Supplemental
Supporting Statement
Amendments to the Contact Lens Rule
16 CFR § 315
(OMB Control # 3084-0127)

(1-2) Necessity for Collecting the Information/Use of the Information

The Federal Trade Commission promulgated the Contact Lens Rule ("Rule") pursuant to the Fairness to Contact Lens Consumers Act ("FCLCA"), Public Law 108-164 (December 6, 2003), which was enacted to enable consumers to purchase contact lenses from the seller of their choice. The Rule became effective on August 2, 2004. As mandated by the FCLCA, the Rule requires contact lens prescribers to provide prescriptions to their patients upon the completion of a contact lens fitting, and provide or verify such prescriptions to authorized third parties, such as contact lens sellers. Sellers may provide contact lenses only in accordance with a valid prescription that is presented directly to the seller or verified with the prescriber.

Section 315.3(a)(1) of the Rule requires a prescriber to provide a copy of the contact lens prescription to the patient after completing a contact lens fitting, regardless of whether it was requested by the patient. Section 315.3(a)(1) of the Rule tracks the language of the Act verbatim.[1] This provision, referred to as automatic prescription release, was intended to empower consumers to comparison shop for contact lenses. However, even though the law and implementing Rule (effective in 2004) already required that prescriptions be provided by the prescribers to patients, there is no readily verifiable enforcement mechanism.

Based on twelve years of experience enforcing the Rule and careful consideration of public comments during the rule review,[2] the Commission determined that compliance with the law's automatic prescription release provision could be substantially improved.[3] The Commission concluded that the potential benefits of increasing the number of patients in possession of their prescriptions were substantial: increased patient flexibility and choice in shopping for lenses; a reduced number of verification requests, which many prescribers find burdensome; a reduced likelihood of errors associated with incomplete or invalid prescriptions, which can jeopardize patient eye health; and a reduction in the number and complications of

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[1] 15 U.S.C. 7601(a)(1).

[2] Contact Lens Rule, Request for Comment, 80 Fed. Reg. 53,272 (September 3, 2015) ("Request for Comment").

[3] In fact, the Commission has received evidence that a majority of consumers—between 56-65% —are not receiving their contact lens prescriptions automatically as required by law, and millions of consumers are not receiving them at all. Supplemental Notice of Proposed Rulemaking, 84 Fed. Reg. 24,664 (May 28, 2019) ("SNPRM").

failed attempts at verification. Increasing prescription-release compliance also would likely spur competition and innovation among contact lens sellers and manufacturers, and reduce attempts by sellers to verify incorrect, expired, and invalid prescriptions, or to verify with the wrong prescriber. The Commission also determined that the cumulative effect of increased automatic-release compliance would thus be lower costs and improved convenience and flexibility for patients, sellers, and prescribers, as well as increased accuracy of prescriptions presented to sellers, thereby reducing potential consumer harm.

In 2016, the Commission proposed to amend the Rule to require that prescribers obtain a signed acknowledgment after releasing a contact lens prescription and maintain each such acknowledgment for a period of not less than three years.[4] Requiring a signed acknowledgment would increase the Commission's ability to assess and verify compliance with the Rule.

In 2019, after a comprehensive review of additional public comments, workshop transcripts, and various empirical surveys and analyses,[5] the Commission proposed a Supplemental Notice of Proposed Rulemaking ("SNPRM") modifying its prior proposal for a signed acknowledgment requirement by instituting a more flexible Confirmation of Prescription Release provision.[6] The modifications to the Rule proposed in the SNPRM required that prescribers either (1) obtain from patients, and maintain for a period of not less than three years, a signed confirmation of prescription release on a separate stand-alone document; (2) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's prescription; (3) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's contact lens fitting sales receipt; or (4) provide each patient with a copy of the prescription via online portal, electronic mail, or text message, and for three years retain evidence that such was sent, received, or, if provided via an online-patient portal, made accessible, downloadable, and printable by the patient.

As discussed in the SNPRM, the Commission believed that this modified proposal would achieve the goals of the original proposal while imposing less of a burden on prescribers. Specifically, the modified proposal would improve compliance with the congressionally-mandated automatic prescription release requirement, and thereby benefit consumers and

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[4] Notice of Proposed Rulemaking, 81 Fed. Reg. 88,526 (Dec. 7, 2016) ("NPRM").

[5] Comments received in response to the NPRM are available at https://www.ftc.gov/policy/public-comments/2016/10/initiative-677. Comments received in connection with the workshop are available at https://www.ftc.gov/news-events/events-calendar/2018/03/contact-lens-rule-evolving-contact-lens-marketplace. *See also* Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 Fed. Reg. 57,889 (Dec. 8, 2017).

[6] See SNPRM (footnote 3).

competition by ensuring that contact lens users have the ability to comparison shop for lenses. Furthermore, the modified proposal would provide much-needed improvements to the Commission's ability to evaluate and enforce compliance with this core provision of the Rule. Also, by allowing prescribers more options and flexibility, the modification would impose even less of an overall burden on prescribers than the prior proposal, which the Commission had determined was relatively minimal.[7]

After reviewing comments to the SNPRM, the Commission determined to retain the Confirmation of Prescription Release requirement in the Final Rule, with a modification to require, for instances when a patient refuses to sign a confirmation, that the prescriber note this refusal and preserve such record as evidence of compliance. Furthermore, in response to issues raised by commenters, the Final Rule also requires that in instances where prescriptions are delivered electronically to consumers, prescribers must identify the specific method or methods of electronic delivery to be used and keep evidence of patients' consent for at least three years, and that sellers who utilize automated telephone verification messages must record such calls and preserve the recordings.

The requirement to collect patient signatures (both for Confirmation of Prescription Release and consent to electronic prescription delivery), and the associated recordkeeping requirements, each constitute an information collection as defined by 5 CFR 1320.3(c), as does the requirement to record automated telephone verification messages. Accordingly, the Commission is providing PRA burden estimates for these amendments to the Rule, as set forth below.

(3) <u>Consideration of Using Improved Technology to Reduce Burden</u>

The Final Rule amendments permit the covered firms to use paper or electronic format to reduce the burden of information collection. Moreover, in its SNPRM, the Commission specifically sought comments on ways to minimize the burden of the Rule's collections of information through the use of information technology.

Consistent with the Government Paperwork Reduction Elimination Act, Pub L. No. 105-227, Title XVII, 112 Stat. 2681-749, nothing in the Rule amendments prescribes that the disclosures be made, records be filed or kept, or signatures be executed, on paper or in any particular format that would preclude the use of electronic methods to comply with the Rule's requirements.

(4) <u>Efforts to Identify Duplication</u>

The new recordkeeping requirements do not duplicate any other information collection requirements imposed by the Commission. To the extent some state laws may already require

[7] NPRM, 81 Fed. Reg. at 88,534, 88,557-58.

prescription release, and/or recordkeeping, similar to that required by the Act, prescribers and sellers likely can comply with both requirements through a single release or record-keeping system, thereby avoiding duplication.

(5) Efforts to Minimize Burden on Small Organizations

The new recordkeeping requirements in the Final Rule are designed to impose the minimum burden on all affected members of the industry, regardless of size. For the most part, the Act itself does not allow the Commission any latitude to treat small businesses differently just because they are small businesses.[8]

While some contact lens prescribers subject to the Rule's requirements are small businesses, staff believes that everything consistent with the requirements of the Rule has been done to minimize the compliance burden. Although the Act requires the Rule to apply to all covered entities irrespective of whether they are small entities, the Commission sought and addressed comments about minimizing impact on small businesses.

(6) Consequences of Conducting the Collection Less Frequently

The new recordkeeping requirements in the Final Rule would require that prescribers and sellers retain the required records for a period of not less than three years. Staff believes that a record retention period shorter than this would hamper the Commission's ability to confirm compliance with the Rule, because the statute of limitations applicable to Commission rule violations is three years.[9]

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The new information collection requirements in the Final Rule are consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2). Under the Rule amendments, covered entities are only required to maintain the records for three years. Instances where records are required to be maintained longer than three years are mandated by individual state laws.[10]

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[8] The Commission's Final Rule exempts businesses that do not have a direct or indirect financial interest in the sale of lenses from the confirmation requirement, but this exemption is not based on the size of the business.

[9] *See* Section 19(d) of the FTC Act, 15 U.S.C. 57b(d).

[10] *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).

(8) Consultation Outside the Agency

On September 3, 2015, the Commission solicited comment on the Contact Lens Rule as part of its periodic review of its rules and guides.[11] As with other regulatory rule reviews, the Commission sought comment on whether there is a continuing need for the Rule as currently promulgated and about the Rule's costs and benefits. The comment period closed on October 26, 2015. The Commission reviewed the 660 comments received in response to the initial request for comments. Virtually all commenters agreed that there is a continuing need for the Rule and that it benefits consumers and competition. The majority of commenters recommended some modifications to the Rule in order to maximize the benefits to consumers and competition, decrease the burden on businesses, protect consumers' eye health, or improve overall compliance with the Rule's existing requirements.

The Commission subsequently published an NPRM on December 7, 2016. The sixty-day comment period closed on January 30, 2017. In its NPRM, 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 that requirement. Accordingly, the NPRM proposed to amend the Rule to require that prescribers request that patients sign an acknowledgement form upon receiving a copy of their contact lens prescription, and maintain each such acknowledgement form for three years.[12] In response to the NPRM, the Commission received over 4,000 additional comments, many from prescribers concerned about the burden of the proposed signed acknowledgment requirement.[13]

In light of the comments received on the NPRM, the Commission determined that it would be beneficial to hold a public workshop on the Contact Lens Rule and the evolving contact lens marketplace to explore issues raised throughout the comment process as well as topics related to the evolution of the contact lens marketplace. On December 8, 2017, the Commission published a Federal Register Notice announcing the March 7, 2018 workshop[14] with a comment period closing on April 6, 2018. The workshop included six panels, covering issues relating to the overall

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[11] 2015 Request for Comment. Comments received in response to this request are available at https://www.ftc.gov/policy/public-comments/2015/09/initiative-621.

[12] The Commission also proposed a technical amendment, to remove the words "private label" from Section 315.5(e) to conform the language of the Rule to that of the FCLCA. In addition to seeking comment on these proposals, the NPRM sought comment on 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.

[13] Comments received in response to the NPRM are available at https://www.ftc.gov/policy/public-comments/2016/10/initiative-677.

[14] Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 Fed. Reg. 57,889 (Dec. 8, 2017).

contact lens marketplace, health and safety, competition, purchasing and verification, the proposed signed acknowledgment and consumer choice, and the future of contact lens prescribing and selling. In response to the Commission's comment request and workshop, the Commission received approximately 3,400 additional comments from a wide range of commenters, including numerous consumers and prescribers, as well as industry associations, state attorneys general, contact lens manufacturers, and retailers.[15]

After a thorough review of comments, workshop transcripts, and various empirical surveys and analyses, the Commission issued a Supplemental Notice of Proposed Rulemaking, as opposed to implementing a Final Rule.[16] In response to the SNPRM, it received approximately 200 unique (and approximately 900 overall) comments.[17] The Commission reviewed those comments and considered the commenter concerns, and now issues a Final Rule containing some modifications from the SNPRM stage. In addition to the modifications detailed above in Specific Instructions #1-2 (**Necessity for Collecting the Information/Use of the Information**), the Final Rule requires that sellers not only make the method of prescription presentation prominent, but also clearly and prominently disclose such method. The method of presentation and the related disclosure must be provided prior to requesting the prescriber's contact information for verification of a prescription. The method offered to present the prescription must be the same medium used to place the order or by electronic mail, text message, or file upload.

(9) Payments and Gifts to Respondents

Not applicable.

(10-11) Assurances of Confidentiality/Matters of a Sensitive Nature

Not applicable. No assurance of confidentiality is necessary because although the Contact Lens Rule requires regulated entities to disclose and/or maintain records, it does not require the submission of any such records to the agency. Thus, to the extent, if any, that the

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[15] Comments received in response to the workshop notice, as well as transcripts of, and materials from, the workshop, are available at https://www.ftc.gov/news-events/events-calendar/2018/03/contact-lens-rule-evolving-contact-lens-marketplace.

[16] In the SNPRM, the Commission modified its previous proposal for a Signed Acknowledgment by instituting a more flexible Confirmation of Prescription Release provision. 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.

[17] Comments received in response to the SNPRM are available at https://www.regulations.gov/docket?D=FTC-2019-0041.

agency may require production of such records for law enforcement purposes in specific proceedings, such production would not constitute an information collection activity within the meaning of the PRA. In any event, in such proceedings, records would be protected by law from mandatory public disclosure.[18]

(12) Estimated Annual Hours Burden and Associated Labor Cost

Estimated Additional Annual Hours Burden: 875,000 total hours (derived from 93,750 and 31,250 hours, respectively, to obtain signatures confirming release and consenting to electronic delivery plus 562,500 and 187,500 hours, respectively, to maintain such records for three years).

Commission staff estimates the PRA burden of the modifications based on its knowledge of the eye-care industry. The staff believes there will be an additional burden on individual prescribers' offices to generate and present to patients the confirmations of prescription release, to collect and maintain the confirmations of prescription release for a period of not less than three years, and, in instances where a patient opts for electronic prescription delivery instead of paper, to collect and preserve patient consents to electronic delivery. The number of contact lens wearers in the United States is currently estimated to be approximately 45 million.[19] Therefore, assuming an annual contact lens exam for each contact lens wearer, every year approximately 45 million people would either read and sign a Confirmation of Prescription Release or consent to receive their prescription electronically.[20]

The Commission believes that generating and presenting the confirmation of prescription release to patients will not require significant time. Creating the confirmation of prescription release should be relatively straightforward for prescribers since the requirement is flexible in that it allows any one of several different modalities and delivery methods to satisfy the requirement, including adding the confirmation to existing documents that prescribers routinely provide (sales receipts) or are already required to provide (prescriptions) to patients. The Commission's 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 in-person, the confirmation from the consumer must be in writing. At the same time, the new amendment does not require that prescribers spend time generating their own content for the confirmation, since the Commission has provided draft language that prescribers are free to use to satisfy the requirement, if they so desire. Furthermore, the requirement is flexible enough to cover situations

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[18] *See, e.g.*, Section 21 of the FTC Act, 15 U.S.C. 57b-2; Exemption 6 of the Freedom of Information Act, 5 U.S.C. 552(b)(6).

[19] Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, https://www.cdc.gov/contactlenses/fast-facts.html.

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

where a contact lens fitting is completed remotely, since a prescriber can readily satisfy the requirement by various methods, including email, text, or uploading the prescription to a patient portal.

The four options for a prescriber to confirm a prescription release to a patient are set out in § 315.3(c) in the Final Rule. The first three options (§ 315.3(c)(1)(i), (ii), and (iii)), which direct a prescriber to provide information to a patient in the form of a confirmation of prescription release, are not disclosures constituting an information collection under the PRA because the FTC has supplied the prescriber with draft language the prescriber can use to satisfy this requirement.[21] However, as noted above, the collection of a patient's signature and the associated recordkeeping required constitutes an information collection as defined by OMB regulations that implement the PRA. Nonetheless, the Commission believes it will require minimal time for a patient to read the confirmation of prescription release and provide a signature. Based on public comments, a consumer survey submitted to the Commission, and estimates by staff, the Commission estimates it will take ten seconds for the consumer to read and provide a signature.

The fourth option, § 315.3(c)(1)(iv), does not constitute an information collection under the PRA, since no new information is provided or requested of the patient. Excluding that from consideration and assuming the remaining three options are exercised with equal frequency, three-fourths or 75% of approximately 45 million annual prescription releases otherwise entail reading and signing a confirmation statement. Thus, 93,750 hours, cumulatively (75% × 45 million prescriptions yearly × ten seconds each) would be devoted to those tasks.[22]

Maintaining the signed confirmations for a period of not less than three years should not impose a substantial new burden on individual prescribers and their office staff. The majority of states already require that optometrists keep records of eye examinations for at least three years,[23] 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

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[21] "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).

[22] The FTC has previously accounted for and retains active OMB clearance regarding its separate PRA burden estimates for prescriber release of prescriptions to patients (as opposed to the instant burden estimate for the time to read and sign a confirmation statement) and seller verification recordkeeping estimated to be 1,045,650 hours for contact lens prescribers and 1,058,400 hours for contact lens sellers. 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.

[23] *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).

already retain customer sales receipts for financial recordkeeping purposes, and thus prescribers who opt to include the confirmation of prescription release on the sales receipt also could be retaining that document, regardless. Moreover, storing a one-page document per patient per year should not require more than a few seconds, and an inconsequential, or *de minimis*, amount of record space. As noted above, some prescribers might present the confirmation of prescription release electronically, and such format would allow the confirmation to be preserved without any additional burden. For other prescribers, the new recordkeeping requirement would likely require that office staff either preserve the confirmation in paper format or electronically scan the signed confirmation and save it as an electronic document. For prescribers who preserve the confirmation electronically, Commission staff estimates that scanning and saving the document would consume approximately one minute. Commission staff do not possess detailed information on the percentage of prescribers' offices that use paper forms, electronic forms, or that scan paper files and maintain them electronically. Thus, for purposes of its PRA analysis, Commission staff conservatively has assumed that *all* prescriber offices require a full minute per confirmation for recordkeeping arising from the new requirements.

Excluding from PRA consideration the fourth option, §315.3(c)(1)(iv), as there is no signature to obtain or retain, and assuming that prescribers elect the remaining options three-fourths or 75% of the time, the recordkeeping burden for prescribers to scan and save such confirmations amounts to 562,500 hours (75% × 45 million prescriptions yearly × one minute) 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 has used the assumption that consumers will sign such consents for electronic delivery pursuant to § 315.3(c)(1)(i)(D) for a full one quarter of the 45 million prescriptions released per year,[24] 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 has allotted 218,750 hours[25] for the time required for prescribers to obtain affirmative consents and maintain records of same.

Therefore, the total estimated incremental PRA recordkeeping burden for prescribers and their staff resulting from the Confirmation of Prescription Release modifications to the Rule amounts to 875,000 total hours ((93,750 and 31,250 hours, respectively, to obtain signatures confirming release and consenting to electronic delivery) plus (562,500 and 187,500 hours,

[24] 11,250,000 (45 million prescriptions × 25%).

[25] 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.

respectively, to maintain such records for three years)).

Arguably, the overall burden of the Rule—including verification costs previously approved by the Office of Management and Budget[26]—could lessen (or not increase by as much as the incremental burden from the Rule modifications), given potentially offsetting effects presented by the modifications. As some commenters have noted, the increased burden from the Confirmation requirement would be lessened or even outweighed by a reduced verification burden, because with more patients in possession of their prescriptions and able to present them to third-party sellers, fewer time-consuming verifications would be necessary.[27] Based on some commenter and Commission projections, a decrease of between 13%-23% in verifications could be sufficient to offset the entire cost of the Confirmation of Prescription Release requirement.[28] These estimates rely on a number of assumptions, however, not all of which are as yet confirmed as accurate.[29] Furthermore, the Commission does not possess empirical data or projections as to how much the number of verifications will decline due to the Rule modifications, 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 has not made an adjustment for offsetting effects and benefits at this time.

The Confirmation of Prescription Release requirement's exemption for prescribers who do not have a direct or indirect financial interest in the sale of contact lenses will also reduce the burden created by the new requirement. The Commission, however, does not currently possess information as to how many prescribers would qualify for the exemption due to a lack of financial interest in the sale of lenses. The Commission therefore has not reduced its PRA burden estimate accordingly.

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[26] The Commission has estimated that prescribers' offices spend five minutes per verification request, based on information provided by the American Optometric Association. Agency Information Collection Activities; Submission for OMB Review, 81 FR 62501 (Sept. 9, 2016). The Commission has also estimated that sellers spend five minutes per verification request, and one minute on recordkeeping in non-verification circumstances (to preserve the prescription when presented by a patient); OMB Control No. 3084-0127.

[27] SNPRM at 24,678 [notes 183-190 and accompanying text].

[28] *See* SNPRM, 84 FR at 24693-94 (analysis of verifications and projection of decrease sufficient to offset burden); 1-800 CONTACTS (SNPRM Comment #135) (estimating that a reduction of 13%-15% in verifications would offset the estimated costs of the proposal).

[29] *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.

Estimated Total Annual Labor Cost Burden: $19,900,000.

Commission staff derives labor costs by applying appropriate hourly cost figures to the burden hours described above. The prescriber task to obtain patient signed acknowledgments theoretically could be performed by medical professionals (e.g., optometrists, ophthalmologists) or support staff (e.g., dispensing opticians, ophthalmic medical technicians). To estimate associated labor costs, staff has conservatively assumed that optometrists would perform the task.[30] Applying a mean hourly wage of $57.68[31] for optometrists to the above-noted estimate of 125,000 hours, resultant aggregate labor costs to obtain patient signatures would be $7,210,000.

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,[32] to the above-noted estimate of 750,000 hours, cumulative labor costs for those tasks would total $12,690,000.

Therefore, combining the aggregate labor costs for both prescribers and office staff to obtain patient signed confirmations and preserve the associated records, the Commission estimates the total labor burden of its rule modifications to be $19,900,000.

(13) <u>Estimated Annual Capital or Other Non-Labor Costs</u>

Estimated Total Annual Capital or Other Non-Labor Cost Burden: $591,300

The recordkeeping requirements detailed above regarding prescribers impose negligible capital or other non-labor costs, as prescribers likely have already the necessary equipment and supplies (e.g., prescription pads, patients' medical charts, scanning devices, recordkeeping storage) to act upon those requirements. However, the Final Rule's new requirement that sellers who use automated verification messages record the calls and preserve the recordings for three years will likely require a minimal amount of 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

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[30] It is not certain that this assumption is well founded. *See* CLR Panel IV Tr., SNPRM at 24,674 [note 126, at 8] (statements of David Cockrell that, in his office, the staff handle all the verification calls). Many prescribers may use office staff to handle verification calls, which would result in a significantly lower burden calculation for prescribers' offices than what the Commission previously calculated. Without more empirical data as to who handles most verification requests, however, the Commission will continue to use the estimate for prescribers, even if it might overstate the actual burden.

[31] Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics – May 2018.

[32] *Id*.

rapidly declining and has been for some time.[33] For purposes of calculating the PRA burden, the Commission has estimated that each three-minute verification call costs five cents to record.[34]

According to recent survey data, approximately 36% of contact lens purchases are from a source other than the prescriber.[35] 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 × 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 its PRA analysis, the Commission has assumed 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 has assumed 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[36] at an annual capital and non-labor cost to third-party sellers, in the aggregate, of $591,300 (11,826,000 × $.05).

(14) Estimated Cost to Federal Government

Staff believes that the cost to the FTC for administering the Rule modifications will be *de minimis*. Accordingly, Commission staff retains the previous estimate of $52,000 per year as the cost to the Government for administering the prior version of the Rule. This estimate is based on the assumption that 15-20% of one Attorney work year, 2.5% of one Economist work year, 15% of one Investigator work year, and 15% of one Paralegal work year will be expended to enforce the Rule's requirements.

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[33] *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).

[34] Despite a request for information, the Commission did not receive any comments providing empirical data or cost figures that would help inform the estimated burden for recording calls. The Commission's estimate, therefore, is based on a relatively small survey of advertised prices for call recording, in which prices varied from a quarter of one cent ($.0025) for each minute recorded to about 4/10th of a cent per verification call, plus additional charges for storage, The costs of these services would vary considerably 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.

[35] 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.

[36] 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.

(15) Program Changes/Adjustments

As detailed above, the Commission estimates that the amendments in the Final Rule will result in an additional 875,000 burden hours, annualized, and cumulative of all affected manufacturers, $19,900,000 in associated labor costs, and $591,300 in capital/non-labor costs. The estimated increase in burden is correlated with Rule modifications creating a verifiable enforcement mechanism to ensure that pre-existing FCLCA and Rule requirements that contact lens prescriptions be provided by the prescribers to patients are complied with.

(16) Plans for Tabulation and Publication

Not applicable. There are no plans to publish for statistical use any information required by the Rule.

(17) Requested Permission Not to Display the Expiration Date for OMB Approval

This is not applicable, since the Commission will display the expiration date of the clearance.

(18) Exceptions to the "Certification for Paperwork Reduction Act Submissions"

Not applicable.