicited public comment.<sup>610</sup> In this section, the Commission discusses the SNPRM comments that addressed the IRFA,<sup>611</sup> as appropriate, below. The Final Rule is similar to the rule proposed in the SNPRM. The Commission continues to believe that the amendments it is adopting will not have a significant economic impact upon small entities, but has nonetheless deemed it appropriate as a matter of discretion to provide this FRFA.

#### **A. Need for and Objectives of the Rule Amendments**

The Commission's Final Rule incorporates changes affecting prescribers and sellers. These changes were, in large part, previously addressed in the Commission's NPRM and SNPRM, including in the Regulatory Flexibility Act sections. As explained in the earlier IRFAs, the need for and objective of these changes is to clarify and update the Rule in accordance with marketplace practices.

##### **1. Amendments Affecting Prescribers**

The following changes affect prescribers, many of whom are small businesses:

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<sup>610</sup> SNPRM, 84 FR at 24694. The Commission's NPRM also included an IRFA. NPRM, 81 FR at 88588.

<sup>611</sup> Unlike many other commenters who addressed the IRFA indirectly, the AOA commented on the RFA by name stating its belief that the Commission "has not fully considered the regulatory burden under which physicians are already operating" and cited to the Office of Advocacy of the U.S. Small Business Administration's FY 2018 Report on the Regulatory Flexibility Act. According to the AOA, that report stated that "[s]mall businesses have told advocacy stories that exemplify how federal regulations drain small businesses' resources, energy, and in some cases even their desire to stay in business." The AOA indicated that it "has heard the same concerns voiced by doctors of optometry who after years of service in patient care find that the regulatory framework is so intrusive to the doctor patient relationship, [*sic*] that some consider leaving the profession." SNPRM Comment #96.

(1) Should the prescriber so choose, allow for electronic delivery of prescriptions as a means for automatic prescription release when agreed to by the patient (and in such cases, prescribers must retain evidence for not less than three years that the prescription was sent, received, or made accessible, downloadable, and printable). The prescriber must identify to the patient the specific method of electronic delivery and obtain the patient's consent to that method, and maintain the evidence of consent for a period of not less than three years; (2) Request the patient sign a confirmation of receipt of a contact lens prescription (and if a patient declines to sign, must note the patient's refusal on the document and sign it);<sup>612</sup> and (3) Respond to authorized seller requests for copies of a prescription within forty business hours, and require the prescriber to make a notation in the patient's record when responding to such requests.

As explained in detail in this Final Rule notice, the Commission has determined that a Confirmation of Prescription Release is necessary for several reasons, including: (1) multiple consumer surveys consistently show prescriber non-compliance with, and lack of consumer awareness of, the Rule's prescription-release requirement; (2) numerous personal accounts of prescribers' failure to release prescriptions; (3) the persistently high number of verifications, many of which would be unnecessary were consumers in possession of their prescriptions; (4) the regulatory structure of the contact lens market, which requires a consumer to obtain lenses pursuant to a prescription while permitting prescribers to sell what they prescribe, thus creating an incentive for prescribers to withhold prescriptions; and (5) the lack of credible empirical evidence

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<sup>612</sup> This requirement does not apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses.

rebutting or contradicting the evidence that prescribers are not automatically releasing prescriptions, and that consumers are not fully aware of their rights.<sup>613</sup>

The Commission further determined that allowing prescribers to satisfy the automatic prescription release requirement by using an online patient portal or other electronic method in lieu of a paper copy, when the patient gives verifiable affirmative consent, offered benefits for sellers, prescribers, and patients. Patients would be able to access their prescriptions and have electronic copies to send to sellers. With the prescription, a seller would no longer need to submit a verification request, which would also benefit prescribers by reducing the volume of requests.<sup>614</sup>

The Commission is also instituting a forty-business-hour requirement for prescribers to provide additional copies of prescriptions upon request from a patient's agent to ensure that patients or their agents can receive additional copies of their prescription in a timely manner.<sup>615</sup> Additionally, prescribers would be required to note in the patient's file the name of the requester and the date and time the prescription was provided so that the Commission is able to determine, if necessary, whether a prescriber has complied with the Rule.

## **2. Amendments Affecting Sellers**

The amendments affecting sellers require them: (1) when using automated telephone messages to verify prescriptions, to record the entire call (and maintain such recordings for a period of not less than three years), commence the call by identifying it

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<sup>613</sup> See Section II, *supra*.

<sup>614</sup> For a more detailed analysis of the reasons the Commission allowed prescribers to satisfy the automatic release requirement electronically in the Final Rule, see Section II.C.5., *supra*.

<sup>615</sup> See Section VIII, *supra*.

as a request for prescription verification made in accordance with the Contact Lens Rule, deliver the required information in a slow and deliberate manner and at a reasonably understandable volume, and make the required information repeatable at the prescriber's option; (2) to provide consumers with a method that allows consumers to submit their prescriptions to sellers; and (3) to verify only the contact lens brand or manufacturer that appears on the consumer's prescription, unless the consumer has provided an unprescribed contact lens manufacturer or brand in response to a specific request from the seller.

The Commission implemented the additional requirements for automated verification calls to relieve the burden on prescribers and reduce potential health risks to patients from incomplete or incomprehensible automated telephone messages. Specifically, the Commission noted that prescribers must be able to understand automated messages so they can, if necessary, respond to sellers to prevent improper sales. The Commission imposed the amendments in response to concerns about the quality of automated telephone messages, and instated the recording requirement because without such a record, the Commission cannot reliably assess whether a call was compliant, and further, whether the seller has a pattern of placing non-compliant calls (and unlawfully selling after such calls).

The Commission also imposed a requirement for sellers to accept prescription presentation to reduce the number of verifications, reduce errors associated with incorrect verification attempts, and make it more difficult for ill-intentioned sellers to abuse the passive verification framework and take advantage of consumers who might not realize that the seller intends to verify a different lens than the one written on their prescription.

The Commission modified the definition of alteration, and included an exception for sellers that verify only the contact lens brand or manufacturer that consumers indicate is on their prescriptions in order to address the emergence of several businesses that rely exclusively, or almost exclusively, on passive verification as a means to substitute their own brand of contact lenses for those originally prescribed by the patient's prescriber. The Commission continues to receive reports about the proliferation of passive verification abuses. The implementation of the alteration definition, including the exception, should serve as an effective deterrent against sellers that try to game the verification system to sell non-prescribed contact lenses.<sup>616</sup>

**B. Significant Issues Raised by Public Comments in Response to the IRFA, Including Any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration, and the Agency's Response, Including Any Changes Made in the Final Rule Amendments**

The Commission did not receive any comments from the Small Business Administration on this Rule Review. The Commission did receive comments from various interested parties in response to the SNPRM, and it discusses them below.

**1. Amendments Affecting Prescribers**

As discussed in detail in this notice, the Commission, in the SNPRM, determined that the Rule needs to contain some form of patient confirmation requirement, but the Commission made changes to its prior signed-acknowledgment proposal (put forth in the NPRM) in an effort to reduce the burden associated with, and address other criticisms surrounding, the proposal. These changes included: (1) adding an option for prescribers to satisfy the confirmation requirement by releasing the prescription electronically under

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<sup>616</sup> The reasons for this Final Rule amendment are more fully discussed in Section VI, *supra*.

certain conditions; (2) excluding from the requirement eye care prescribers who have no direct or indirect financial interest in the sale of contact lenses; and (3) allowing prescribers to craft their own wording of the signed confirmation, while providing sample confirmation language that prescribers can use at their discretion.<sup>617</sup> In response to the SNPRM proposal, the Commission received a number of comments, mostly from prescribers, criticizing, and detailing the burden of, and other issues associated with complying with, the Commission's Confirmation of Prescription Release requirement.<sup>618</sup>

Other SNPRM commenters provided new views or concerns about the NPRM's proposal to require that prescribers respond to requests from patients or their agent for an additional copy of a prescription within forty business hours. Some commenters felt that the Commission should not impose a time period for prescribers to respond to requests from patients or their agents for an additional copy of a prescription. Other commenters recommended that the Commission require prescribers to respond to such requests within a shorter period of time. The Commission has determined that a defined time period is necessary, and that its SNPRM proposal of forty business hours should be sufficient to ensure prescribers comply within a reasonable amount of time, while at the same time limit the additional burden on them to do so.<sup>619</sup>

## **2. Amendments Affecting Sellers**

In response to the SNPRM's proposal to require that each verification call: commence by identifying it as a request for prescription verification made in accordance

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<sup>617</sup> In the Final Rule, for instances where a patient refuses to sign the confirmation, the Commission directs the prescriber to note the refusal and preserve this record as evidence of compliance.

<sup>618</sup> See Section II, *supra*.

<sup>619</sup> These commenters' concerns and the Commission's response to such concerns are addressed more fully in Section VIII, *supra*.

with the Contact Lens Rule; deliver the required information in a slow and deliberate manner and at a reasonably understandable volume; and make the required information repeatable at the prescriber's option, the Commission did not receive any comments suggesting that this resulted in a burden. Some commenters did raise objections, however, to the Commission's recording requirement, as discussed in detail in Section III.C., *supra*. For the reasons discussed in that Section and reiterated in A.2. of this Section, the Commission determined to retain the recording requirement.

The Commission did not receive any comments opposing the SNPRM's proposal requiring that sellers provide a method of, and a disclosure of the method of, prescription presentation. The Commission did receive a comment, however, suggesting that the Commission require that the method to present prescriptions be in close proximity to the option to provide the parameters of the contact lens for verification. Although the Commission did not impose that requirement, it took that comment into account in determining that, to maximize the potential benefit from the amendment, the seller must provide and disclose the method for the patient to present the seller with a copy of the patient's prescription prior to requesting a prescriber's contact lens prescription. In addition, the Commission, in response to comments addressing the issue, provided more guidance on the methods that sellers need to use (*i.e.*, the method by which the order is taken or email, text or file upload).

The Commission also received comments on the SNPRM's proposed modification defining alteration, and providing an exception to alteration for sellers that verify only the brand or manufacturer that consumers indicate is on their prescription. Some commenters felt the modification was unnecessary, and that other Rule changes

were adequate to curb the practices of substitution to non-prescribed brands through use of the verification system. As addressed in Section VI.B., *supra*, the Commission has determined that there are benefits to retaining this modification. In response to comments, however, the Commission provided additional guidance on the acceptable methods for obtaining brand and manufacturer information.

**C. Description and Estimate of the Number of Small Entities to Which the Amendments Will Apply or Explanation Why No Estimate Is Available**

Prescribers of contact lenses are affected by the amendments concerning the option for electronic delivery of prescriptions as a means for automatic prescription release, Confirmation of Prescription Release, and the imposition of a forty-business-hour time frame for responding to authorized requests for additional copies of prescriptions. There are approximately 43,000 optometrists and 16,700 ophthalmologists in the United States,<sup>620</sup> though not all optometrists and ophthalmologists would be affected by the amendments since some do not prescribe contact lenses. Some prescribers who prescribe contact lenses also would not be affected by the Confirmation of Prescription Release requirement if they do not have a direct or indirect interest in the sale of contact lenses. Of the contact lens prescribers who are affected by the modifications, the Commission—based on its knowledge of the eye-care industry—believes that many fall into the category of small entities (*e.g.*, offices of optometrists with less than \$7.5 million in average annual receipts).<sup>621</sup> Determining a precise estimate of the number of small entities covered by the Rule’s prescription-release requirements is not readily feasible,

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<sup>620</sup> See note 269, *supra*.

<sup>621</sup> 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](https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf).

however, because most prescribers' offices are private entities that do not release the underlying revenue information necessary to make this determination.<sup>622</sup> The Commission sought comment in its SNPRM regarding the estimated number or nature of such small business entities, if any, for which the proposed amendments would have a significant impact, and did not receive commenter guidance in return.

Non-prescriber sellers of contact lenses are affected by the amendments concerning the additional requirements for using an automated telephone verification message, requirements to accept prescription presentation, and requirements to verify only the contact lens brand or manufacturer that consumers indicate is on their prescriptions.<sup>623</sup> Based on its knowledge of the industry, staff believes that the number of these entities that likely qualify as small businesses (less than \$22 million in average annual receipts) is not likely to be substantial.<sup>624</sup>

**D. Description of the Projected Reporting, Recordkeeping and Other Compliance Requirements of the Amendments, Including an Estimate of the Classes of Small Entities That Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record**

**1. Amendments Affecting Prescribers**

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<sup>622</sup> 5 U.S.C. 601(6).

<sup>623</sup> Most prescribers who sell lenses do so after fitting the patient with the prescribed lens, and thus do not rely on prescription verification. The amendments affecting sellers pertain to verification or prescription presentation and do not pertain to these sales. As a result, the Commission does not consider prescribers in its estimated burden for the proposals affecting sellers.

<sup>624</sup> See U.S. Small Business Admin., "Table of Small Business Size Standards Matched to North American Industry Classification System Codes" (Aug. 19, 2019), [https://www.ecfr.gov/cgi-bin/text-idx?SID=b919ec8f32159d9edaaa36a7eaf6b695&mc=true&node=pt13.1.121&rgn=div5#se13.1.121\\_1201](https://www.ecfr.gov/cgi-bin/text-idx?SID=b919ec8f32159d9edaaa36a7eaf6b695&mc=true&node=pt13.1.121&rgn=div5#se13.1.121_1201).

The Confirmation of Prescription Release amendment requires that prescribers with a direct or indirect interest in the sale of contact lenses request that patients sign, and maintain for a period of not less than three years, either (A) a statement confirming receipt of the contact lens prescription; (B) a prescriber-retained copy of a contact lens prescription that contains a statement confirming receipt of the contact lens prescription; or (C) a prescriber-retained copy of the receipt for the examination that contains a statement confirming receipt of the contact lens prescription.

As an alternative to (A), (B), and (C), under certain conditions, prescribers can provide a contact lens prescription digitally. In order to avail themselves of this option, prescribers must maintain, for a period of not less than three years, evidence that the prescriptions were sent, received, or made accessible, downloadable and printable. In addition, the prescriber must identify to the patient the specific method or methods of electronic delivery to be used, such as text message, electronic mail, or an online patient portal, obtain the patient's verifiable affirmative consent to receive a digital copy through the identified method or methods, and maintain records or evidence of a patient's affirmative consent for a period of not less than three years.

The small entities potentially covered by these amendments will include all such entities subject to the Rule. The professional skills necessary for compliance with the Rule as modified will include office and administrative support supervisors to create the language and format of the confirmation, and clerical personnel to collect signatures from patients and maintain records, or in the case of digital prescriptions, retain evidence that the prescription was sent, received, or made accessible, downloadable and printable and retain evidence of a patient's affirmative consent. Compliance may include some

minimal training time as well. The Commission has provided language that prescribers can use for the Confirmation of Prescription Release which, should a prescriber elect to use such language, negates the burden of formulating appropriate language. The Commission believes the overall burden imposed on small businesses by these requirements is relatively small, for the reasons described previously in Section II.C.7. of this notice. That section also addresses in detail the comments received, which discuss the burden from this amendment.

The amendment relating to providing a designated agent with an additional copy of a prescription requires that the prescriber respond within forty business hours of receipt of the request, and note in the patient's record the name of the requester and the date and time that the prescription was provided to the requester. The professional skills necessary for compliance with this amendment will include office and administrative support staff to respond to the request within forty business hours. Previously, office and administrative support staff were already required to respond to such requests, just not within a specific time frame. The forty-business-hour time period, in and of itself, should not impose a significant new burden. The office and administrative support staff will also need to make the required notations in the patient's records. As noted, the required notation would be limited to the name of the requester and the date and time the prescription was provided to the requester. Although the Rule does not require that prescribers retain the notations, the Commission expects prescribers would make and retain such notations in the ordinary course of their business and thus believes the proposal would not create much, if any, additional burden.

## **2. Amendments Affecting Sellers**

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

The Commission believes that most small sellers who are covered by the Rule, if any, are unlikely to have undergone or to undergo the expense associated with creating and maintaining an automated telephone system for verification requests.<sup>625</sup> Instead, the Commission believes that small sellers typically comply with the Rule by receiving copies of prescriptions from patients, or making verification requests to prescribers via fax, email, or telephone calls using "live" agents. If a small seller already has an automated system for verification, the Commission does not believe the costs to accommodate the changes would be more than minimal, if any. For a seller who was following the FTC's prior guidance that automated messages be delivered at a volume and cadence that a reasonable person can understand,<sup>626</sup> it already complies with the new proposal that all such messages be at a "reasonably understandable volume" and delivered in a "slow and deliberate manner." Similarly, if not already in compliance, a seller might need to modify its model verification recording to identify at the start that a

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<sup>625</sup> 1-800 CONTACTS also believes this to be the case. *See* 1-800 CONTACTS (SNPRM Comment #135) (stating that the number of sellers that use this particular technology is likely limited).

<sup>626</sup> Prior guidance from the FTC directed sellers to deliver verification messages at a volume and cadence that a reasonable person can understand. *See* note 301, *supra*.

call is being made in accordance with the Contact Lens Rule and to make the required information repeatable at the prescriber's option.

The Commission also has little reason to believe that the new requirement that sellers who use automated messages record such calls and retain them for no less than three years creates a substantial burden for small sellers. The Commission's SNPRM invited comment on the frequency with which small sellers use automated telephone messages for verification and the costs associated with the proposals pertaining to these messages, including whether existing verification systems include the capability to record and the capacity for storage, and the costs associated with recording the calls and maintaining the recordings for no less than three years. The Commission received little guidance in response. 1-800 CONTACTS, a large contact lens seller, stated the proposal to record and store these calls imposes a "costly" burden, but did not detail the costs associated with recording and maintaining the calls. The Commission's own research surrounding such costs for recording phone calls does not support this contention.<sup>627</sup> And as noted above, the number of sellers that employ this technology is limited, and the Commission does not believe that small sellers use or are likely to use automated messages for verification calls.

The new requirement that sellers provide a method, and a clear and prominent disclosure of the method, for the consumer to present the seller with a copy of the patient's prescription also does not impose a large burden on small sellers. A small seller would need to update its website or other consumer interface to inform consumers about the ability to provide the seller with a prescription, or alternatively, if an order occurs via

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<sup>627</sup> See PRA discussion of the cost of recording calls, Section XI.B., *supra*.

telephone or in person, to verbally inform the consumer about the ability to provide the seller with a prescription. The professional skill or time necessary for this task would include personnel with the skills required to update the website or other consumer interface, and the time it takes to make the updates, or if the information is relayed over the phone or in person, the additional time for an employee or agent of the seller to inform a consumer that he or she is able to provide a prescription, and of the method by which a consumer can do so. These proposals may also require training time for staff. The seller would also need to provide a mechanism for a consumer to provide the prescription to the seller. Because a small seller almost certainly already has the capacity to accept prescriptions via an existing electronic system or email account, the Commission believes there is little additional burden of complying with this part of the proposal.

The small seller would also need to maintain prescriptions it receives via patient presentation. The Commission has not received any comments that alter its understanding that such retention does not create more than a minimal burden. Further, by retaining a patient's prescription, a seller is relieved of the burden to verify that prescription or maintain records of verification. As a result, the burden from obtaining and retaining prescriptions likely offsets the burden from making verification requests and storing records of such requests.

Both the FCLCA and the Rule prohibit illegal alteration of a prescription. The modification of the Rule's definition of alteration would clarify what constitutes alteration, and permit sellers to avail themselves of an exception by verifying only the contact lens brand or manufacturer that consumers indicate is on their prescriptions when

asked by the seller. As a result, all non-prescriber sellers that qualify as small businesses would need to request and obtain manufacturer or brand information via website or other consumer interface, telephone, or in person to qualify for the exception. The professional skill or time necessary for this task would include personnel with the skills required to update the website or other consumer interface and the time it takes to make the updates, or if the information is relayed over the phone or in person, the additional time for an employee or agent of the seller to obtain the information. Such employees would also need to be trained on this requirement.

Although there is no associated document retention requirement set forth in the Rule, the Commission is aware that without the evidence that the manufacturer or brand provided on the verification request was the one provided by the customer, the seller would not be able to avail itself of the exception to illegal alteration. As a result, the Commission has considered the associated document retention as a new burden. However, since many contact lens sales by non-prescriber sellers occur online, the burden of such record retention may be minimized by the ability to keep electronic sales records. For sales that occur via telephone or in person, the seller would be required to maintain records of the request made by, and the information supplied by, the consumer. The Commission believes that sellers retain phone-order records in the ordinary course of business and any additional recordkeeping sellers may do to qualify for the exception is likely to be minimal.

**E. Steps Taken to Minimize the Significant Impact, if Any, of the Amendments, Including Why Any Significant Alternatives Were Not Adopted**

**1. Steps and Alternatives for Amendments Affecting Prescribers**

The Commission considered a number of alternatives to the requirement for prescribers to request the patient sign a confirmation of receipt of a contact lens prescription, including signage and educating consumers about their rights to a contact lens prescription. The Commission determined that signage would be significantly less effective than a Confirmation of Prescription Release requirement. It also determined that consumer education in itself, whether provided via information entry forms, a patients' bill of rights, advertising, or public service announcements, would not have a significant impact on prescriber compliance with automatic prescription release, and would not increase the Commission's ability to monitor and enforce the Rule.<sup>628</sup> In response to commenter concerns about its proposal as outlined in the NPRM and SNPRM, the Commission took steps to minimize the impact of the Confirmation of Prescription Release. First, the Commission included an option for prescribers to satisfy the confirmation by releasing the prescription electronically. While not every prescriber will be able to use this option to deliver a prescription electronically, the Commission is confident that this option will still reduce the burden for many, especially as more prescribers move toward electronic recordkeeping. Second, the Commission excluded from the requirement eye care prescribers who have no direct or indirect financial interest in the sale of contact lenses. By more narrowly targeting the requirement to only those with an incentive to withhold prescriptions, the Commission further reduced the overall burden and avoided unnecessarily impacting prescribers who are unlikely to violate the Rule. Third, the Commission reduced the burden by allowing a significant degree of

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<sup>628</sup> These alternatives and the reasons the Commission found them to be insufficient alternatives to Confirmation of Prescription Release are more fully described in Section II.C.6., *supra*, of this notice.

flexibility in how prescribers comply with the confirmation requirement. The Final Rule allows prescribers to craft their own wording for statements confirming receipt of contact lens prescriptions (on a stand-alone statement, on a prescriber-retained copy of a prescription, or on a prescriber-retained copy of an examination receipt), while providing sample language for prescribers to use, should they not wish to formulate their own confirmation. This change reduces the possible paperwork burden and limits potential interference with the prescriber-patient relationship.<sup>629</sup>

In considering the amendment requiring prescribers to respond to requests for copies of a prescription within a defined period (forty business hours), the Commission considered, but rejected, the option to simply rely on the expectation that all prescribers would fulfill their responsibilities to their patients. It is the Commission's understanding that prescribers do not always comply, or comply expediently, and therefore believes the time-limit requirement is necessary. In order to minimize the burden on prescribers, however, the Commission rejected commenter requests to make the time limit significantly shorter, such as eight business hours. As for the new requirement that prescribers make a notation in the patient's record when responding to such requests, the Commission declined to shift the recordkeeping burden to the designated agent making a request because, to determine whether a particular prescriber is complying with the Rule, the Commission would need to obtain records from a wide variety of agents.

## **2. Steps and Alternatives for Amendments Affecting Sellers**

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<sup>629</sup> In the Final Rule, for instances where a patient refuses to sign the confirmation, the Commission directs the prescriber to note the refusal and preserve this record as evidence of compliance.

The Commission did not consider specific alternatives to the Final Rule's requirement that sellers, when using automated telephone messages to verify prescriptions, commence the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule, deliver the required information in a slow and deliberate manner and at a reasonably understandable volume, and make the required information repeatable at the prescriber's option.<sup>630</sup> The Commission included these amendments in the Final Rule to relieve the burden on prescribers and reduce potential health risks to patients from incomplete or incomprehensible automated telephone messages. Specifically, the Commission noted that prescribers must be able to understand automated messages so they can, if necessary, respond to sellers to prevent improper sales. Commenters presented additional suggestions to improve call quality, but did not suggest alternatives to commencing the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule, and to make the required information repeatable at the prescriber's option, nor did they express opposition to such requirements.

The Commission considered whether to require sellers to retain a sample recording of the standard script leaving blanks for prescription and patient details instead of recording all calls using automated telephone messages. However, the Commission determined that a script or a sample recording would not reveal whether the required information was transmitted effectively or if, for instance, it was transmitted before a representative or machine answered, after an answering machine cut off, when a

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<sup>630</sup> The requirements that the seller deliver the required information in a slow and deliberate manner and at a reasonably understandable volume have been part of the FTC's prior guidance that the information be delivered at a volume and cadence that a reasonable person can understand.

prescriber's office put the call on hold, or over hold music, in which case the call could not be used as a basis for the sale. In addition, a script or sample recording would not permit the Commission to assess whether a particular call was delivered in a "slow and deliberate manner" and at a "reasonable understandable volume." Without knowing this information, the Commission would be unable to determine conclusively whether any particular verification request was valid. Therefore, the Commission did not adopt this recommendation.

With respect to the requirement that sellers accept prescription presentation, the Commission did not receive any comments opposing this proposal, and thus did not consider alternatives. In response to commenter concerns, however, the Commission determined not to permit sellers to select any method of communication, but opted instead to maximize the benefits from the amendment by requiring the seller to present the prescription through the same medium by which the order is placed, or electronic mail, text message, or file upload.

For verification requests, the Commission expressly defined alteration as occurring when sellers provide prescribers with the name of a manufacturer or brand other than that specified on a patient's prescription. However, the Commission provided an exception such that it would not amount to alteration in instances when sellers verify only the contact lens brand or manufacturer that consumers indicate is on their prescriptions after a seller requests that information. As possible alternatives to these changes, the Commission considered whether it could instead rely on the new requirements that sellers (a) provide a method for prescription presentation and (b) meet quality standards for verification calls, but the Commission determined that those

requirements alone are inadequate to curb the practice of unlawful substitution to non-prescribed brands through abuse of the verification system. Although the Commission has previously stated that a verification request is not valid and does not commence the eight-business-hour verification period if a seller knows or should know that the verification request includes a different brand and manufacturer than that prescribed, the FTC continues to receive reports about the proliferation of passive verification abuses, and sellers “gaming the system” to substitute a different brand or manufacturer.

Furthermore, without the changes to the definition of alteration, sellers may argue that they are technically compliant with the Rule because they submitted verification requests and prescribers had an opportunity to respond to the requests, and may also argue that they did not have knowledge that a consumer did not have a prescription for that manufacturer or brand of lens. The Final Rule amendment will give them a basis of knowledge by requesting that a consumer state the brand or manufacturer of her brand of lens. Additionally, the Commission determined that without the express definition of alteration and the exception thereto, enforcement would not, in and of itself, be adequate to protect consumers, because alteration via abuse of the verification system does not occur with only one bad actor, and because of an increase in companies that appear to alter prescriptions in this way.

Seller 1-800 CONTACTS also commented that the amendment should not refer to “brand” as that language does not appear elsewhere in the Rule. It pointed out that the Rule defines a prescription as including a “material or manufacturer or both” and that the Commission’s inclusion of the reference to brand imposes an additional limit on consumer choice that is not required by the Act. 1-800 CONTACTS requested that the

exception to the Rule be applicable to “providing the prescriber with the name of a manufacturer or material other than that specified by the patient’s prescriber . . . .” The reference to brand in the definition of alteration and in the exception are the only references to brand in the Rule. However, because many, if not most, prescriptions list the manufacturer’s brand, not the manufacturer or material, and very few consumers know the manufacturer or material of contact lens that they wear (typically referring to their lenses by brand name), the Commission declines to follow 1-800 CONTACTS’ recommendation because many consumers would be unable to respond to a seller’s request.

1-800 CONTACTS expressed concern that the Commission’s amendment might interfere with its ability to improve the user experience. It indicated that it sells hundreds of brands of lenses and offers consumers a variety of methods to identify their brand, including drop-down menus, a search box, and filters that display lenses by brand, modality, and other parameters and that some consumers do not enter their brand information on an order form. In response, the Commission, in the Final Rule, removed the language from its earlier proposal that sellers must obtain the information on “an order form.” In comparison, other commenters requested greater specificity or even prohibitions on the acceptable mechanisms for sellers to request and consumers to select their brand. In response, the Commission clarified that, at a minimum, in order for sellers to consider the consumer’s indication of manufacturer or brand as adequate to qualify for the exception, the manufacturer or brand must be: (1) provided in response to a seller’s

request for the manufacturer or brand listed on the consumer’s prescription; and (2) an affirmative statement or selection by the consumer, not a preselected or prefilled entry.<sup>631</sup>

### **XIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated these rule amendments as not a “major rule,” as defined by 5 U.S.C. 804(2).

#### **List of Subjects in 16 CFR Part 315**

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

For the reasons discussed in the preamble, the Federal Trade Commission amends title 16 of the Code of Federal Regulations, part 315, as follows:

#### **PART 315—CONTACT LENS RULE**

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

**Authority:** 15 U.S.C. 7601-7610.

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

#### **§ 315.2 Definitions.**

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*Provide to the patient a copy* means giving a patient a copy of his or her contact lens prescription:

(1) On paper; or

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<sup>631</sup> See Section VI.B., *supra*.

(2) In a digital format that can be accessed, downloaded, and printed by the patient. For a copy provided in a digital format, the prescriber shall identify to the patient the specific method or methods of electronic delivery to be used, such as text message, electronic mail, or an online patient portal, and obtain the patient's verifiable affirmative consent to receive a digital copy through the identified method or methods; and maintain records or evidence of a patient's affirmative consent for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

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

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

3. Amend § 315.3 by:
  - a. Revising paragraphs (a)(1) and (2);
  - b. Adding paragraph (a)(3);
  - c. Revising paragraphs (b)(1) through (3); and
  - d. Adding paragraph (c).

The additions and revisions read as follows:

**§ 315.3 Availability of contact lens prescriptions to patients.**

(a) *In general.* When a prescriber completes a contact lens fitting, the prescriber:

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

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

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

(b) *Limitations.* A prescriber may not:

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

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

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

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

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

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

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

or

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

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

(iii) In the event the patient declines to sign a confirmation requested under paragraph (c)(1)(i)(A), (B), or (C) of this section, the prescriber shall note the patient’s refusal on the document and sign it.

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

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

4. Amend § 315.5 by:
  - a. Redesignating paragraphs (d), (e), (f), and (g) as paragraphs (e), (f), (h), and (i), respectively;
  - b. Adding new paragraph (d);
  - c. Revising newly redesignated paragraph (f);
  - d. Adding new paragraph (g);
  - e. Adding new paragraph (h)(2)(iii);
  - f. Revising newly redesignated paragraph (i).

The additions and revisions read as follows:

**§ 315.5 Prescriber verification.**

\* \* \* \* \*

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

- (1) Record the entire call;
- (2) Commence the call by identifying it as a request for prescription verification made in accordance with the Contact Lens Rule;
- (3) Deliver the information required by paragraph (b) of this section in a slow and deliberate manner and at a reasonably understandable volume; and
- (4) Make the information required by paragraph (b) of this section repeatable at the prescriber's option.

\* \* \* \* \*

(f) *No alteration of prescription.* A seller may not alter a contact lens prescription. In the context of prescription verification, alteration includes, but is not limited to, providing the

prescriber with the name of a manufacturer or brand other than that specified by the patient's prescription, unless such name is provided because the patient entered or orally provided it when asked for the manufacturer or brand listed on the patient's prescription. Notwithstanding the preceding sentences, for private label contact lenses, a seller may substitute for contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(g) *Seller requirement to accept prescription presentation*: A seller shall provide a prominent method, and a clear and prominent disclosure of that method, for the patient to present the seller with a copy of the patient's prescription. Such method and the disclosure shall be provided prior to requesting a prescriber's contact information for verification of the prescription; provided, however, in the case of an order placed by telephone, a seller shall comply by providing a disclosure of the method prior to requesting a prescriber's contact information for verification of the prescription. The method to present the prescription shall be provided through (i) the same medium by which the order is placed, or (ii) electronic mail, text message, or file upload.

(h) \* \* \*

(2) \* \* \*

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

\* \* \* \* \*

(i) *Recordkeeping requirement—Saturday business hours*. A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for a request for a copy of the prescription specified in § 315.3(a)(3) or for verification

specified in paragraph (c)(3) of this section shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

By direction of the Commission.

**April J. Tabor,**

Secretary.

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