Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 C.F.R. Part 315
(OMB Control # 3084-0127)

The Federal Trade Commission ("FTC" or "Commission") requests approval for a three-year extension of an existing clearance relating to the disclosure and recordkeeping requirements under the Contact Lens Rule ("Rule"), 16 C.F.R. Part 315. There is no change in the instrument collection.

(1) & (2) Necessity for and Use of the Information Collected

The Fairness to Contact Lens Consumers Act (the "Act"), Pub. L. No. 108-164 (December 6, 2003), helps consumers by requiring the release and verification of contact lens prescriptions, among other things. The Act directed the Federal Trade Commission ("FTC" or "Commission") to prescribe rules implementing the Act not later than 180 days after the Act took effect on February 4, 2004.[1] Accordingly, the Commission issued the Contact Lens Rule ("Rule"), 16 C.F.R. Part 315, on July 2, 2004. The Rule was most recently reissued in amended form in 2020.[2] As mandated by the Act, the Rule contains disclosure and recordkeeping requirements applying to prescribers and sellers of contact lenses. The extent to which these requirements are subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35 ("PRA"), is described below.

(a) Disclosures

The Rule requires that contact lens prescribers provide patients with a copy of their contact lens prescriptions upon completion of a contact lens fitting and provide prescriptions to, or verify prescriptions with, third parties authorized to act on behalf of patients. The primary purpose of the prescription release requirement is to enable consumers to purchase their contact lenses from the seller of their choice. Without their prescription, consumers may be forced to purchase lenses from their prescriber. By requiring prescribers to provide prescriptions to their patients, the Act enables consumers to compare prices and modes of delivery among competing sellers, and ultimately purchase their lenses from the seller of their choice. In addition, the Rule, as amended in 2020, now requires that prescribers either: (a) obtain from patients a signed confirmation of prescription release on a separate stand-alone document; (b) obtain from patients a signature on a confirmation of prescription release included on a copy of a patient's prescription; (c) obtain from patients a 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 prescription via online portal, electronic mail, or text message.[3] The primary

[1] 15 U.S.C. § 7607.

[2] Final Rule, Contact Lens Rule, 85 FR 50668 (Aug. 17, 2020).

[3] *Id.*

purpose of the confirmation requirement is to ensure that patients receive their prescriptions, and to enable the Commission to verify that this is occurring. For prescribers who choose to offer an electronic method of prescription delivery, the Rule requires that such prescribers collect affirmative consent from patients to such digital delivery.

(b) Recordkeeping

The Rule also implements recordkeeping requirements imposed by the Act. First, the Act sets a minimum expiration date of one year for contact lens prescriptions, with an exception based on the medical judgment of a prescriber with respect to a patient's eye health. In cases in which a prescriber sets an expiration date shorter than one year, the Rule requires the prescriber to document in the patient's record the medical reasons for the shorter period. The Rule further requires that such records be kept for three years.

Second, the Act provides that a contact lens seller may sell contact lenses only in accordance with a prescription that the seller either (a) has received from the patient or prescriber, or (b) has verified with the prescriber. The Act, and hence the Rule, requires contact lens sellers to maintain records of verification communications with prescribers. The records to be kept depend on the mode of communication – telephone, facsimile, or email. The Rule also requires sellers to keep the prescriptions they receive directly from the patient or prescriber. The Rule requires that sellers keep these records for three years and make them available for inspection by the Commission, but does not otherwise require production of the records.

Third, the Rule requires that contact lens prescribers collect and maintain confirmations of prescription release, or an electronic record showing the prescription was provided electronically, for a period of not less than three years. For prescribers who choose to offer an electronic method of prescription delivery, the Rule requires that such prescribers maintain records or evidence of affirmative consent by patients to such digital delivery for a period of not less than three years.

The required records will allow the Commission to determine compliance with the Rule and provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult to ensure that entities are complying with the Rule's requirements or to prove Rule violations.

(3) <u>Consideration of the Use of Information Technology to Reduce Burden</u>

The Rule contemplates that covered entities may use information technologies in complying with their recordkeeping obligations under the Act. Such technologies may help reduce the burden of information collection imposed by the Act. For example, contact lens sellers who seek to verify prescriptions via facsimile and/or email may use information technology to create and/or retain those records as required by the Rule, and thereby reduce the time it may take to produce and maintain verification requests. Similarly, contact lens prescribers

may present confirmations of prescription release in digital format, and maintain electronic records of patient receipt. In addition, nothing in the Act or Rule prohibits regulated entities from using the least burdensome information technology available. Moreover, in its 2004 Notice of Proposed Rulemaking,[4] and its subsequent proposals to revise the Rule,[5] 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 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) Efforts to Identify Duplication

The Rule's disclosure and recordkeeping requirements do not duplicate any other information collection requirements imposed by the Commission. To the extent some state laws may already require 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 Rule's disclosure and recordkeeping requirements are designed to impose the minimum burden on all affected members of the industry, regardless of size. The Act itself does not allow the Commission any latitude to treat small businesses differently, such as by exempting a particular category of firm or setting forth a lesser standard of compliance for any category of firm.

However, staff believes that the burdens imposed by the Rule on small businesses will be relatively low. Based on staff's knowledge of the eyewear industry, the small businesses affected by the Rule primarily consist of contact lens prescribers in solo or small practices. Their burdens under the Rule primarily entail providing contact lens prescriptions to patients or their agents, providing and preserving patient confirmations of prescription receipt, documenting in exceptional cases the medical reasons for setting a contact lens prescription date of less than one year, and verifying prescriptions for some of their patients who seek to purchase their contact lenses from another seller. The Rule permits some limitation on prescription release and verification.

[4] 69 FR 5440 (Feb. 4, 2004).

[5] *See* e.g., Supplemental Notice of Proposed Rulemaking, 84 FR 24664 (May 28, 2019); Notice of Proposed Rulemaking, 81 FR 88526 (Dec. 7, 2016).

(6) Consequences of Conducting the Collection Less Frequently

Less frequent "collection" would violate the express statutory language of the Fairness to Contact Lens Consumers Act, 15 U.S.C. §§ 7601 *et seq*. Specifically, the Act's requirements that prescribers release contact lens prescriptions to their patients upon completion of a contact lens fitting, and document the medical reasons for setting a contact lens prescription expiration date shorter than one year, do not permit less frequent disclosure.[6] Similarly, the Act's requirement that contact lens sellers retain records of all direct communications involved in obtaining prescription verification does not permit less frequent collection of information.[7]

The Commission's Rule requires that sellers retain the required records for a period of three years. Staff believes that a record retention period shorter than three years would hamper the Commission's ability to verify contact lens prescribers' and sellers' compliance with the Rule, because the statute of limitations applicable to Commission rule violations is three years.[8]

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The collection of information in the Rule is consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2).

(8) Public Comments/Consultation Outside the Agency

On August 14, 2023, the FTC sought public comment on the Rule's information collection requirements and on the associated estimates of PRA burden. 88 FR 55044. The FTC received one comment germane to the issues that the agency sought comment on pursuant to the PRA renewal request. That comment was from the American Optometric Association ("AOA"), an organization representing more than 50,000 optometrists and optometric professionals. In its comment, the AOA contends that the 2020 Rule amendment requiring that prescribers obtain a signed confirmation-of-prescription has created a greater compliance burden than previously projected by the FTC.[9]

As noted above, the 2020 Rule amendments require that upon completion of a contact lens fitting, the prescriber must request that a patient sign a statement confirming receipt of their contact lens prescription (unless a digital copy of a prescription is provided to the patient via

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[6] *See* 15 U.S.C. §§ 7601, 7604.

[7] *See* 15 U.S.C. § 7603(b).

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

[9] American Optometric Association (PRA Comment #7) *available at* https://www.regulations.gov/comment/FTC-2023-0049-0007.

portal, email, or text message).[10] The prescriber may, but is not required to, use the one-sentence confirmation 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, and such statement can be on a stand-alone document or included on a contact lens prescription or exam receipt.[11]

In approving the Rule amendments in 2020, the FTC estimated that the time required to collect a patient signature and confirmation of prescription takes ten seconds on average.[12] The FTC's estimate of ten seconds was derived from two sources. The first was a similar previously-approved patient-acknowledgment-requirement under HIPAA, the Health Insurance Portability and Accountability Act, which requires, among other things, that each health provider obtain a patient signature confirming receipt of that provider's HIPAA Notice of Privacy Practices.[13] The HIPAA acknowledgment requirement,[14] which has been in effect for more than 20 years, faced objections prior to implementation over concerns it would be burdensome and costly to implement.[15] The U.S. Department of Health and Human Services rejected those contentions and determined that its signed acknowledgment would require just ten seconds to hand out and ten seconds to obtain a patient's signature.[16]

The second source for the FTC's estimate of 10 seconds was a consumer survey by the polling firm Survey Sampling International ("SSI") of how long it took consumers to read a proposed two-sentence statement, "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." The survey found that it took consumers,

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[10] 16 C.F.R. 315.3(c). In order to provide digital copies of prescriptions, the prescriber must first obtain a single signed consent-to-electronic-delivery from each patient.

[11] 16 C.F.R. 315.3(c)(ii).

[12] 85 FR 50709.

[13] Standards for Privacy of Individually Identifiable Health Information, 67 FR 53182, 53261 (Aug. 14, 2002) (implementing 45 C.F.R. 164.520(c)(2)(ii)).

[14] 45 C.F.R. 164.520(c)(2)(ii).

[15] Standards for Privacy of Individually Identifiable Health Information, 67 FR 53182, 53240-43 (Aug. 14, 2002) (implementing 45 C.F.R. 164.520(c)(2)(ii)).

[16] *Id*. at 53240-43, 53260-61. HHS also calculated three cents per signed acknowledgment for the cost some doctors might incur for the paper. *Id.* at 53256. Since 2018, HHS has been considering a proposal to eliminate its signed-acknowledgment requirement as no longer necessary to compel providers to distribute Notices of Privacy Practices to patients, but HHS has not determined that the 10-second time estimate for obtaining a patient signature is inaccurate. Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 FR 64302, 64302–03 (2018), *https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf#page=1*.) For a more fulsome discussion about the HHS proposal to eliminate its signed acknowledgment, and why this has little relevance with respect to the Contact Lens Rule, *see* CLR Final Rule, 85 FR 50684-85, footnotes and accompanying text.

on average, twelve seconds to review those two sentences, and 90% of respondents read it in 20 seconds or less.[17] Additionally, 90% of consumers surveyed indicated they understood the proposed acknowledgement statement, and 94% indicated that they had no follow-up questions.[18] The Commission's Final Rule did not include the second sentence of the surveyed confirmation statement, thereby shortening the final confirmation statement by nearly half, with the expected result that it might only take six or seven seconds for consumers to read and comprehend. Based on the survey average of 12 seconds to read the previously-proposed two-sentence statement, and on the approved HHS signed-acknowledgment estimate, the Commission, in its Rule amendments of 2020, estimated ten seconds to read and provide a signature for the Rule's one-sentence confirmation-of-prescription-release statement.[19]

In its new PRA comment, however, the AOA contends that the FTC "significantly underestimated" how long it would take to confirm prescription releases.[20] According to the AOA, a 2023 survey it conducted of some of its member optometrists found that 84.8% indicate it takes 30 seconds or more to obtain the patient's signed confirmation, not counting additional time necessary to address patient questions about the form they are signing, and 69.9% of prescribers said patients "typically" have questions regarding the acknowledgment.[21]

AOA's comment accords with some written and verbal comments provided to the Commission during an ongoing review of the Eyeglass Rule,[22] which includes a proposal to add a similar confirmation-of-prescription-release requirement. The Commission's Eyeglass Rule review has examined, among other things, the burden arising from the existing Contact Lens Rule's confirmation-of-prescription-release requirement, and thus some of the comments received during the Eyeglass Rule review pertain to the Rule burden discussed herein. For

[17] 1-800 CONTACTS (Contact Lens Rule Workshop Comment #3207); Laurence C. Baker, "Analysis of Costs and Benefits of the FTC Proposed Patient Acknowledgment and Recordkeeping Amendment to the Contact Lens Rule," 11 (2017), *https://www.ftc.gov/system/files/summaries/initiatives/677/10192017_meeting_summary_from_mko_for_the_contact_lens_rule_rulemaking_proceeding.pdf* (SSI online survey of 500 respondents). Twelve seconds was the average, the median was 10 seconds.

[18] *Id.* at 18.

[19] 84 FR 24693.

[20] AOA (PRA Comment #7), *supra* note 9.

[21] *Id*. According to AOA, the survey was conducted in-house by its Health Policy Institute and Research Departments, and distributed to member optometrists via AOA's weekly email newsletter with a link and invite to the survey titled "Voice your concerns by Oct. 9: Complying with the FTC Contact Lens Rule." Of members who responded to the AOA's link request, 327 completed the survey.

[22] This is officially the Ophthalmic Practice Rules, 16 C.F.R. Part 456.

instance, at a 2023 FTC workshop on the Eyeglass Rule, [23] panelist Dr. Stephen Montaquila, a Rhode Island optometrist, estimated that it takes his staff four minutes to complete the entire Contact Lens Rule process of printing out a patient's prescription, handing it to the patient, explaining why it needs to be signed, having the patient sign it, making a copy of it, and storing the signed copy as a record.[24] Dr. Montaquila did not break down his estimate by task, so it is unclear how long he estimates it takes for a consumer to simply read and sign the confirmation statement, as opposed to the time it takes for his staff to print out the prescription and confirmation and store the confirmation as a record. As detailed in this submission, the Commission has allowed for one minute for prescribers to print out the prescription, and an additional minute for staff to store the signed confirmation.

In addition, the National Taxpayers Union, an Alexandria, Virginia-based advocacy organization, submitted a comment to the Eyeglass Rule review stating that while it generally supports the confirmation requirement, "[G]iven the various reading speeds of customers who may be elderly or have limited proficiency in English, the 10 second estimate [used for the Contact Lens Rule's confirmation requirement] could prove low."[25]

Some commenters, however, disagreed that it takes a significant amount of time to obtain a patient's signed confirmation. The National Association of Retail Optical Companies ("NAROC"), a trade association comprised of retail optical companies with co-located eye care services (such as LensCrafters, Costco Optical, and Walmart Vision Center), commented that thousands of optometrists affiliated in co-location with NAROC member companies "regularly comply with [Contact Lens Rule requirements] with little or no added cost or other burden on the eye care practice."[26] According to NAROC representative and Eyeglass Rule Workshop panelist Joseph Neville, "I've personally witnessed a couple of situations where the process for contact lenses seemed very easy. … the Rx was handed over at the front desk by the staff person, and the staff person maybe a bit simplistically said, "We'd like to ask you to sign this receipt for your prescription. We're required to get your signature acknowledging that you've received it." And a couple of people, and again, anecdotes here that I witnessed on this, just said, "Okay, fine,

[23] "A Clear Look at the Eyeglass Rule," Public Workshop (May 18, 2023), transcript *available at* https://www.ftc.gov/news-events/events/2023/05/clear-look-eyeglass-rule [hereinafter ER Workshop Transcript].

[24] Montaquila, ER Workshop Transcript at 23-24.

[25] National Taxpayers Union (ER NPRM Comment #28) *available at* https://www.regulations.gov/comment/FTC-2023-0001-0028. *See also* Prine (ER Workshop Comment #38) (simply stated that having patients sign a receipt of their prescription and then scan that into their chart "took a lot of extra time") *available at* https://www.regulations.gov/comment/FTC-2023-0001-0038; Michaels, ER Workshop Transcript at 9 (stating, "There's a lot of time, effort, discussion around [the confirmation requirement]. I think that is something that is greatly underestimated in terms of how long it takes and how effort it takes to go through that process.").

[26] NAROC (ER NPRM Comment #24) *available at* https://www.regulations.gov/comment/FTC-2023-0001-0024. *See also* Consumer Action (ER NPRM Comment #26) ("we do not believe it is a burden on providers to obtain, document, and retain a consumer's affirmative receipt of their prescription.").

thank you."[27]

Discussion of the Comments and Evidence Regarding the Time Required

In considering how much time it takes to complete the confirmation-of-prescription-release requirement for this Paperwork Reduction Act purpose, the Commission has evaluated the evidence in the record, including the previously-approved HHS estimate for a similar signed-acknowledgment, the comments in response to the PRA request for comment in the 60-Day Federal Register notice and the Contact Lens Rule and Eyeglass Rule rulemakings, and the two surveys mentioned above, one of consumer read-times and the other of prescriber-estimates for staff time.

The Commission finds none of the comments, and neither survey, dispositive in and of itself. The surveys, in particular, are suggestive but not determinative. The SSI survey of consumer read-times on a computer monitor is helpful, but may not take into account elderly patients or those for whom English is not their first language. It also does not take into account the time it takes for prescribers' staff to hand a paper confirmation document to the patient and for the patient to sign it and hand it back. The AOA survey, meanwhile, very likely overestimates the time necessary to obtain a confirmation because of the manner in which the survey solicited its respondents. The prescribers were self-selected in response to an AOA invitation to "Voice your concerns" about complying with the Contact Lens Rule. Because the poll only included prescribers who responded to this invitation, its findings may not be representative of the average prescriber. In fact, it is probable that a large number of those who responded were prescribers who *have* concerns about the patient-confirmation requirement and the time it takes to obtain a confirmation, while prescribers who do not have concerns, or have fewer concerns, did not bother to respond. By framing the survey as an invitation to voice concerns about complying with the Rule, the survey has been transformed from a disinterested information-gathering tool into a motivating call to action. So while it is possible that prescribers who did not respond to the survey also share the concerns raised by survey respondents, that cannot be concluded from the survey.[28]

The Commission also has concerns that some of the time prescribers ascribe to patients reading and signing the confirmation is, in fact, due to non-mandated choices by prescribers with respect to the design of the confirmation statement. As noted above, the Rule merely requires that patients read and sign a simple statement confirming receipt of their prescription, and the Commission allowed that the one-sentence statement, "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting," would

[27] Neville, ER Workshop Transcript at 28-29.

[28] The Commission also notes that while the AOA states that it represents some 50,000 optometric professionals, only 327 members responded to AOA's invitation and completed the survey, which could indicate that most AOA members do not have concerns about complying with the Contact Lens Rule. However, there could be other reasons for the relatively small number of prescribers (in proportion to the total membership) who responded, so the Commission will not draw any inferences from the low response rate.

fully satisfy the requirement. According to the AOA survey, nearly 60% of prescribers use a separate form with a statement confirming receipt (as opposed to obtaining a patient signature on a prescription copy or sales receipt), but the survey did not specify or ask prescribers what confirmation statement they used on their form, making it difficult to determine the true average time it takes to comply with the confirmation-of-prescription-release requirement. Moreover, the AOA has supplied its members with a model template confirmation form that includes four additional paragraphs consisting of "important information to review prior to receiving your contact lens prescription."[29] This information includes various recommendations from the Centers for Disease Control and the Food and Drug Administration about healthy contact lens use (such as "Take out your contacts and call your eye doctor if you have eye pain, discomfort, redness, or blurry vision") as well as five bullet points listing some of the symptoms for an eye infection ("Irritated, red eyes, worsening pain in or around the eyes," etc.).[30] While the document is titled "Contact Lens Prescription Acknowledgment Form," only at the very end is there a statement, "Sign below to acknowledge that you were provided a copy of your contact lens prescription at the completion of your contact lens fitting."

According to Workshop Panelist Dr. Montaquila, the AOA template is a common form used to obtain patient confirmations.[31] If this is indeed the case, the Commission is not surprised that many prescribers report it takes patients 30 seconds or longer to read and sign, nor that patients might have questions, or be confused, as to why they now have to sign and acknowledge not just receipt of their prescription, but that they read these recommendations from the CDC and FDA. The additional information from these two other federal agencies may be useful for patients, but is not required by the Rule, nor considered part of the PRA burden of compliance.

Despite the aforementioned concerns about the reliability of the AOA survey in establishing the time it takes for a patient confirmation, the Commission does not discount the survey altogether, and views it as suggestive, and an additional indication that many prescribers sincerely believe the 10-second estimate does not accurately reflect the time required to obtain a patient's signed confirmation. The Commission has therefore decided to increase the estimated time to obtain a patient confirmation signature (and the time to collect an affirmative consent to electronic delivery, in instances where the prescription is provided digitally rather than in paper) from 10 to 20 seconds. The Commission believes that 20 seconds may better reflect the time required for a patient to not just read a one-sentence confirmation, but also to physically sign and return the document to staff, and for any staff explanation as to why the patient's signature is required. The 20-second estimate may also better align with the original HIPAA estimate, which accorded 10 seconds to hand out the acknowledgment and another ten seconds to obtain a patient's signature and collect the document.[32]

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[29] *See* AOA Contact Lens Rule Compliance Toolkit, sample template, 8, available at https://documents.aoa.org/Documents/CLCS/Contact-Lens-Rule-Compliance-Toolkit.pdf.

[30] *Id*.

[31] Montaquila, ER Workshop transcript at 23.

[32] *See supra* notes 15-16.

Pursuant to OMB regulations, 5 CFR Part 1320, that implement the PRA, 44 U.S.C. 3501 et seq., the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule.

(9) Payments and Gifts to Respondents

Not applicable.

(10) Assurances of Confidentiality

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 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 Paperwork Reduction Act. In any event, in such proceedings, records would be protected by law from mandatory public disclosure.[33]

(11) Matters of a Sensitive Nature

Not applicable. The Contact Lens Rule does not require the disclosure or production of sensitive or confidential information to the Commission. To the extent that confidential information covered by a recordkeeping requirement is collected by the Commission for law enforcement purposes, the confidentiality provisions of Section 21 of the FTC Act, 15 U.S.C. 57b-2, will apply.

(12) Estimated Annual Hours and Labor Cost Burden

Estimated annual hours burden: 3,104,050 hours.

This figure is derived by adding disclosure and recordkeeping-hours for contact lens prescribers to recordkeeping hours for contact lens sellers.

1. Prescribers and Their Office Staff

The Rule requires prescribers to collect information and make disclosures in three ways. Upon completing a contact lens fitting, the Rule requires that prescribers (1) provide a copy of

[33] *See, e.g.*, Section 21 of the FTC Act, 15 U.S.C. 57b-2; Exemption 7(A) of the Freedom of Information Act, 5 U.S.C. 552(b)(7)(A).

the contact lens prescription to the patient,[34] (2) collect a patient's signature on either a Confirmation of Prescription Release or a consent-to-electronic-prescription-release and preserve such record, and (3) as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription. Prescribers can verify a prescription either by responding affirmatively to a request for verification, or by not responding at all, in which case the prescription will be "passively verified" after eight business hours. Prescribers are also required to correct an incorrect prescription submitted by a seller, and notify a seller if the prescription submitted for verification is expired or otherwise invalid. Staff believes that the burden of complying with these requirements is relatively low.

The number of contact lens wearers in the United States is estimated by the Centers for Disease Control to be approximately 45 million.[35] Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 45 million people would receive a copy of their prescription each year under the Rule and be required to either sign a Confirmation of Prescription Release or consent to electronic delivery of their prescription.[36]

At an estimated one minute per prescription, the annual time spent by prescribers complying with the requirement to release prescriptions to patients would be approximately 750,000 hours. [(45 million × 1 minute)/60 minutes = 750,000 hours] Since the Rule requires that prescriptions be released automatically at completion of a fitting, the Commission—for purposes of calculating the PRA burden—assumes that prescription releases to patients are handled by the prescriber rather than the prescriber's office staff.[37] In all likelihood, this estimate overstates the actual burden because it includes the time spent by prescribers who already release prescriptions to patients in the ordinary course of business. Furthermore, this estimate allocates the same time for both paper and electronic delivery of prescriptions, even

[34] The 2020 amendments to the Contact Lens Rule altered the definition of "provide to the patient a copy" of the contact lens prescription to include electronic delivery of the prescription, such as via email, text, or by uploading it to a patient portal. In order to avail themselves of this option, prescribers must obtain and maintain evidence of the patients' affirmative consent to electronic delivery for three years.

[35] Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, *https://www.cdc.gov/contactlenses/fast-facts.html*. *See also* U.S. Food & Drug Administration, Focusing on Contact Lens Safety, *https://www.fda.gov/consumers/consumer-updates/focusing-contact-lens-safety*.

[36] In the past, some commentators have suggested that typical contact lens wearers obtain annual exams every 18 months or so, not every year. However, because prescriptions under the Rule are valid for a minimum of one year, we continue to estimate that patients seek exams every 12 months. Staff believes a calculation that assumes adherence to the Rule will provide the best estimate of the Rule's contemplated burden, even if, in practical terms, it overestimates the burden.

[37] This assumption may be incorrect, particularly in instances where a contact lens fitting is not completed during the prescriber's examination itself, but rather after the patient tests out the lenses for a few days. Nonetheless, the Commission does not have information as to what percentage of prescriptions are released by prescribers or by prescribers' staff, and thus will calculate the PRA with the assumption that they are all released by the prescriber.

though the latter likely takes less time for the prescriber.[38]

The time required to collect a signature from a patient confirming release of a prescription is estimated at twenty seconds, as discussed above. It is estimated that 25% of patients would opt for electronic delivery of their prescriptions and thus would not need to sign a Confirmation of Prescription Release. Based on our knowledge of the industry and how the medical field operates, the Commission believes most signed patient confirmations are obtained by prescribers' office staff rather than by the prescribers themselves.[39] The time spent by prescribers' staff complying with the requirement to obtain signed confirmations from the other 75% of patients is approximately 187,500 hours annually [(75% × 45 million prescriptions yearly × 20 seconds) = 187,500 hours].

As noted above, it is estimated that approximately 25% of patients would opt for electronic delivery of their prescriptions. In order to opt for electronic delivery, patients are required to sign an affirmative consent to receive their prescription via email, text, or patient portal. The time required to collect an affirmative consent signature is estimated at twenty seconds, and the annual time spent complying with the requirement to obtain such signatures is approximately 62,500 hours [(25% × 45 million prescriptions yearly × 20 seconds) = 62,500 hours]. Based on our knowledge of the industry and how the medical field operates, the Commission believes most signed patient consents are obtained by prescribers' office staff rather than by the prescribers themselves.[40]

As stated above, prescribers may also be required to provide or verify contact lens prescriptions to sellers. According to survey data, approximately 36% of contact lens purchases are from a source other than the prescriber.[41] Assuming that each of the 45 million contact lens

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[38] *See* Michaels, Workshop Transcript at 18 (noting that in his office, prescriptions are automatically uploaded to a patient portal "the very second the prescription is finalized.")

[39] In prior PRA submissions, the task of collecting a patient signature on a confirmation-of-prescription-receipt was attributed to prescribers, but based on more recent conversations with prescribers and others in the industry, the Commission now believes that this task is more appropriately designated as performed by prescribers' office staff. This is further supported by comments during the Eyeglass Rule Workshop, such as that of panelist Dr. Montaquila, who noted that his staff completes the process "from explaining why we're doing it to the patient, providing them with their prescription, making copies, providing their prescription back to them, and ultimately storing it. … Our staff has to explain, 'You're signing this for this reason." Montaquila, ER Workshop Transcript at 22, 28. *See also* Neville, ER Workshop Transcript at 28 (commenting that he has observed situations where the doctor pushed a button to have the prescription printed out at the front desk, the prescription was handed over at the desk by the staff person, and the staff person obtained the patient's signature on the confirmation.); AOA Report for Complying with the FTC Contact Lens Rule, (survey to prescribers, Question 3, "Have you experienced challenges in training staff on the new requirements for the Contact Lens Rule?"; Question 9 "How much time per day does your staff spend on addressing patient questions with the acknowledgment form and process?").

[40] *See supra* note 39.

[41] Jason J. Nichols & Deborah Fisher, "2018 Annual Report," Contact Lens Spectrum, Jan. 1, 2019, *https://www.clspectrum.com/issues/2019/january-2019*.

wearers in the U.S. makes one purchase per year, this means that approximately 16,200,000 contact lens purchases (45 million × 36% = 16,200,000) are made from sellers other than the prescriber.

Based on prior discussions with industry, approximately 73% of sales by non-prescriber sellers require verification, and prescribers affirmatively respond (by notifying the seller that the prescription is invalid or incorrect) to approximately 15% of those verification requests. Using a response rate of 15%, the FTC therefore estimates that prescribers' offices respond to approximately 1,773,900 verification requests annually [(16,200,000 purchases × 73%) × 15% = 1,773,900 responses]. Additionally, some prescribers may voluntarily respond to verification requests and confirm prescriptions (as opposed to simply letting the prescription passively verify). Because correcting or declining incorrect prescriptions is mandated by the Rule and occurs in response to approximately 15% of requests, staff assumes that prescribers voluntarily confirm prescriptions less often, and confirm at most an additional 15% of prescriptions (and, in all likelihood, significantly less). Using a combined response rate of 30%, the FTC estimates that prescribers' offices respond to approximately 3,547,800 requests annually.

According to prior industry comments,[42] responding to verification requests requires approximately five minutes per request. Using that data, we estimate that these responses require an additional 295,650 hours annually. [(3,547,800 × 5 minutes)/60 minutes = 295,650 hours]. Based on investigations and anecdotal comments, FTC staff is aware that many verification requests are handled by office staff rather than by the prescribers themselves. FTC staff, however, does not possess reliable information as to what percentage of verification requests are performed by prescribers or their staff, and thus will allocate all such time to prescribers.

Lastly, the Rule and FCLCA also impose recordkeeping requirements on prescribers' offices. First, they must maintain signed confirmations, or signed consent to electronic prescription delivery and proof that such prescriptions were delivered via email, text, or patient portal, for a period of three years. For purposes of PRA analysis, the Commission has used the assumption that all prescriber offices require a full minute to store and maintain each confirmation record, and a full minute to store and maintain each consent to electronic prescription delivery and proof of electronic prescription delivery.[43] The Commission thus allots an additional 750,000 annual hours for prescribers' offices to store and maintain records of patient confirmations and consents. The Commission believes these labor hours are most likely performed by prescribers' office staff.

The Rule also requires prescribers to document the specific medical reasons for setting a contact lens prescription expiration date shorter than the one-year minimum established by the FCLCA. This burden is likely to be nil because the requirement applies only in cases when the prescriber invokes the medical judgment exception, which is expected to occur infrequently, and

[42] Notice and Request for Comment, 81 FR 62501 (Sept. 9, 2016).

[43] 85 FR 5709.

prescribers are likely to record this information in the ordinary course of business as part of their patients' medical records. As mentioned previously, the OMB regulation that implements the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement.

Combining all hours spent annually disclosing prescriptions to consumers, obtaining confirmations of prescription release from consumers, obtaining affirmative consent to electronic prescription delivery from consumers, responding to verification requests, and maintaining records as required by the Rule, we estimate a total of 2,045,650 hours for all contact lens prescribers to comply with the Rule. [750,000 prescription-release hours + 187,500 confirmation-collection hours + 62,500 electronic-delivery-consent-collection hours + 295,650 verification-response hours + 750,000 recordkeeping hours = 2,045,650 hours] Of this total, we estimate 1,045,650 are prescriber labor hours, and 1,000,000 are labor hours performed by prescribers' clerical office staff.

2. Sellers

As noted above, a seller may sell contact lenses only in accordance with a valid prescription that the seller has (a) received from the patient or prescriber, or (b) verified through direct communication with the prescriber. The FCLCA also requires sellers to retain prescriptions and records of communications with prescribers relating to prescription verification for three years.

As stated previously, there are approximately 16,200,000 sales by non-prescriber sellers annually and approximately 73% of such sales require verification. Therefore, sellers verify approximately 11,826,000 orders annually and retain two records for such sales: the verification request and any response from the prescriber. Staff estimates that sellers' verification and recordkeeping for those orders will entail a maximum of five minutes per sale. At an estimated five minutes per sale to each of the approximately 11,826,000 orders, contact lens sellers will spend a total of 985,500 burden hours complying with this portion of the requirement. [(11,826,000 × 5 minutes)/60 minutes = 985,500 hours]

Approximately 27% of sales to non-prescriber sellers do not require verification and thus require only that the seller retain the prescription provided. Staff estimates that this recordkeeping burden requires at most one minute per order (in truth, in many cases this retention is electronic and automatic and will not require any time) for 4,374,000 orders [16,200,000 sales × 27%], resulting in 72,900 recordkeeping burden hours. [(4,374,000 orders × 1 minute)/60 minutes = 72,900 hours]

Combining burden hours for all orders [985,500 hours + 72,900 hours], staff estimates a total of 1,058,400 hours for contact lens sellers. It is likely that this estimate overstates the actual burden because it includes the time spent by sellers who already keep records pertaining to contact lens sales in the ordinary course of business, and those whose records are generated and preserved automatically when a customer orders online, which staff believes is the case for many online sellers.

Estimated total labor cost burden: Approximately $117,606,598.

This figure is derived from applying hourly wage figures for optometrists, ophthalmologists, and office clerical staff to the burden hours described above. This estimate is higher than the $84,548,448 labor cost estimate submitted to OMB in 2019 due to new information collection and recordkeeping requirements in the Rule, and to wage increases for optometrists, ophthalmologists, and office staff.

According to Bureau of Labor Statistics (BLS), salaried optometrists earn an average wage of $63.99 per hour, ophthalmologists—which are listed by BLS under "surgeons"—earn an average wage of $127.62 per hour, and general office clerks earn an average wage of $19.78 per hour.[44] Based on our knowledge of the industry and the number of optometrists and ophthalmologists in the United States, we assume that of the 1,045,650 prescriber labor hours relating to the Rule, optometrists are performing 85% of such hours and ophthalmologists are performing the remaining 15% of prescriber hours.[45] We credit general office clerks for performing the remaining hours, both for prescribers' offices (1,000,000 hours) and for non-prescriber sellers (1,058,400 hours). Based on these assumptions and estimates above, the estimated total labor cost attributable to the Rule is approximately $117,606,598. [($63.99 × 888,803 optometrist hours = $56,874,504) + ($127.62 × 156,848 ophthalmologist hours = $20,016,942) + ($19.78 × 1,000,000 prescribers' office clerk hours = $19,780,000) + ($19.78 × 1,058,400 sellers' office clerk hours = $20,935,152) = $117,606,598.]

(13) Capital and Other Non-Labor Costs

Estimated annual non-labor cost burden: $591,300.

Staff believes that the Rule's disclosure and recordkeeping requirements described above impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (e.g., prescription pads, patients' medical charts, facsimile machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage) to perform those requirements. The 2020 Rule amendments, however, modified the Rule to require that sellers who use automated verification messages record the calls and preserve the recordings for three years. The Commission does not believe that requiring sellers who use automated messages for verification to record the calls and preserve them will create a

[44] Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment and Wage Statistics – May 2022, https://www.bls.gov/news.release/ocwage.t01.htm. Median salaries for prescribers and clerks are slightly lower than average salaries and, consequently, would result in a lower overall burden imposed by the Rule. It is possible that medians are more representative since they do not include salary outliers that can distort the average. Salaries can also vary significantly by region. However, since Contact Lens Rule PRA submissions have historically used national salary averages to estimate the burden, the FTC will continue to do so for this submission.

[45] *See* Proposed Collection Request, 81 FR 31938, 31940 (May 20, 2016); Proposed Collection Request, 84 FR 32170, 32172 (July 5, 2019).

substantial burden. The requirement will not require additional labor time, since the calls will be for the same duration as they were previously, but may require capital and other non-labor costs to record the calls and store them electronically. Based on comments supplied during the Rule modification process, the Commission estimates the cost to record each verification call at five cents apiece.[46]

Based on survey data, approximately 36% of contact lens purchases are from a source other than the prescriber. Assuming that each of the 45 million contact lens wearers in the U.S. makes on purchase per year, this would mean that approximately 16,200,000 contact lens purchases are made annually from sellers other than the prescribers. And since approximately 73% of sales by non-prescriber sellers require verification, this means that approximately 11,826,000 contact lens purchases would require verification calls, faxes, or emails. The Commission does not possess information as to the percentage of verifications completed by telephone versus fax or email, and thus for purposes of this analysis will assume that all verifications are performed via phone and deliver automated messages that are subject to the call-recording requirement. Based on the aforementioned assumptions, the Commission estimates that the requirement to record automated telephone verification messages will cost sellers, in aggregate, $591,300 (11,826,000 × $.05).

Total Costs to the Industry (including Labor and Non-labor Costs)

Combining the annual labor cost burden with the non-labor cost burden, the total cost burden of the Rule is estimated at $118,197,898 ($117,606,598 + $591,300 = $118,197,898).

This burden is not insubstantial, but to put it in perspective, a recent survey estimated the value of the U.S. contact lens market at approximately $9.6 billion (not counting examination revenue).[47] Therefore, the total cost burden estimate of $118,197,898, imposed by the Rule, represents a cost of approximately 1.2% of the overall retail revenue generated through the sale of contact lenses.

(14) Estimated Cost to the Federal Government

Staff estimates that the fiscal year cost to the FTC of enforcing the Rule's requirements will be approximately $52,000 per year. 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

[46] 85 FR 50711. It is possible this would be a one-time expense for sellers to invest in recording equipment, as opposed to an annual outlay. But in the absence of information as to how sellers manage such recordings, the Commission will assume, for the purpose of this PRA analysis, that recording expense is a recurring annual cost burden.

[47] *See* https://www.globenewswire.com/en/news-release/2022/09/05/2509723/0/en/Contact-Lenses-Market-Size-Will-Achieve-USD-17-4-Billion-by-2030-growing-at-6-9-CAGR-Exclusive-Report-by-Acumen-Research-and-Consulting.html. Some estimates already put the U.S. contact lens market as high as $17 billion, *see* https://www.visionmonday.com/business/article/us-optical-retail-market-estimated-at-765-billion-in-the-vision-councils-first-comprehensive-market-insights-report/.

year, and 15% of one Paralegal work year will be expended to enforce the Rule's requirements.

(15) Program Changes or Adjustments

There is an upward adjustment in our annual burden hours from 2,979,050 (2020) to 3,104,050 (2023). The annual labor costs stemming from slightly higher estimated burden hours and average hourly rates go from $104,448,448 (2020) to $117,606,598 (2023).

(16) Statistical Use of Information/Publication of Results

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

The OMB control number and expiration date associated with this PRA submission will be displayed on the Federal government's electronic PRA docket at www.reginfo.gov. There are no government forms or other documents upon which display of the control number and expiration date would be appropriate.

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

Not applicable.