

Federal Trade Commission
Ophthalmic Practice Rules (Eyeglass Rule)
16 C.F.R. Part 456
OMB Control Number 3084-XXXX
Justification – Part A Supporting Statement

Overview of Information Collection:

- The Federal Trade Commission (“FTC” or “Commission”) has issued a Notice of Proposed Rulemaking (“NPRM”) to amend the Ophthalmic Practice Rules (“Eyeglass Rule” or “Rule”) to add new information collection and recordkeeping requirements for ophthalmologists and optometrists, and is requesting approval for the New Collection.
- Since 1978, the Eyeglass Rule has required that an ophthalmologist or optometrist automatically release a copy of a consumer’s prescription immediately following the completion of an eye examination.
- The proposed rule changes include information collection requirements that would require covered entities to obtain a signed confirmation of prescription receipt after providing a copy of the prescription to the patient, and to retain records to demonstrate compliance with the proposed rule’s prescription release requirements.
- Specifically, the proposed rule would require that certain eyeglass prescribers: (i) obtain a signed confirmation after releasing a prescription to a patient, (ii) maintain each such confirmation for a period of not less than three years, (iii) if releasing a prescription to a patient in a digital format, obtain the patient’s verifiable affirmative consent to receive a digital copy through the identified method or methods, (iv) maintain records or evidence of a patient’s affirmative consent for a period of not less than three years, and (v) if a digital copy of the prescription was provided to the patient, retain evidence for a period of not less than three years that such prescription was sent, received, or made accessible, downloadable, and printable. Such records shall be available for inspection by the FTC, its employees, and its representatives.
- Ophthalmologists and optometrists are exempt from the information collection and recordkeeping requirements related to the confirmation of prescription release if they do not have a direct or indirect financial interest in the sale of eye wear.

1. Need & Method for the Information Collection.

The FTC promulgated the Eyeglass Rule in 1978 pursuant to section 18 of the FTC Act, which grants the Commission the authority to adopt rules defining unfair or deceptive acts or practices in or affecting commerce, 15 U.S.C. 57a(a)(1)(B). The Eyeglass Rule requires ophthalmologists and optometrists to provide prescriptions to their patients upon the completion of an eye examination, and prohibits charging an additional fee for the prescription, or requiring patients to purchase any ophthalmic goods or sign a waiver or disclaimer of liability before releasing the prescription. The Rule was enacted to enable consumers to comparison-shop and purchase eyeglasses from the seller of their choice, and to promote competition in the eyeglass

marketplace. The FTC has reconfirmed the continuing need for the Eyeglass Rule via numerous rulemaking proceedings over the past forty years after determining that prescribers' failure to release eyeglass prescriptions is an ongoing, prevalent problem, and that this failure causes harm to consumers and competition.

Section 456.2(a) of the Rule requires an ophthalmologist or optometrist to provide one copy of the patient's prescription for lenses for eyeglasses immediately after the eye examination is completed, regardless of whether the patient requested the prescription.¹ This requirement is referred to as automatic prescription release, and failure to follow the requirement is an unfair practice under the FTC Act. Based on over forty years of experience enforcing the Rule, and after carefully considering the 868 comments that were submitted in response to the Advanced Notice of Proposed Rulemaking,² the Commission believes that the overall weight of evidence indicates that compliance with the automatic prescription release provision could—and should—be substantially improved.

To further the goals of the Eyeglass Rule, the Commission proposes to amend the Rule to require that ophthalmologists and optometrists obtain a signed confirmation after releasing an eyeglass prescription to a patient, and maintain each such confirmation for a period of not less than three years.³ Such signed confirmations shall be available for inspection by the FTC, its employees, and its representatives. The Commission believes this provision will help inform patients of their right to their prescriptions, increase the number of patients who receive their prescriptions, and, consequently, increase competition in the eyeglass market, and increase the number of purchases made via presentations of complete and valid prescriptions, thus reducing the number of seller requests to prescribers for eyeglass prescriptions, which some sellers find burdensome. The addition of a signed confirmation requirement would accomplish the desired objectives with little increased burden on prescribers.

The proposed requirement that the prescriber request that the patient acknowledge receipt of the eyeglass prescription would be triggered once the prescriber has provided the prescription to the patient. The patient would receive the prescription prior to being asked to sign the confirmation form, and signing the confirmation form is not a condition to obtaining the prescription. If the patient refuses to sign or cannot sign the confirmation form, the prescriber must note the refusal or inability on the confirmation form and must maintain the form.

For increased flexibility, the proposed confirmation form may be either paper or in electronic format. The proposed amendments also provide prescribers with optional language that they can use on a confirmation form, which will relieve prescribers of the burden of drafting a form, if they so choose.⁴ The confirmation form can be in a format that allows either conventional or electronic

¹ 16 C.F.R. § 456.2.

² Ophthalmic Practice Rules (Eyeglass Rule), Advanced Notice of Proposed Rulemaking; Request for Comment, 80 FR 53274 (Sept. 3, 2015).

³ Proposed section 456.3.

⁴ The prescriber may, but is not required to, use the statement, "My eye care professional provided me with

signatures. Prescribers may maintain copies of the confirmation forms in paper or electronically.

The Commission also proposes to amend the Rule to expressly allow prescribers to release a patient's eyeglass prescription electronically, so long as they first obtain the patient's verifiable consent to receive their prescription via the specific method of delivery identified by the prescriber.⁵ If they use this option for prescription release, the prescriber does not need to obtain a signed confirmation from the patient, but they must maintain records or evidence of a patient's affirmative consent for a period of not less than three years, and must also retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable for a period of not less than three years.⁶

2. Use of the Information.

The proposed information requirements are intended to ensure consumers automatically receive a copy of their eyeglass prescription at the end of their eye exam so that they can comparison-shop and purchase eyeglasses from the seller of their choice. The requirements are further intended to ensure prescribers retain records of electronic prescription release and of patients' confirmations of prescription receipt sufficient to demonstrate prescribers' compliance with the Rule and its disclosure requirements.

The Commission believes that the proposed recordkeeping requirements will also improve the Commission's ability to monitor overall compliance and target enforcement actions, reduce evidentiary issues, complaints, and disputes between prescribers and consumers, and bring the Eyeglass Rule into congruence with the Confirmation of Prescription Release requirement of the Contact Lens Rule,⁷ thereby reducing any confusion or complexity that two different sets of requirements might pose for prescribers or consumers.

3. Use of Information Technology.

The proposed rule changes allow prescribers to comply with the existing disclosure requirement (*i.e.*, to provide a copy of the patient's eyeglass prescription at the end of the eye examination) using electronic disclosure methods such as email, text message, or an online patient portal. To provide the prescription via electronic delivery, the prescriber must first obtain the patient's verifiable affirmative consent. If the patient chooses not to consent to electronic delivery, the prescription must be provided on paper.

The proposed amendments' information collection and recordkeeping provisions permit ophthalmologists and optometrists to keep records in whatever form, manner, format, or location they choose in the ordinary course of business. Accordingly, the Rule's recordkeeping provisions

a copy of my prescription at the completion of my examination" to satisfy the requirement.

⁵ Proposed section 456.1(h).

⁶ Proposed sections 456.1(h) and 456.3.

⁷ 16 C.F.R. Part 315.

are consistent with the requirements of the Government Paperwork Elimination Act (“GPEA”).⁸ Moreover, in its NPRM, the Commission specifically sought comments on ways to minimize the burden of the Rule’s collections of information. This could include the use of information technology.

4. Non-duplication.

The proposed 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 proposed amendments, prescribers likely can comply with both requirements through a single release or record-keeping system, thereby avoiding duplication. The Contact Lens Rule imposes similar information collection and recordkeeping requirements for contact lens prescriptions, and the proposed amendments would allow prescribers to use the same mechanism to obtain confirmation of receipt of a contact lens prescription (in accordance with the Contact Lens Rule) and an eyeglass prescription in cases when the prescriber provides both prescriptions to the patient at the same time, so long as the prescriber asks for separate signatures for each.

5. Burden on Small Business.

The proposed recordkeeping requirements are designed to impose the minimum burden on all affected members of the industry, regardless of size. While many eyeglass prescribers subject to the Rule’s requirements are small businesses, the Commission drafted the proposed rule in a manner designed to minimize the compliance burden and avoid imposing undue burden on small entities. In its NPRM, the Commission also sought comment about additional ways to minimize the impact on small businesses.

6. Less Frequent Collection.

The proposed recordkeeping requirement would require that prescribers retain the required records for a period of not less than three years. Staff believes that a shorter record retention period would hamper the Commission’s ability to verify eyeglass prescribers’ compliance with the Rule, because the statute of limitations applicable to Commission rule violations is three years.⁹

7. Paperwork Reduction Act Guidelines.

The proposed amendments’ information collection requirements are consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2). Under the proposed rule amendments, the Commission’s Rule would only require that covered entities maintain the form for three years. Instances where records are required to be maintained longer than three years are mandated by

⁸ Pub. L. No. 105-277, Title XVII, 112 Stat. 2681-749 (1998) *codified at* 44 U.S.C. § 3501 *et seq.*

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

individual state laws.¹⁰

8. Consultation and Public Comments.

In developing the proposed requirements, the Commission considered 868 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, eyeglass sellers (both online and brick-and-mortar), and consumer and competition advocates.¹¹ 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 is seeking further public comment on the proposed information collection requirements and its associated Paperwork Reduction Act ("PRA") burden analysis.

9. Gifts or Payment.

Not applicable.

10. and 11. Privacy & Confidentiality/Sensitive Questions.

Not applicable. No assurance of confidentiality is necessary because although the Eyeglass 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 PRA. In any event, in such proceedings, records would be protected by law from mandatory public disclosure.¹²

12. Burden Estimate.

Estimated Annual Hours Burden: 2,979,167 hours.

The Commission is proposing a number of modifications to the Rule that contain recordkeeping requirements that are collections of information as defined by OMB regulations that

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).

¹¹ See *supra* note 2.

¹² 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).

implement the PRA. First, the Commission is proposing to modify the Rule to require that prescribers either: (i) 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; (ii) 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; (iii) 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 refractive eye examination sales receipt; or (iv) 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 prescription was sent, received, or made accessible, downloadable, and printable by the patient. For prescribers who choose to offer an electronic method of prescription delivery, the proposed Rule would require 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. For instances where a consumer refuses to sign the confirmation or accept digital delivery of their prescription, the proposed Rule directs the prescriber to note the refusal and preserve this record as evidence of compliance. None of the proposed new requirements, however, would apply to prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses.

The Commission hereby provides PRA burden estimates, analysis, and discussion for the burden of automatically releasing a prescription at the completion of a refractive eye exam, as well as the proposed requirement to collect patient signatures as confirmation of prescription release and as consent to electronic prescription delivery. Commission staff estimates these PRA burdens based on its knowledge of the eye care industry.

The number of adult eyeglass wearers in the United States is estimated to be approximately 165 million.¹³ Assuming a biennial refractive eyeglass exam for each eyeglass wearer,¹⁴ approximately 82.5 million people would receive a copy of their eyeglass prescription every year. Historically, the Commission has estimated that it takes one minute to provide the patient with a prescription copy, and that it is the prescriber, and not the prescriber's office staff, that provides the prescription to the consumer.¹⁵ We therefore estimate an annual disclosure burden for prescribers

¹³ See Vision Council, "VisionWatch—The Vision Council Market Analysis Report," Dec. 2019, at 24.

¹⁴ The Commission relies on industry sources for its estimate that eyeglass wearers typically obtain one refractive eye exam every two years. See, e.g., AOA, Excel and Jobson Medical Information, The State of the Optometric Profession: 2013, at 4, <https://www.reviewob.com/wp-content/uploads/2016/11/8-21-13stateofoptometryreport.pdf> (showing an average interval between exams of 25 months); AOA, Comprehensive Eye Exams, <https://www.aoa.org/healthy-eyes/caring-for-your-eyes/eye-exams?sso=y> (showing recommended examination frequency for adult patients 18-64 of "at least every two years" for asymptomatic/low risk patients). The Eyeglass Rule does not discuss or define prescription expiration terms, and many states do not set any limit for eyeglass prescriptions. Some eyeglass wearers, therefore, can legally go many years between refractive eye examinations. But the Commission will use two years as a basis for purposes of this assessment, since that is recommended interval for the majority of eyeglass wearers.

¹⁵ See, e.g., Contact Lens Rule, Agency Information Collection Activities; Proposed Collection; Comment Request, 81 FR 31938, 31939 (May 20, 2016); Contact Lens Rule, Agency Information Collection Activities; Submission for OMB Review; Comment Request, 81 FR 62501 (Sept. 9, 2016).

of approximately 1,375,000 hours (82.5 million annual exams \times 1 min/60 mins).

Staff anticipates there will be an additional burden on individual prescribers' offices to maintain signed confirmation forms for a period of not less than three years, but believes the overall burden imposed by the Rule remains relatively small in the context of the overall market for eyeglasses and refractive examinations. Based on the Commission's assumption of the number of refractive eye examinations that occur annually, staff estimates that 82.5 million people would either read and sign a confirmation of prescription release, or sign a confirmation agreeing to receive their prescription electronically every year.

The Commission believes that generating and presenting the confirmation of prescription release will not require significant time or effort. The proposed 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 proposed 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 § 456.3(a)(1), the confirmation from the patient must be in writing. At the same time, prescribers would not have to spend time formulating their own content for the confirmation, since the proposed Rule provides draft language that prescribers are free to use, should they so desire.

The four options for a prescriber to confirm a prescription release to a patient are set out in proposed § 456.3(a)(1)(i), (ii), (iii), and (iv). The requirement in options § 456.3(a)(1)(i), (ii), and (iii) to provide the patient with a confirmation of prescription release are not disclosures constituting an information collection under the PRA because the FTC, in § 456.3(a)(2), has supplied the prescriber with draft language the prescriber can use to satisfy this requirement.¹⁶ As noted above, however, the requirement in (i), (ii), and (iii) 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 estimated in the Contact Lens Rule that it would take patients ten seconds to read the one-sentence confirmation of prescription release and provide a signature,¹⁷ and the Commission believes that ten seconds is an appropriate estimate for the Eyeglass Rule confirmation as well.

The fourth proposed option, § 456.3(a)(1)(iv), does not, in and of itself, constitute an

¹⁶ "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 C.F.R. 1320.3(c)(2). It is also notable that for the options in proposed §§ 456.3(a)(1)(ii) and (iii), the confirmation information would be printed on the same document—the prescription copy or sales receipt—that the prescriber would ordinarily provide to the consumer in any event.

¹⁷ Contact Lens Rule, Final Rule, 85 FR 50668, 50709 (Aug. 17, 2020). This estimate was based on responses to a consumer survey regarding how long it would take consumers to read the form, and a prior PRA estimate for consumers to complete a similar signed acknowledgment. *See* Contact Lens Rule, Supplemental Notice of Proposed Rulemaking, 84 FR 24664, 24693 (May 28, 2019).

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.¹⁸ Excluding that option from consideration, and assuming the remaining three options are exercised with equal frequency, 75% of approximately 82.5 million annual prescription releases will entail reading and signing a confirmation statement. Thus, assuming ten seconds for each release, prescribers would devote 171,875 hours, cumulatively ($75\% \times 82.5$ million prescriptions yearly $\times 10$ seconds each/60secs/60mins) to obtaining patient signatures as confirmations of prescription release.¹⁹

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 for at least three years,²⁰ and thus many prescribers who opt to include the confirmation of prescription release on the prescription itself would be preserving that document, regardless.²¹ 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 proposed 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 or electronic forms, or that scan paper files and maintain them electronically. Thus, for purposes of

¹⁸ In order to utilize § 456.3(a)(1)(iv), however, a prescriber must obtain and maintain records or evidence of affirmative consent by patients to electronic delivery of their prescriptions. 16 C.F.R. 456.1(h)(2). The burden to do so is included in the recordkeeping burden calculation.

¹⁹ Section 456.3(a)(3) also requires that in the event that a patient declines to sign a confirmation requested under paragraphs (a)(1)(i), (ii), or (iii), 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 (a)(1)(i), (ii), or (iii) require the same amount of time.

²⁰ 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).

²¹ Since October 2020, the Contact Lens Rule has included similar requirements that prescribers maintain, for a period of at least three years, patient confirmations related to the release of contact lens prescriptions. 16 C.F.R. 315.3(c); Contact Lens Rule, Final Rule, 85 FR at 50717.

this PRA analysis, Commission staff will assume that all prescriber offices who opt for § 456.3(a)(1)(i), (ii), or (iii) require a full minute per confirmation for recordkeeping arising from the modifications. Excluding from PRA consideration the fourth option, § 456.3(a)(1)(iv), 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' offices to scan and save such confirmations would amount to 1,031,250 hours ($75\% \times 82.5$ million prescriptions yearly \times one minute for scanning and storing/60mins) 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 their prescription. However, as explained in § 456.1(h)(2), under the Rule's new proposed definition of *Provide to the patient one 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. The Commission will use the assumption that consumers sign such consents for electronic delivery pursuant to § 456.3(a)(1)(iv), for one quarter of the 82.5 million prescriptions released per year,²² 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 401,042 hours²³ for the time required for prescribers to obtain patients' affirmative consent to electronic delivery of their prescriptions 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 1,604,167 total hours (171,875 and 57,292 hours, respectively, to obtain signatures confirming release and consenting to electronic delivery, plus 1,031,250 and 343,750 hours, respectively, to maintain records of confirmation and consent for three years). Adding the estimated incremental PRA recordkeeping burden for prescribers and their staff from the confirmation of prescription release proposal to the burden from the existing requirement that prescribers provide patients with copies of their prescriptions yields a total disclosure and recordkeeping burden from the Rule of 2,979,167 hours for prescribers and their staff (1,375,000 disclosure hours + 1,604,167 recordkeeping hours).

Estimated Annual Labor Cost: \$122,528,562.

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 its Contact Lens Rule review, the Commission requested comment as to whether prescribers or office staff are more likely to collect patient signatures and retain associated

²² 20,625,000 prescriptions (82.5 million prescriptions \times 25%).

²³ 57,292 hours (20,625,000 prescriptions yearly \times 10 seconds/60secs/60mins) for obtaining the signature plus 343,750 hours (20,625,000 affirmative consents \times one minute/60mins) for storing such records.

recordkeeping, but did not receive significant guidance on this.²⁴ Therefore, the Commission will continue to assume that optometrists will perform the task of collecting patient signatures, and that prescribers' office staff will perform the labor pertaining to printing, scanning, and storing of documents, even though these assumptions may lead to some overcounting of the burden (if, in actuality, prescribers' office staff obtain patient signatures).

According to the U.S. Bureau of Labor Statistics, salaried optometrists earn an average wage of \$60.31 per hour, and general office clerks earn an average wage of \$18.75 per hour.²⁵ Using the aforementioned estimate of 229,167 total prescriber labor hours for obtaining patient signatures,²⁶ the resultant aggregate labor costs to obtain patient signatures is \$13,821,062 (229,167 hours × \$60.31). Applying a mean hourly wage for office clerks of \$18.75 per hour to the aforementioned estimate of 1,375,000 hours for printing, scanning and storing of prescription release confirmations and consent agreements,²⁷ labor costs for those tasks would total \$25,781,250. 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 annual labor burden of the confirmation of prescription release modification to be \$39,602,312.

Adding the \$39,602,312 burden from the confirmation of prescription release requirement to the \$82,926,250 burden²⁸ from the prescription release requirement already in place yields a total estimated annual labor cost burden for the Eyeglass Rule of \$122,528,562. While not insubstantial, this amount constitutes approximately one half of one percent of the estimated overall retail market for eyeglass sales in the United States.²⁹ Furthermore, the actual burden is likely to be less, because many prescribers' offices will require less than a minute to store the confirmation form.

13. Estimated Nonrecurring Costs.

Staff believes that the Rule's recordkeeping requirements 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, scanning devices, and recordkeeping

²⁴ Contact Lens Rule, Final Rule, 85 FR at 50710.

²⁵ Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics, <https://www.bls.gov/news.release/ocwage.t01.htm>.

²⁶ This would be derived from 171,875 and 57,292 hours, respectively, to obtain signatures confirming release and consenting to electronic delivery.

²⁷ This would be derived from 1,031,250 and 343,750 hours, respectively, to maintain records of confirmation and consent for three years.

²⁸ 1,375,000 hours × \$60.31 (average hourly wage for optometrists) = \$82,926,250.

²⁹ According to The Vision Council, the eyeglass market (for frames and lenses) in the United States for the twelve months ending December 2019, totaled roughly \$24.3 billion. See Vision Council, "VisionWatch—The Vision Council Market Analysis Report," at 69, 89; Vision Council, "Consumer Barometer," Dec. 2019, at 18-19. The estimated total burden of the Rule of \$122,528,562 thus amounts to approximately 0.5 percent of the total market.

facilities such as filing cabinets or other storage).

14. Estimated cost to the Government.

FTC staff estimates that the cost to the Federal Government of implementing the proposed Rule will total approximately \$53,289. This estimate is based on the assumption that 15-20% of one Attorney work year (\$186,342) and 15-20% of one Investigator work year (\$118,166) will be expended to enforce the proposed Rule. These estimates include employee benefits.

15. Reasons for Changes.

The proposed amendments added to existing disclosure requirements, will result in an estimated 2,979,167 burden hours annualized, \$122,528,562 in labor costs, and negligible capital/non-labor costs.

16. Publicizing Results.

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

17. OMB Not to Display Approval.

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

18. Exceptions to “Certification for Paperwork Reduction Act Submissions.”

Not applicable. The FTC certifies that this collection of information is consistent with the requirements of 5 C.F.R. 1320.9, and the related provisions of 5 C.F.R. 1320.8(b)(3), and is not seeking an exception to these certification requirements.