Federal Trade Commission
Final Rule amending
Ophthalmic Practice Rules (Eyeglass Rule)
16 C.F.R. Part 456
OMB Control Number 3084-0174
Justification – Part A Supporting Statement

Overview of Information Collection:

On January 3, 2023, the Federal Trade Commission ("FTC" or "Commission") submitted a Notice of Proposed Rulemaking ("NPRM") to amend the Ophthalmic Practice Rules ("Eyeglass Rule" or "Rule") and an accompanying Supporting Statement to the Office of Management and Budget ("OMB") for review under the Paperwork Reduction Act ("PRA"). On February 23, 2023, OMB directed the Commission to resubmit its request when the proposed rule was finalized. The Commission is now submitting the Final Rule amendments and a Supplemental Supporting Statement to OMB.[1] The Final Rule will be effective on September 24, 2024.

The rule changes include information collection requirements that will 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 rule's prescription release requirements. Specifically, the rule will 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 these 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

[1] Ophthalmic Practice Rules (Eyeglass Rule), Final Rule, 89 FR 60742 (July 26, 2024).

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.

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.[2] 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 Advance Notice of Proposed Rulemaking,[3] the 27 comments that were submitted in response to the NPRM,[4] the discussion at a May 2023 workshop on the subject,[5] and 20 comments submitted after the workshop,[6] 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, in the NPRM, the Commission proposed to: (1) require that prescribers 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; (2) permit prescribers to comply with automatic prescription release via electronic delivery if the prescription is provided in a digital format that can be accessed, downloaded, and printed by the patient, and if the prescriber obtains the patient's verifiable affirmative consent to the electronic delivery method; (3) clarify that the presentation of proof of insurance coverage shall be deemed to be a payment for the purpose of determining when a prescription must be provided; and (4) amend the term "eye examination" to "refractive eye examination" throughout the Rule.

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[2] 16 C.F.R. § 456.2.

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

[4] Ophthalmic Practice Rules (Eyeglass Rule), Notice of Proposed Rulemaking, Request for Public Comment, 88 FR 248 (Jan. 3, 2023).

[5] Staff convened a workshop, titled "A Clear Look at the Eyeglass Rule," with three panels and a total of 13 panelists in Washington, DC, on May 18, 2023, and the discussion was transcribed. The workshop transcript (along with the agenda and a video recording) is available on the FTC website at https://www.ftc.gov/news-events/events/2023/05/clear-look-eyeglass-rule.

[6] At the conclusion of the workshop, panelists, audience members, and the general public were invited to share additional views, data, and other information related to the NPRM and the subjects discussed. Public Workshop Examining Proposed Changes to the Ophthalmic Practice Rules (Eyeglass Rule), Public Workshop and Request for Public Comment, 88 FR 18266 (Mar. 28, 2023).

The Commission issues a final rule that largely adopts the amendments proposed in the NPRM, with some minor modifications based on public comments and other considerations. The final rule provides prescribers with two broad options that give them flexibility in how to satisfy the confirmation-of-prescription-release requirement, a paper option and a digital delivery option.[7] If a paper copy of the prescription is provided, the prescriber must request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription.[8] If a prescriber provides the prescription digitally, after obtaining verifiable affirmative consent, the prescriber need not request the patient sign a separate statement confirming receipt, but merely needs to retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable, a task the prescriber most likely does in any event. In the final rule's digital option, which differs slightly from that proposed in the NPRM,[9] that evidence serves as the "confirmation of prescription release."

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[7] *See* Final Rule, 16 C.F.R. § 456.4(a)(1)(i)-(ii). In contrast, the NPRM enumerated four options for compliance. 88 FR at 287 (proposed Sec. 456.3(a)(1)(i)-(iv), to be redesignated as Sec. 456.4). The final rule options encompass those options and thus still allow them, but are deliberately broader in order to allow more flexibility by the prescriber. The paper option in the final rule is the same as NPRM option (i) -- i.e., the prescriber must request that the patient sign a separate statement confirming receipt of the prescription. This encompasses the proposed NPRM options (ii) (where a prescriber can retain a copy of a prescription that contains a signed statement confirming receipt of the prescription) and (iii) (where a prescriber can retain a signed copy of the sales receipt for the examination that contains a statement confirming receipt of the prescription). The NPRM's proposed options (ii) and (iii) are essentially examples of documents—prescriptions and sales receipts—that can contain separate statements confirming receipt of the prescription, and these methods of obtaining confirmation continue to be permitted under the final rule's broader paper delivery option.

[8] The signature can be provided "on paper or in a digital format." *See* Final Rule, 16 C.F.R. § 456.4(a)(1)(i). That language was added to the final rule after the NPRM stage in response to questions about whether a digital signature was permitted, and to a suggestion at the workshop that the Rule expressly permit prescribers to obtain patient signatures digitally.

[9] First, the NPRM proposed adding a digital delivery provision to the Rule via the addition of the definition of the phrase "provide to the patient one copy." 88 FR at 286 (proposed § 456.1(h)(2)). This definition would have stated both the option for the prescriber to offer the patient a digital copy of their prescription, and the requirements for obtaining verifiable affirmative consent to the digital delivery and maintaining a record or evidence of the patient's affirmative consent for a period of not less than three years. However, the Final Rule moves the digital delivery provision out of the definitions section and into the body of the Rule in order to ensure that prescribers do not overlook the requirements for providing prescriptions digitally, and to make the requirement more noticeable and understandable to consumers. *See* Final Rule, 16 C.F.R. § 456.2(a)(1)(ii).

Second, in the NPRM, the proposed digital delivery provision stated that the prescriber "shall identify to the patient the specific method or methods of electronic delivery to be used." 88 FR at 286 (proposed § 456.1(h)(2)). The Final Rule modifies the language to "shall identify to the patient the specific method or methods of electronic delivery that will be used." Final Rule, 16 C.F.R. § 456.3(a). Staff has seen examples of prescriber consent forms that list numerous digital delivery methods (*i.e.* "email, text, and /or portal"), and believes prescribers should notify consumers of which form of delivery will be used to deliver their prescription. As such, this change should provide clarity to prescribers that they should not identify all digital delivery methods unless they in fact deliver the prescription using all of the referenced methods.

The Commission believes the addition of the signed confirmation requirement 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 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 confirmation form may be either paper or in electronic format. The 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.[10] The confirmation form can be in a format that allows either conventional or electronic signatures. Prescribers may maintain copies of the confirmation forms in paper or electronically.

The Commission also amends the Rule to expressly allow prescribers to release a patient's eyeglass prescription electronically, so long as they first obtain the patient's verifiable affirmative consent to receive their prescription via the specific method of delivery identified by the prescriber.[11] If prescribers use this option for prescription release, they do not need to obtain a signed confirmation from the patient, but they must maintain records or evidence of a patient's verifiable 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.[12]

2. <u>Use of the Information.</u>

The 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.

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[10] The prescriber may, but is not required to, use the statement, "My eye care professional provided me with a copy of my prescription at the completion of my examination" to satisfy the requirement.

[11] Sections 456.3 and 456.4.

[12] Sections 456.3 and 456.4.

The Commission believes that the 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,[13] thereby reducing any confusion or complexity that two different sets of requirements might pose for prescribers or consumers.

3. Use of Information Technology.

The 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 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 are consistent with the requirements of the Government Paperwork Elimination Act ("GPEA").[14] Moreover, in its NPRM, and at the workshop, the Commission specifically sought comments and engaged in discussion 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 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 amendments, prescribers likely can comply with both requirements through a single release or recordkeeping system, thereby avoiding duplication. The Contact Lens Rule imposes similar information collection and recordkeeping requirements for contact lens prescriptions, and the 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.

5. Burden on Small Business.

The 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 rule in a manner designed to minimize

[13] 16 C.F.R. Part 315.

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

the compliance burden and avoid imposing undue burden on small entities. In its NPRM and in discussions at the workshop, the Commission also sought comment about additional ways to minimize the impact on small businesses.

6. Less Frequent Collection.

The recordkeeping requirement requires prescribers to 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.[15]

7. Paperwork Reduction Act Guidelines.

The amendments' information collection requirements are consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2). Under the rule amendments, the Commission's Rule would generally require that covered entities maintain the form for three years.[16] In most cases, instances where records are required to be maintained longer than three years are mandated by individual state laws.[17]

8. Consultation and Public Comments.

In developing the requirements, the Commission considered the comments from and discussions at the workshop among 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.[18] 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's responses to those concerns are set forth in more detail in Section IV - Final Rule Pertaining to Confirmation of Prescription Release, and in Section VIII – Paperwork Reduction Act. As described therein, the Commission attempts to

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

[16] If a prescriber intends to provide digital delivery to a patient for more than three years following that patient's signed consent, they should not dispose of the consent record after three years. Rather, the prescriber should retain the patient's signed consent for as long as the prescriber relies on it to authorize digital delivery of the prescription, plus another three years.

[17] *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).

[18] *See supra* notes 3-6.

minimize the burdens of the Rule in various ways, including providing prescribers with different compliance options and the adoption of the exemption to the confirmation-of-prescription-release requirements for prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses.

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.[19]

12. Burden Estimate.

Estimated Annual Hours Burden: 3,208,333 hours.

The Commission is implementing modifications to the Rule that contain recordkeeping requirements that are collections of information as defined by OMB regulations that implement the PRA. First, the Commission is modifying 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, or (ii) 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 Rule will 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 at least three years. For instances where a consumer refuses to sign the confirmation or accept digital delivery of their prescription, the Rule directs the prescriber to note the refusal and preserve this record as evidence of compliance. None of the new requirements, however, apply to prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses.

The Final Rule differs from the NPRM in that it has fewer enumerated options for prescribers to satisfy the confirmation requirement. However, in actuality prescribers have the same options, if not more, since the options in the Final Rule are broader and less prescriptive than those proposed in the NPRM, and thus prescribers have many choices as to what to use as a

[19] *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).

statement confirming receipt of prescription. The Final Rule, and this Supporting Statement, also increase the calculated burden estimate for the time required to obtain a confirmation of prescription receipt, due to feedback from commenters.

The Commission hereby provides PRA burden estimates, analysis, and discussion for the existing Rule burden of automatically releasing a prescription at the completion of a refractive eye exam, as well as the new Rule 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 public comment and the FTC's longstanding knowledge of the eye care industry.

(a) The existing burden of releasing eyeglass prescriptions

The number of adult eyeglass wearers in the United States is estimated to be approximately 165 million.[20] Assuming a biennial refractive eyeglass exam for each eyeglass wearer,[21] 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 for the provider to provide the patient with a prescription copy.[22] It is possible (even likely) that one minute is an overestimate of the amount of time required, particularly as more doctors complete the transition to digital

[20] Determining the precise number of adults, and adult eyeglass wearers, in the United States at any given moment, is not possible, and estimates will change every year. According to the U.S. Census Bureau, in 2020 there were 258.3 million adults in the United States. "U.S. Census Bureau, Age and Sex Composition: 2020," 2020 Census Briefs (2023), https://www2.census.gov/library/publications/decennial/2020/census-briefs/c2020br-06.pdf. Meanwhile, four different surveys of U.S. residents in 2021 and 2022 by The Vision Council found that 61-65% of adults wear glasses, which—based on the 2020 census—equates to approximately 158-168 million adults who wear eyeglasses. Vision Council Consumer inSights reports 2022 Q1, Q2, Q3, Q4. In its Eyeglass Rule NPRM, the Commission used a prior Vision Council estimate of 165 million adult eyeglass wearers, which is within the 158-168 million range, and the Commission finds this remains an appropriate estimate at this time. *See* 88 FR at 283.

[21] 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 burden assessment, since two years is the AOA's recommended interval for the majority of eyeglass wearers.

[22] *See, e.g.*, NPRM, 88 FR at 283; 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).

prescription delivery via portal, email, or text. As of now, however, we have not seen detailed evidence sufficient to merit making a change to the burden-calculation approach we have taken in the past. We therefore estimate an annual disclosure burden for prescribers to formulate and release prescriptions of approximately 1,375,000 hours (82.5 million annual exams × 1 min/60 mins).

Staff anticipates there will be an additional burden on individual prescribers' offices to collect and maintain signed confirmation forms, or consents to receive digital prescription delivery, 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 consent agreeing to receive their prescription electronically every year.[23]

(b) The incremental burden of obtaining and maintaining patient prescription release confirmations

The Commission believes that generating and presenting the confirmation of prescription release will not require significant time or effort. The requirement is flexible in that it allows 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 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 § 456.4(a)(1)(i), 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 Rule provides draft language that prescribers are free to use, should they so desire.

The options for a prescriber to confirm a prescription release to a patient are set out in §§ 456.4(a)(1)(i) and (ii). The requirement in § 456.4(a)(1)(i) to *provide the patient with a confirmation of prescription release* is not a disclosure constituting an information collection under the PRA because the FTC, in § 456.4(a)(2), has supplied the prescriber with draft language the prescriber can use to satisfy this requirement.[24] As noted above, however, the requirement to

[23] The 82.5 million figure is, again, an overestimate by the Commission, since it does not deduct for the number of patients who visit a prescriber who does not have a direct or indirect financial interest in the sale of eye wear, and would not be required to confirm receipt of prescriptions under the Rule amendment § 456.4 (c). However, staff does not currently possess information as to what number of prescribers will qualify for the exception in § 456.4 (c), and so has assumed that all patients receiving a prescription will sign a confirmation of prescription release, or sign a confirmation agreeing to receive their prescription electronically every year.

[24] "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 under § 456.4(a)(1)(i), the confirmation information could be printed on the same document—the prescription copy or sales receipt—that the prescriber would ordinarily

collect a patient's signature on the confirmation of prescription release and preserve it does constitute 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, in the Eyeglass Rule NPRM, estimated that it would take patients 10 seconds to read the one-sentence confirmation of prescription release and provide a signature.[25] The 10-second estimate was based on prior estimates for a signed acknowledgment made during the Contact Lens Rule rulemaking, which, in turn, were based primarily on two sources, consumer survey responses as to how long it would take to review a prescription-confirmation form, and a prior OMB-approved PRA estimate of 10 seconds for consumers to read a similar signed acknowledgment in the HIPAA context.[26] However, in reconsidering the confirmation requirement burden in 2023 while seeking renewed OMB record-collection clearance for the Contact Lens Rule, the Commission decided to increase the estimated time for patients to read and sign the confirmation of prescription release from 10 to 20 seconds.[27] This change came in response to input from the public and the ophthalmological community regarding the OMB clearance request and the NPRM.[28] In light of that change, the Commission believes 20 seconds is an appropriate estimate for the amount of time for patients to read and sign a one-sentence Eyeglass Rule confirmation in instances when prescribers employ the "paper method" of obtaining a confirmation set forth in § 456.4(a)(1)(i).[29]

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provide to the consumer.

[25] NPRM, 88 FR at 282.

[26] *See* Contact Lens Rule, Final Rule, 85 FR 50668, 50708-09 (Aug. 17, 2020); Contact Lens Rule, Supplemental Notice of Proposed Rulemaking, 84 FR 24664, 24693 (May 28, 2019). *See also* Supporting Statement for Information Collection Provisions of the Contact Lens Rule (OMB Control #3084-0127) at 5-6 (Dec. 15, 2023), https://omb.report/icr/202312-3084-003/doc/138082100.

[27] FTC Notice, Proposed Collection, 88 FR 88076, 88079, Dec. 20, 2023 ("2023 CLR PRA"). Following this notice and response to commenters, on Jan. 26, 2024, OMB approved the extension request for the CLR clearance. Notice of Office and Management and Budget Action, OMB Control No. 3084-0127.

[28] FTC Notice, Proposed Collection, 88 FR 88077-82.

[29] As noted in the Commission's proposed collection request, the Commission is aware that some prescribers have been providing patients with much lengthier paper confirmation statements for contact lens prescriptions, which may require more than 10 or 20 seconds for patients to read and sign. Such statements often include information about how to use contact lenses, and symptoms of an eye infection. Such information, while perhaps helpful for patients, is not required by the Contact Lens Rule and its required confirmation of prescription release, and thus is not considered in determining how long it takes to read and sign a confirmation statement. *Id.* at 88079. It is also worth noting that the Commission permits prescribers to use a single document to obtain confirmations for both CLR and eyeglass prescriptions, and thus the burden calculated herein could be duplicative, or overstated, to the extent that prescribers use the same document that they are already using to obtain contact lens prescription-release confirmation.

The second option available to prescribers for confirming patient receipt of prescriptions, § 456.4(a)(1)(ii) (digital prescription delivery), does not, in and of itself, constitute an information collection under the PRA, since no new information that would not otherwise be provided under the Rule is provided to or requested from the patient.[30]

In estimating the burden from the confirmation requirement, therefore, the Commission must determine how often prescribers will use the paper prescription delivery option of § 456.4(a)(1)(i), and how often they will rely on the digital prescription delivery of § 456.4(a)(1)(ii). In its NPRM, the Commission assumed that prescribers would elect the latter (digital prescription delivery) 25% of the time, and thus would be required to obtain a signed confirmation for the other 75% of patients receiving prescriptions.[31] That assumption was rooted in the fact that the NPRM offered prescribers four confirmation options (confirmation on a stand-alone document, confirmation on a prescription copy, confirmation on a sales receipt, or digital delivery with no confirmation required). Lacking specific details as to which option prescribers would prefer, the Commission employed the assumption that they would choose each of the four options in equal numbers.

The Final Rule differs from the NPRM, however, in that it only has two options, paper delivery or digital delivery, and thus if the Commission used the same equal-share assumption it followed in the NPRM, the percentage attributed to digital delivery (thereby not implicating the burden of a confirmation) for PRA purposes would be 50%. But based on conversations with prescribers and the industry, the Commission has reason to believe that regardless of the increasing adoption of electronic health records, many prescribers still do not provide patient with portals or deliver prescriptions digitally to patients, and thus it would not be appropriate to designate half of all prescription releases as digital delivery not requiring a confirmation. Further supporting this view, a survey by the American Optometric Association found that only 35% of prescribers said they provided prescriptions electronically.[32] Therefore, in order to ensure that the Rule's burden is not underestimated, the Commission will retain the previously-used assumption that just 25% of prescribers employ digital-prescription delivery, and the other 75% of approximately 82.5 million annual prescription releases require that a consumer read and sign a paper confirmation statement. Thus, assuming twenty seconds for each instance where a prescription is released and the consumer reads and signs a confirmation statement, prescribers' offices would cumulatively devote

[30] In order to utilize § 456.4(a)(1)(ii), 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. 456.3(c). The burden to do so is included in the recordkeeping burden calculation.

[31] NPRM, 88 FR at 283.

[32] AOA (CLR PRA Comment #0007 submitted by Benner). Even the AOA survey might overcount the number of prescriptions actually delivered digitally, since the prescribers surveyed were permitted to select more than one option for their prescription-delivery method, so some of the 35% who selected digital delivery of prescription (and thus no confirmation) may also have responded that they use other options, which would mean that the overall percentage of prescriptions released electronically is actually less than 35%.

343,750 hours (75% × 82.5 million prescriptions yearly × 20 seconds each/60secs/60mins) to obtaining patient signatures as confirmations of prescription release.[33]

Maintaining those signed confirmations for a period of not less than three years should 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,[34] and thus many prescribers who opt to include the confirmation of prescription release on the prescription itself would be preserving that document, regardless.[35] 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 might 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 recordkeeping requirement will 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 as to the percentage of prescribers' offices that currently use and maintain paper forms versus electronic forms, or that scan paper files and maintain them electronically. Thus, for purposes of this PRA analysis, Commission staff will assume that all prescriber offices who opt for § 456.4(a)(1)(i) require a full minute per confirmation for recordkeeping, and that prescribers elect the § 456.4(a)(1)(i) paper prescription-delivery option 75% of the time (as explained above). The recordkeeping burden for all prescribers' offices to scan and save such confirmations would amount to 1,031,250 hours (75% × 82.5 million prescriptions yearly × one minute for scanning and storing/60mins) per year.

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[33] Section 456.4(a)(3) also requires that in the event that a patient declines to sign a confirmation requested under § 456.4(a)(1)(i), 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 § 456.4(a)(1)(i) require the same amount of time.

[34] *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).

[35] Additionally, 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.

(c) The incremental burden of obtaining and maintaining consents to digital prescription delivery

As noted previously, the second 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 the newly added § 456.3, in order to avail themselves of the second option, prescribers must obtain and maintain records or evidence of the patients' affirmative consent to electronic delivery for at least three years. The Commission will use the assumption that consumers sign such consents for electronic delivery for one quarter of the 82.5 million prescriptions released per year,[36] 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 assign 114,583 hours for the time required for prescribers' offices to obtain patients' affirmative consent to electronic delivery of their prescriptions[37] and 343,750 hours for the time to store and maintain such records.[38]

In total, the estimated incremental annual PRA recordkeeping burden for prescribers and their staff resulting from modifying the Rule to add the confirmation-of-prescription-release and consent-to-digital-release requirements amounts to 1,833,333 total hours (343,750 and 114,583 hours, respectively, to obtain patient signatures confirming release and consenting to electronic delivery, plus 1,031,250 and 343,750 hours, respectively, to maintain records of confirmation and digital-release consent for at least three years) for prescribers' offices. Adding the 1,833,333-hours incremental burden to the existing 1,375,000-hours burden derived from the longstanding prescription-release requirement yields a new total PRA disclosure and recordkeeping burden from the Rule of 3,208,333 hours for prescribers and their staff. This is an increase from the 2,979,167-hour burden estimate for the NPRM,[39] due to the Commission decision to double the estimated amount of time for patients to read, sign, and return confirmation forms and consents to digital delivery.

[36] 20,625,000 prescriptions (82.5 million prescriptions × 25%). In all likelihood this is a significant overestimate since prescribers do not need to obtain new patient consent to digital prescription delivery at every visit. Prescribers need only obtain consent to digital delivery for new patients, or after changing office prescription-delivery method (from, say, email prescription delivery to prescription delivery via portal). But the Commission does not possess reliable information as to the percentage of office visits that involve new customers as opposed to repeat visitors, or as to how often prescribers change their digital delivery method and thus would require new patient consents. Thus, the Commission will assume, for PRA burden calculation purposes, that every time a consumer receives a digital prescription, the prescriber's staff has collected a new signed consent.

[37] 20,625,000 prescriptions yearly × 20 seconds/60secs/60mins.

[38] 20,625,000 affirmative consents × one minute/60mins) for storing such records.

[39] NPRM, 88 FR at 283.

Estimated Annual Labor Cost: $149,691,431.

The Commission derives annual labor costs by applying appropriate hourly-cost figures to the burden hours described above. Since prescribers conduct patient examinations and formulate the prescriptions, the time spent releasing prescriptions to patients has traditionally been attributed for PRA purposes to prescribers, rather than their office staff. As for the task of obtaining patient confirmations and consent to electronic delivery, this could be performed by prescribers or their support staff. In the past, the task of collecting patient signatures was attributed to prescribers, but based on more recent conversations with prescribers and others in the industry, it has become evident that this task is more appropriately designated as performed by prescribers' office staff.[40] Therefore, the Commission will assume that prescribers release prescriptions to patients, but that prescribers' office staff perform the task of collecting patient signatures on confirmations and digital-release consents, and perform the labor pertaining to printing, scanning, and storing of such documents.

According to the U.S. Bureau of Labor Statistics ("BLS"), general office clerks earn an average wage of $20.94 per hour, optometrists earn an average wage of $68.75 per hour, and ophthalmologists—which are listed by BLS under "surgeons"—earn an average wage of $150.06 per hour.[41] Using the $20.94 average wage for office clerks, and the aforementioned estimate of 1,833,333 total annual hours for office staff to obtain signed patient confirmations and consents to digital prescription delivery and to store such documents, the Commission calculates an incremental annual burden of $38,389,993 from adding the confirmation of prescription release to the Eyeglass Rule.

Based on our knowledge of the industry, we assume that of the 1,375,000 prescriber-labor hours relating to the Rule's requirement to release a copy of the prescription to the patient, optometrists are performing 85% (1,168,750) of such hours and ophthalmologists are performing the remaining 15% (206,250) of such hours. Applying this to the BLS wage figures results in an annual prescriber-labor burden for the existing burden of releasing prescriptions of $111,301,438 ($80,351,563 for optometrists + $30,949,875 for ophthalmologists).

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[40] This is supported by, among other things, 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 (WS Transcript at 22, 28). *See also* Neville (WS 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?").

[41] Bureau of Labor Statistics, U.S. Department of Labor, May 2023 Occupational Employment Statistics (released on April 3, 2024), https://www.bls.gov/news.release/ocwage.htm.

Adding the $38,389,993 staff burden from the confirmation-of-prescription-release requirement to the $111,301,438 prescriber burden from the automatic prescription-release requirement already in place yields a total estimated annual labor cost burden for the Eyeglass Rule of $149,691,431. This is an increase from the total annual labor cost estimate of $122,528,562 in the NPRM.[42] The increase is due to the additional time allotted for obtaining patient signatures, and due to an increase in average wage rates for optometrists, ophthalmologists, and office clerks. As in the NPRM, however, the total estimated burden figure still constitutes less than one half of one percent of the estimated total retail market for eyeglass sales in the United States in 2022.[43] Furthermore, the actual burden is likely to be less, because—as noted *supra*—prescribers who do not have a financial interest in the sale of eyewear will not be required to obtain patient confirmations, many prescribers' offices will require less than a minute to store a confirmation form or patient consent to digital delivery, prescribers can use the same document to obtain confirmations for eyeglass prescriptions and contact lens prescriptions, and as more prescribers transition to digital prescription delivery, the overall burden will correspondingly decrease.

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 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 amended Rule will total approximately $70,000. This estimate is based on the assumption that 15-20% of one Attorney work year ($221,417) and 15-20% of one Investigator work year ($175,772) will be expended to enforce the Rule as amended. These estimates include employee benefits.

15. Reasons for Changes.

The amendments are a program change that will result in an estimated 3,208,333 annual burden hours, $149,691,431 in annual 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.

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[42] NPRM, 88 FR at 284.

[43] The Vision Council, Market inSights 2022. Total market value of eyeglass frames and lenses. Does not include exams, reading glasses, or contact lenses. The $149,691,431 cost of the Eyeglass Rule is 0.0042 of the total $35.6 billion market value. In the NPRM, the estimated burden of $122,528,562 amounted to 0.0050 of the then-total $24.3 billion market value. NPRM, 88 FR at 284, n. 450 and text.

17. OMB Not to Display Approval.

The OMB control number and expiration date associated with this Paperwork Reduction Act submission will be displayed on the Federal government's electronic Paperwork Reduction Act 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 "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.