FEDERAL TRADE COMMISSION

16 CFR Part 456
RIN 3084–AB37

Ophthalmic Practice Rules (Eyeglass Rule)

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking: request for public comment.

SUMMARY: The Federal Trade Commission (“FTC” or “Commission”) proposes to amend the Ophthalmic Practice Rules (“Eyeglass Rule” or “Rule”) to 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. The Commission also proposes to permit prescribers to comply with automatic prescription release via electronic delivery in certain circumstances. The Commission further proposes a clarification 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. Finally, the Commission proposes to amend the term “eye examination” to “refractive eye examination” throughout the Rule. The Commission seeks comment on these proposals.

DATES: Written comments must be received on or before March 6, 2023.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the SUPPLEMENTARY INFORMATION section below. Write “Eyeglass Rule, Project No. R511996” on your comment, and file your comment through https://www.regulations.gov. If you prefer to file your comment on paper, write “Eyeglass Rule, Project No. R511996” on your comment and on the envelope and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex C), Washington, DC 20580.


SUPPLEMENTARY INFORMATION: The Commission finds that using the procedures set forth in this notice of proposed rulemaking will serve the public interest by supporting the Commission’s goals of clarifying and updating existing regulations without undue expenditure of resources, while ensuring that the public has an opportunity to submit data, views, and arguments on whether the Commission should amend the Rule. The Commission, therefore, has determined, pursuant to 16 CFR 1.20, to use the following procedures: (1) publishing this notice of proposed rulemaking; (2) soliciting written comments on the Commission’s proposals to amend the Rule; (3) holding a workshop; and (4) announcing final Commission action in a document to be published in the Federal Register.

The Commission will host a workshop to gather additional public input regarding the proposed changes. After publishing this notice of proposed rulemaking (“NPRM”), the Commission will publish a document in the Federal Register announcing the workshop and providing instructions on how interested persons may request an opportunity to participate.

The Commission, in its discretion, has not chosen to schedule an informal hearing and has not made any initial designations of disputed issues of material fact necessary to be resolved at an informal hearing. The Commission believes that a workshop will provide sufficient opportunity for obtaining additional public input on its proposal. Interested persons who wish to make an oral submission at an informal hearing must file a comment in response to this NPRM and submit a statement identifying their interests in the proceeding and describing any proposals regarding the designation of disputed issues of material fact to be resolved at the informal hearing, on or before March 6, 2023. 16 CFR 1.11. Such requests, and any other motions or petitions in connection with this proceeding must be filed with the Secretary of the Commission.

Table of Contents

I. Background
A. Overview of the Eyeglass Rule
B. History of the Rule
1. Eyeglass I Report and Rule
2. Eyeglass II Report and Rule
3. The 1997 to 2004 Eyeglass Rule Review
4. The 2015 to 2020 Contact Lens Rule Review
C. The Evolving Eyeglass Marketplace
D. State Regulation of the Sale of Eyeglasses
II. Eyeglass Rule Review
A. Evidentiary Standard
B. Overview of Comments in Response to ANPR
III. Requirements for Eyeglass Sellers
IV. Section 456.2—Separation of Examination and Dispensing

A. Automatic Prescription Release
1. Comments on Whether To Retain Automatic Prescription Release
2. Compliance With the Automatic Prescription Release Requirement
3. Evidence Regarding Consumers’ Awareness of Their Right To Receive Their Prescription
4. Analysis of Evidence Regarding Automatic Prescription Release Provision
5. Proposals for Improving Compliance and Consumer Awareness
   a. Proposal To Increase Enforcement
   b. Proposal To Require an Eye Care Patients’ Bill of Rights
   c. Proposal To Require Signage
   d. Proposal To Require a Confirmation of Prescription Release
6. The Commission’s Proposal To Require a Signed Confirmation of Prescription Release
B. Other Issues Surrounding Patients’ Access To Eyeglass Prescriptions
1. Prescriber Responsibilities To Provide Additional Copies of Prescriptions
   a. Analysis of Whether To Require Provision of Additional Copies of Prescriptions Upon Request
b. Analysis of Whether To Permit Prescribers to Charge Fees for Provision of Additional Copies of Prescriptions
2. Electronic Delivery of Prescriptions as a Means for Automatic Prescription Release Under Section 456.2(a)
   a. The Commission’s Proposal To Add a Definition to Section 456.1 To Permit Electronic Delivery of the Patient’s Prescription
b. Technological Advances That May Improve Prescription Portability
   c. HIPAA Concerns Regarding Emailed Prescriptions
3. Insurance Coverage as Payment Under Section 456.2(a)
C. Requiring Prescribers To Respond to Authorized Third-Party Seller Requests for a Copy of Prescription or Verification of Prescription Information
   1. Comments on Requiring Prescriber Response to Third-Party Seller Requests
   2. Analysis of Whether To Amend the Rule To Require Prescriber Response
V. Prescription Requirements
A. Requiring Prescribers To Include Pupillary Distance on Eyeglass Prescriptions
  1. Comments on Whether To Require Pupillary Distance
  2. Analysis of Whether To Amend the Rule To Require Pupillary Distance
B. Amending the Rule To Set an Expiration Date for Eyeglass Prescriptions
C. Amending Other Rule Definitions
VI. Recommendations Regarding the Commission’s Complaint System
VII. Request for Comment
VIII. Communications by Outside Parties to the Commissioners or Their Advisors
IX. Paperwork Reduction Act
A. Estimated Burden
B. Estimated Labor Cost
C. Capital and Other Non-Labor Costs
X. Preliminary Regulatory Analysis and Regulatory Flexibility Act Requirements
A. Description of the Reasons the Agency Is Taking Action
B. Statement of the Objectives of, and Legal Basis for, the Proposed Amendments
C. Small Entities to Which the Proposed Amendments Will Apply
D. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed To Comply
E. Duplicative, Overlapping, or Conflicting Federal Rules
F. Significant Alternatives to the Proposed Amendments

Proposed Rule Language

I. Background

A. Overview of the Eyeglass Rule

The Eyeglass Rule declares it an unfair practice for an ophthalmist or optometrist to fail to provide a patient with a copy of the patient’s eyeglass prescription immediately after an eye examination is completed. The prescriber may not charge the patient any fee in addition to the prescriber’s examination fee as a condition to releasing the prescription to the patient. The Rule defines a prescription as the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.

The Rule prohibits an ophthalmist or optometrist from conditioning the availability of an eye examination on a requirement that the patient agree to purchase ophthalmic goods from the ophthalmologist or optometrist. The Rule also deems it an unfair practice to require prescribers to give patients copies. The prescriber may withhold a prescription, or require the patient to sign, or deliver to the patient, a waiver or disclaimer of prescriber liability or responsibility for the accuracy of the exam or the ophthalmic goods and services dispensed by another seller.

B. History of the Rule

The FTC has decades of regulatory and research experience with the optical goods industry, which continues to inform the basis and purpose of the Rule and this NPRM. The Commission’s engagement in the industry predates formal adoption of the Eyeglass Rule. In 1962, the Commission first took steps to protect consumers and foster competition in the sale of eyeglasses by adopting the “Guides for the Optical Products Industry,” which included a provision declaring it an unfair trade practice to “tie in or condition” refraction services to the dispensing of eyeglasses when such a practice has a “reasonable probability” of harming competition. Among the conduct considered unfair were charging a higher or additional fee if the patient wanted to take the prescription elsewhere to buy eyeglasses, and refusing to perform examinations if the patient wanted to take the prescription elsewhere. The Guides were not binding, however, and the FTC never undertook litigation to enforce them, even though prescribers routinely violated the directives.

1. Eyeglass I Report and Rule

On September 16, 1975, the Commission directed its staff to examine the retail ophthalmic market, including whether prescribers were tying eyeglass dispensing to examination, and whether such practices harmed consumers. Staff surveyed state laws and regulations, and solicited comment from a variety of interested parties, including ophthalmic licensing boards, professional associations, and consumer groups.

The Commission then sought comment on a proposed rule to eliminate certain advertising restraints on ophthalmic goods and services, and indicated that if evidence showed that consumers were being prevented from price shopping—due to the unavailability of prescriptions—the Commission might require prescribers to give patients copies. FTC staff subsequently released its Eyeglass I Report detailing practices that prescribers used to discourage consumers from taking prescriptions to be filled elsewhere, including (1) outright refusal to release prescriptions or refusal to conduct examinations unless the patient agreed to purchase eyeglasses; (2) charging an additional fee as a condition to releasing the prescription; and (3) conditioning the release of the prescription on the patient signing a release or waiver of liability. Staff explained that significant evidence—including testimony from optometrists, patients, and consumer groups, as well as prescriber surveys and published statements from boards of optometry and opticians—established that such practices were a serious and pervasive problem.

The Report concluded that refusal to release prescriptions, or placing conditions on their release, constituted an unfair act or practice, and recommended that the Commission promulgate a rule “insuring consumers unconditional access to their ophthalmic prescriptions.”

On June 2, 1978, the Commission issued the Advertising of Ophthalmic Goods and Services Rule (the “Eyeglass I Rule”), which, among other things, contained a provision titled “Separation of Examination and Dispensing” requiring prescribers to automatically release prescriptions to their patients—regardless of whether or not the patients requested them—to ensure consumers unconditional access to their prescriptions so they could comparison-shop for eyeglasses. In the Rule’s Statement of Basis and Purpose, the Commission explained that evidence conclusively established that consumers suffered substantial economic loss through the imposition of surcharges for obtaining their prescriptions, and through lost opportunity costs arising from an inability to comparison-shop for eyeglasses. Furthermore, the Commission found that prescribers’ use of waiver notices and disclaimers deceived consumers as to the capabilities of other optical dispensers, and further restricted purchase options. Such practices offended public policy in that they denied consumers the ability to effectively use available information.

2 16 CFR 456.2(c). The Rule thereby also prohibits conditioning the release of the prescription on the requirement that the patient purchase ophthalmic goods from the ophthalmologist or optometrist.

5 16 CFR 456.2(d).

10 Eyeglass I Report, supra note 6, at 235–36.
11 Id.
12 Id.
13 Id. at 241. With respect to liability waivers and releases, the Eyeglass I Report concluded that there could be “little doubt” that their primary intent was to discourage or dissuade consumers from taking their eyeglass prescriptions elsewhere to be filled. Id. at 277.
14 Id. at 241–45, 252–54.
15 Id. at 259, 263–65.
16 Eyeglass I Rule, 43 FR 23992, 23998, 24007–08.
17 Id. at 24003.
18 Id.
and inhibited competition in retail eyeglasses markets.\textsuperscript{19} Following the 1980 Staff Report, the Commission sponsored a survey to determine to what extent prescribers were complying with the Rule. The survey, commonly known as the “Market Facts Study,” found that only about one-third of prescribers automatically provided patients with prescriptions.\textsuperscript{22} Thus, the majority of prescribers were not in compliance. The survey also found that only 38 percent of consumers knew they were entitled to receive their prescription automatically.\textsuperscript{28} The survey found, however, that when consumers requested their prescriptions, by and large prescribers no longer refused to release them,\textsuperscript{29} and that a majority of consumers had become “generally knowledgeable” about the availability of eyeglass prescriptions, appearing to know they could request one.\textsuperscript{30} Five years later, the Commission again reviewed the Rule and sought comment on whether consumers were aware of their right to obtain their prescription, and whether the automatic release provision ought to be terminated, changed to release upon request, or changed to require that prescribers simply “offer” patients their prescriptions rather than automatically provide them.\textsuperscript{32} After public hearings, the hearing officer issued a report to the Commission (“Presiding Officer’s requirement to cover eyeglass dispensers, so that opticians—as well as optometrists and other eyeglass dispensers—would be required to return prescriptions to patients after fabricating the eyeglasses. Id. at 133, 260–61. The aim of staff’s proposal was to guarantee patients access to their prescriptions even after they had been filled, and to ensure that consumers retained a copy so they could obtain duplicate glasses later without having to return to their original prescriber or eyeglass dispenser. Id. at 134, 261–64. Staff later reversed course on this proposal, however, after determining that there was insufficient evidence that dispensers were refusing to return prescriptions to patients. The Commission chose not to adopt the proposal. See “Ophthalmic Practice Rules: State Restrictions on Commercial Practice,” 250, 300–62 (1986), https://www.ftc.gov/reports/ophthalmic-practice-rules-state-restrictions-commercial-practice-eyeglasses-ii-report-staff [hereinafter Eyeglass II Report]; Final Trade Regulation Rule, Ophthalmic Practice Rules, 54 FR 10285, 10303 [Mar. 13, 1989] [hereinafter Eyeglass II Rule].

2. Eyeglass II Report and Rule

Following the court’s remand of the Eyeglass I Rule, FTC staff conducted further investigation, and in 1980 issued a staff report entitled “State Restrictions on Vision Care Providers: The Effects on Consumers” (“1980 Staff Report”).\textsuperscript{25} The 1980 Staff Report did not make recommendations regarding the automatic prescription release provision, but instead suggested the Commission seek comment on whether to change it to release upon request, or to sunset the release requirement altogether.\textsuperscript{26}
The 1997 to 2004 Eyeglass Rule Review

In 1997, as part of its systematic review of its rules and regulations, the Commission again requested comment on whether the Rule’s prescription release requirement should be retained, modified, or eliminated. The Commission received comments from numerous parties but withheld taking action while it considered whether contact lenses should be covered by the Rule. Ultimately, after Congress passed the Fairness to Contact Lens Consumers Act (“FCCLA”), the Commission issued a separate Contact Lens Rule (“CLR”) with prescription release requirements similar, in most respects, to those required by the Eyeglass Rule. When the Commission turned again to the Eyeglass Rule and its prescription release requirement, it held that evidence in the rulemaking record suggested that prescribers continued to refuse to release eyeglass prescriptions, even though such conduct had been unlawful for nearly 25 years. The Commission opined that were it to eliminate the prescription release requirement, even more prescribers might refuse to release prescriptions and thereby benefit from inducing patients to purchase eyeglasses from them. Due to this possibility, and because it found the release of prescriptions enhances consumer choice at minimal compliance cost to prescribers, the Commission opted to retain the prescription release requirement.

Furthermore, after reviewing the record and finding that some consumers still were not aware of their right to obtain their prescription, the Commission decided not to modify the Rule to require release upon request. The Commission stated that absent automatic release, consumers unaware of their right would not know to request their prescription, or their prescriber might discourage them from doing so. In light of these considerations, the Commission determined to retain the Rule in its existing form. In so doing, the Commission also ensured that prescription release requirements for eyeglasses would align with those for contact lenses under the Contact Lens Rule.

The 2015 to 2020 Contact Lens Rule Review

As part of its periodic review of rules and guides, the Commission, on September 3, 2015, initiated a review of the Contact Lens Rule, including its prescription release requirement. While the Contact Lens Rule differs from the Eyeglass Rule in some respects, many of the issues and concerns regarding prescription release and portability are the same, and therefore some of the comments and data submitted during the CLR review are pertinent to the Commission’s review of the Eyeglass Rule.

During its review of the CLR, the Commission considered more than 8,000 public comments as it put forth a notice of proposed rulemaking and supplemental notice of proposed rulemaking before issuing an amended final rule on August 17, 2020. In its CLR final rule, the Commission determined that the evidentiary record, as well as the Commission’s enforcement and oversight experience, supports the view that prescriber compliance with the automatic prescription release requirement is sub-optimal, and, as a result, that millions of consumers are still not receiving their contact lens prescriptions as required by law.

The Commission further found that many consumers remain unaware that they even have a right to receive their prescriptions. To remedy this, the Commission implemented a Confirmation of Prescription Release provision, requiring that prescribers request that a patient confirm receipt of their contact lens prescription. According to the Commission, the patient confirmation requirement should result in, among other things, an increase in the number of patients in possession of their contact lens prescription and improved flexibility and choice for consumers, ultimately fostering improved competition in the market, more efficient contact lens sales, and lower prices for consumers.

The Commission also noted that the requirement would increase the Commission’s ability to enforce and assess the CLR.

C. The Evolving Eyeglass Marketplace

The retail vision care industry in the United States consists of several different kinds of participants, namely ophthalmologists, optometrists, opticians, and eyewear retailers. The services provided by these different participants often overlap, and the different participants often have business affiliations with each other. Ophthalmologists are medical doctors who specialize in treating diseases of the eye. They are the only eye care professionals who can treat all eye and vision system diseases, perform eye surgery, prescribe nearly all manner of drugs, and use any treatment available to licensed physicians. Ophthalmologists can prescribe and sell eyeglasses and contact lenses, and their offices may be attached to an associated optical dispensary. Ophthalmologists have typically completed four years of medical school, a year of general internship, and an additional three years of specialized hospital residency training in ophthalmology. It is estimated that there are approximately 19,000 active ophthalmologists in the United States. Many ophthalmologists, especially those who further specialize, do not sell eyewear, although some do.

Continued
Optometrists are doctors of optometry. They have not completed medical school, but have instead completed four years of training in optometry school, following three or more years of college. They are trained and licensed to examine eyes, diagnose refractive problems, prescribe and dispense eyeglasses and contact lenses, and detect eye disease. As with ophthalmologists, optometrists can prescribe and sell eyeglasses and contact lenses, and their offices are often attached to, or part of, an associated optical dispensary. A government estimate indicates that in 2020 there were approximately 43,000 active optometrists in the United States. While professional services, such as eye health and refraction examinations, generate significant revenue for optometrists, most optometrists still derive a larger percentage of their income from product sales, including the sale of eyeglasses and contact lenses. According to some estimates, product sales typically account for 55 to 65 percent of optometrist revenue.

Opticians, also known as dispensing opticians or ophthalmic dispensers, act primarily as retail providers of eyeglasses and contact lenses. Opticians fabricate, fit, adjust, and repair eyeglasses, primarily on the basis of prescriptions issued by optometrists and ophthalmologists. Opticians typically are not authorized to examine eyes to determine prescriptions, but may conduct pupillary distance examinations in order to fit a pair of eyeglasses to an individual. Twenty-one states currently require opticians to obtain licenses, usually through a state-approved course of study and completion of an exam. The remaining states have no formal requirements for practice, but many opticians in these states complete an apprenticeship or training. A 2020 government estimate indicates that there are approximately 70,000 active opticians in the United States.

Eyewear retailers are companies and independent merchants that sell eyeglasses. They are often owned by, employ, or associate themselves with, ophthalmologists, optometrists, and opticians. Some are considered independent optical retailers (defined as a retailer with three or fewer locations that has an optometrist, optometrist, or optical retailer on site), while others may be optical chain stores, such as LensCrafters and America’s Best, mass merchandisers, such as Costco and Sam’s Club, department stores, such as Macy’s, or online entities, such as Warby Parker and Zenni Optical.

The overall retail eyeglass market continues to experience growth in both the number of eyeglass wearers as well as the number of eyeglasses purchased. As of December 2019, approximately 165 million American adults were regularly wearing prescription eyeglasses, representing nearly two-thirds of the country’s adult populace. In addition, some 30 percent of eyeglass wearers used two or more pairs interchangeably on a regular basis. Overall, in 2019, consumers purchased approximately 79 million pairs of eyeglass frames, and 88 million pairs of lenses for a total sales volume of roughly $10 billion in frames and $14.3 billion in lenses. Of total sales, the largest portion—at least in terms of dollars spent—occurred at independent optical retailers, who accounted for approximately 50 percent of U.S. eyeglass frame and lens sales in 2019. Conventional optical chain stores accounted for approximately 27.5 percent of eyeglass frame and lens sales (in dollars), and mass merchandisers accounted for approximately 10 percent of eyeglass frame and lens sales (in dollars).

Optical sales of eyeglasses remain a small portion of the optical market. According to one industry publication, as of June 2019 just five percent of sales (in dollars) of eyeglass frames derived from online sales during the previous year. Consumers purchased approximately seven and a half million pairs of frames online, representing about 9.4 percent of all pairs of frames sold, in the 12 months ending June 2019. Although online sales are still relatively small, they continue to increase steadily. Total online sales (in dollars) for all vision care products rose 7.7 percent between mid-2018 and 2019, while online sales (in dollars) of frames grew 8.1 percent and of prescription lenses grew 10.8 percent in 2019.

A primary driver for the increase in online sales may be lower pricing. According to an industry source, as of 2015 online sellers were typically 50 to 60 percent less expensive than brick and mortar eyeglass retailers.

In 1975, American consumers purchased approximately 53 million pairs of prescription eyeglasses. Eyeglass I Report, supra note 6, at 11–12.


75 Id. at 18–19.

76 Id. Optical centers in department stores accounted for approximately two percent of all eyeglasses sold, in 2019.


79 See id. at 6.


number of consumers to shop for eyeglasses online, or to delay eyewear purchases altogether, but the long-term impact of the pandemic on consumer purchasing decisions is unknown. A study commissioned by The Vision Council showed that, in March 2020, when the World Health Organization declared COVID–19 a pandemic, over 25% of consumers stated an intention to buy eyewear online to limit human interaction and physical contact, more than double the number who planned to shop online before COVID–19.42

D. State Regulation of the Sale of Eyeglasses

As detailed above, the purpose of the Eyeglass Rule is to facilitate consumer choice and foster competition by separating the functions of the eye examination and the dispensing of prescribed eyeglasses. The Rule accomplishes this separation by requiring that prescribers provide consumers with a copy of their eyeglass prescription at the conclusion of the eye examination, and by prohibiting certain restrictions on the release of the prescription. The Eyeglass Rule, however, regulates only the release of the eyeglass prescription, and does not regulate other aspects of the practice of ophthalmology, optometry, or opticianry.83

State laws and regulations govern most aspects of professional practice and eyewear sales. Typically, individual state licensing boards are responsible for the licensing and oversight of ophthalmologists, optometrists, and opticians and, often, the dispensing of prescribed eyeglasses. These state regulatory frameworks vary widely. Some states have comprehensive regulatory frameworks that govern every aspect of dispensing prescribed eyeglasses: such regulations set forth the required components of an eyeglass prescription, the length and expiration date of an eyeglass prescription, and the allowable modes to transmit eyeglass prescriptions, as well as recordkeeping requirements.4 Other states regulate less comprehensively. For example, some states require opticians to dispense eyeglasses only upon the written prescription of a prescriber,45 while other states allow flexibility.46 Further, some states that require a prescription for the sale of eyeglasses do not explicitly set forth specific components of an eyeglass prescription.47

State regulatory frameworks also differ on expiration dates for eyeglass prescriptions: some states require that eyeglass prescriptions expire within a certain period;48 some states mandate that prescriptions be valid for a certain amount of time;49 other states leave that determination to the prescriber;50 while still other states are silent on the issue.51

II. Eyeglass Rule Review

A. Evidentiary Standard

The Commission promulgated the Eyeglass Rule under 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.92 When amending or repealing the Rule, the Commission must follow the same section 18 procedures governing the adoption of rules,53 and in doing so, engages in a multi-step inquiry. To make a determination that a practice is unfair, the Commission evaluates the following questions: (1) Does the act or practice cause or is it likely to cause substantial injury to consumers? (2) Is the injury to consumers outweighed by countervailing benefits that flow from the act or practice at issue? and (3) Can consumers reasonably avoid the injury? 94

If an act or practice is deemed unfair, the Commission may issue a notice of proposed rulemaking under section 18 only where it has “reason to believe” that the unfair act or practice at issue is “prevalent.”95 The Commission can find prevalence where information available to it indicates a widespread pattern of unfair or deceptive acts or practices.96 Once the Commission finds that an unfair act or practice is prevalent, it has wide latitude in fashioning a remedy and need only show a “reasonable relationship” between the unfair act or practice and the remedy.97

In making this proposal, the Commission has relied on a record that includes public comments received in response to the Commission’s 2015 advance notice of proposed rulemaking (“ANPR”) that initiated this rule review.98 and incorporates the rulemaking record for the 2020 amendments to the CLR to the extent that record provides information pertinent to the prescription release provision of the Eyeglass Rule.99

---


88 DC Mun. Regs. tit. 17, § 6416.1 (expiration of 1 year after the issue date unless there is a medical reason that warrants a prescription for less than 1 year); Fla. Stat. Ann. § 463.012 (eyeglass prescriptions shall be considered valid for a period of 5 years).

89 Cal. Bus. & Prof. Code § 2541.1 (“The expiration date of a spectacle lens prescription shall not be less than two to four years from the date of issuance unless medical reason for earlier recommission.”); Mich. Comp. Laws Ann. § 333.5557 (setting expiration date of no less than 1 year from the date of the examination unless medical reason for shorter time).

90 852 Ind. Admin. Code 1–5–1 (stating it is the optometrist’s responsibility to determine the expiration of the prescription.); Kan. Admin. Regs. §§ 65–4–4 (requiring prescriber to include on the prescription the “expiration date, if appropriate”).

91 Ark. Code Ann. § 17–90–108(A)(3) (providing expiration term for contact lens prescriptions, but not for eyeglass prescriptions); Wis. Admin. Code Opt § 5.02 (providing that a contact lens prescription must contain the date of expiration, making no mention of the expiration of eyeglass prescriptions).


95 Am. Fin. Servs. Ass’n v. FTC, 767 F.2d 957, 988 (D.C. Cir. 1985) (quoting Jacob Siegel Co. v. FTC, 327 U.S. 608, 612–13 (1946)).

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

97 The 2020 Contact Lens Rulemaking record includes comments to the CLR RFC, the CLR NPRM, the Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule; Public Workshop and Request for Public Comment, 82 FR 57889 (Dec. 8, 2017) [hereinafter CLR WS]; and the CLR SNPRM. Public comments received in response to these notices are available on Regulations.gov.


Continued
Commission has also examined the state of the marketplace and the content of consumer complaints about prescriber practices. Further, the Commission remains cognizant of the lengthy history and record that supported the enactment of the Eyeglass Rule and the CLR. Based on the entire record for the Rule, the Commission has reason to believe that prescribers’ failure to automatically provide consumers with prescriptions at the completion of an eye exam—held to be an unfair act or practice when the Eyeglass Rule was enacted—remains prevalent, and millions of Americans every year are not receiving their eyeglass prescriptions as required by law. The Commission also believes that a risk of significant harm to consumers continues to exist and that, without the Rule’s requirements, consumers could not reasonably avoid the injury resulting from the unfair acts and practices prohibited by the Rule. Further, the Commission believes that documentation of prescription release is necessary to better effectuate compliance with, as well as enforcement of, the Rule. Consequently, the Commission proposes amending the Rule to implement a Confirmation of Prescription Release requirement similar to that now required by the CLR.100 Pursuant to these amendments, prescribers would be required to do one of the following:

(i) Request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription;

(ii) Request that the patient sign a prescriber-retained copy of a prescription that contains a statement confirming receipt of the prescription;

(iii) Request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming receipt of the prescription; or

(iv) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable. The Commission’s proposal provides sample language for confirmation options (i), (ii), and (iii), but also allows prescribers to craft their own wording of the signed confirmation for these options if they so desire. As with the CLR’s Confirmation requirement, the proposed Confirmation of Prescription Release requirement for eyeglass prescriptions would apply only to prescribers with a direct or indirect financial interest in the sale of eyeglasses.

The Commission believes that the proposed amendment will prevent consumer harm, and that the proposed amendment is necessary to remedy demonstrated failures of some providers to automatically release prescriptions at the completion of an eye examination, and to ensure a competitive marketplace for eyeglasses. The Commission notes that providers who comply with the automatic release provision of the Rule may face a competitive disadvantage because of the widespread non-compliance of other providers. This creates an unlevel playing field and undermines competition. The Commission is sensitive to any additional burden or cost that this rule change imposes on business. However, it believes that this proposal maximizes the benefits of comparison-shopping with a relatively small burden or cost on business. The potential benefit of increasing the number of patients in possession of their eyeglass prescriptions is substantial: namely, increased flexibility and choice for consumers; a reduced likelihood of errors associated with incorrect, invalid, and expired prescriptions, and consequently, improved patient safety; and an improved ability for the Commission to enforce and monitor prescriber compliance with the Rule’s prescription release requirements.

The proposed rule would also align the prescription release related provisions of the Rule with the CLR, thereby reducing confusion and complexity that might arise for consumers and prescribers from having different prescription release requirements for eyeglass and contact lens prescriptions. In addition, because the CLR already obligates ophthalmologists and optometrists to release contact lens prescriptions, to obtain a confirmation, and to maintain records, the marginal cost of the proposed amendment to the Eyeglass Rule would be extremely low. Prescribers likely have forms and systems in place already, which may need only minor adjustments to accommodate confirmations for eyeglasses prescriptions.

The Commission also proposes permitting prescribers to comply with automatic prescription release via electronic delivery in certain circumstances.101 The Commission does not propose, at this time, to implement other recommendations about which it requested comment in the ANPR, including requiring prescribers to provide duplicate copies of prescriptions to patients; to provide a copy of a prescription to, or verify a prescription with, third-party sellers; or to add pupillary distance to prescriptions.

B. Overview of Comments in Response to ANPR

In September 2015, as part of its routine review of Commission rules and guides, the Commission published the ANPR seeking public comment on, among other things: the continuing need for the Rule; the Rule’s economic impact and benefits; possible conflict between the Rule and state, local, or other federal laws or regulations; and the effect on the Rule of any technological, economic, or other industry changes. The Commission also sought comment on the following specific questions: should the definition of “prescription” be modified to include pupillary distance; should the Rule be extended to require that prescribers provide their patients with a duplicate copy of a prescription; and should the Rule be extended to require that a prescriber provide a copy to or verify a prescription with third parties authorized by the patient?102 This notice of proposed rulemaking summarizes the comments received in response to the ANPR and explains why the Commission believes that the Eye examination is necessary. It also explains why the Commission is proposing certain amendments and why it declines to propose others. Additionally, it seeks additional comment on certain questions. Finally, the NPRM sets forth the Commission’s regulatory analyses under the Regulatory Flexibility and Paperwork Reduction Acts, as well as the text of the proposed amendments.

The Commission received 868 comments in response to the ANPR from a variety of individuals and entities, including ophthalmologists, optometrists, opticians, trade associations, consumers (and representatives of consumers), and eyeglass sellers.103 Virtually all of the

101 See Section IV.B.2.a, infra. The Commission also clarifies 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 under 16 CFR 456.2(a), a clarifying, technical rule amendment. See Section IV.B.3, infra. The Commission further clarifies that the term “eye examination” used in the Rule refers to a refractive eye examination. See Section V.C, infra.

102 Eyeglass Rule ANPR, 80 FR 53274, 53276.

103 The comments are posted at https://www.regulations.gov/document/FTC-2015-0095-0001. This document cites comments from the
comments supported retaining the Rule. Some commenters, including trade associations that represent opticians and retailers that employ optometrists and opticians, stated that the Rule is needed because some prescribers still are not automatically releasing prescriptions and some consumers face resistance when they try to obtain their prescriptions. The AOA, which represents approximately 33,000 doctors of optometry, questioned the continued need for the Rule based on its understanding that doctors of optometry widely comply with the Rule’s requirements, but stated that the Rule—currently drafted—is not necessarily harmful.

Warby Parker, a large online eyeglasses retailer, and a few consumers indicated their belief that ordering eyeglasses online is a good option as it provides consumers with an affordable and convenient choice. Some indicated their support for Rule changes that would permit online sales to occur with greater ease. Specifically, some commenters supported the Eyeglass Rule ANPR using the comment number assigned by Regulations.gov without the preceding identification “FTC–2015–0095.” The citations also include for comments submitted by individuals, the last name of the commenter; and for comments submitted on behalf of organizations, the name of the organization and the last name of the individual submitting on behalf of the organization. For instance, the full comment number assigned by Regulations.gov to the comment submitted by an individual named Publ is FTC–2015–0095–0040. In this document, that comment is cited as “Public (Comment #0040)”.

104 See, e.g., Opticians Association of Virginia (Comment #0647 submitted by Nelms) (stating that patients are becoming complicit before paying for their exam and requesting the Rule be amended to include language that the prescription be given to the patient without additional sales pressure or intimidation); Opticians Association of Ohio (Comment #0686); NAOO (Comment #0748 submitted by Cutler); Professional Opticians of Florida (Comment #0803 submitted by Coach). Other commenters more generally stated their support for the Rule. See Publ (Comment #0040); Santini (Comment #0047); Costa (Comment #0068); Ellis (Comment #0189); Hildebrand (Comment #0220); Prevent Blindness (Comment #0385 submitted by Parry); DiBlasio (Comment #0441); Pulido (Comment #0191); Stuart (Comment #0841).

105 Comment #0849 submitted by Peele: see also Barnes (Comment #0433) (stating she complies with the Rule although it is unnecessary since any ethical doctor will release a non-expired prescription to a patient); Kanovsky (Comment #0364) (optometrist states she and the prescribers she knows comply with the Rule).

106 Warby Parker, which began as an online-only eyeglasses retailer, and a few consumers indicated their belief that ordering eyeglasses online is a good option as it provides consumers with an affordable and convenient choice. Some indicated their support for Rule changes that would permit online sales to occur with greater ease. Specifically, some commenters supported the Eyeglass Rule ANPR using the comment number assigned by Regulations.gov without the preceding identification “FTC–2015–0095.” The citations also include for comments submitted by individuals, the last name of the commenter; and for comments submitted on behalf of organizations, the name of the organization and the last name of the individual submitting on behalf of the organization. For instance, the full comment number assigned by Regulations.gov to the comment submitted by an individual named Publ is FTC–2015–0095–0040. In this document, that comment is cited as “Public (Comment #0040)”.

107 See, e.g., DeMuth, Jr. (Comment #0055); Jozwik (Comment #0002); Schwartz (Comment #0514); Opticians Association of Virginia (Comment #0647 submitted by Nelms); Pulido (Comment #0019); Warby Parker (Comment #0817 submitted by Kumar); see also NAOO (Comment #0748 submitted by Cutler); Professional Opticians of Florida (Comment #0803 submitted by Couch); Optometrists (Note Only) (Comment #0853 submitted by Daliek).

108 See, e.g., Tedesco (Comment #0042) (signage); Warby Parker (Comment #0817 submitted by Kumar) (bill of rights and signage).

109 Tedesco (Comment #0042) (signage); Warby Parker (Comment #0817 submitted by Kumar) (bill of rights and signage). See, e.g., Hildenbrand (Comment #0049) (expiration); Fainzilberg (Comment #0051) (pupillary distance); Wintersmute (Comment #0067) (pupillary distance); Cordivari (Comment #0069) (expiration); Dickens (Comment #0176) (pupillary distance); O’Dea (Comment #0188) (pupillary distance); Nystrom (Comment #0254) (expiration); Mozans (Comment #0310) (expiration); Buntin (Comment #0529) (expiration); Morel (Comment #0712) (expiration); Warby Parker (Comment #0919) (expiration and pupillary distance).

110 See, e.g., Pentecost (Comment #0626); Bolenbaker (Comment #0633); McWilliams (Comment #0635); Cervantes (Comment #0671); Harrison (Comment #0725); Ambler (Comment #0025).

111 AOA (Comment #0849 submitted by Peele); Pentecost (Comment #0626); McWilliams (Comment #0635); Nellis (Comment #0725); Diener (Comment #0017). The AOA also stated its concern that some online retailers may be using foreign manufacturers with questionable labor standards. Comment #0849.

112 The AOAs stated that the Rule should not require prescribers to provide additional copies of prescriptions to consumers because prescribers must be allowed to use their clinical judgment to determine whether it is appropriate to provide additional copies after the eye exam was performed. The organization also questioned the FTC’s authority to add a requirement to the Rule mandating that prescribers respond to authorized third-party requests. The American Academy of Ophthalmology (“AAO”), the largest national membership association of ophthalmologists, stated that it was unaware of any significant issues with consumers receiving duplicate copies of their prescriptions from ophthalmologists, noting that its members put significant time and resources into ensuring patients receive prescriptions in a timely manner and traditionally provide duplicates without charge.

Further, the AOA, the AAO, and individual prescribers commented that the Rule should not require that a prescription include pupillary distance, because, among other reasons, they believe this measurement is part of the dispensing of eyeglasses, and not part of a refractive examination. Prescribers also generally did not support having an expiration date of more than one year for eyeglasses, or requested that the FTC defer to state law and the medical judgment of prescribers to determine if and when a prescription should expire.

A number of optician groups commented that the Rule should require that eyeglass dispensers only sell eyeglasses after obtaining a copy of a prescription, or verifying a prescription with the prescriber, to ensure the safety of their patients. They also largely did not want the Rule to require that...
prescriptions include pupilary distance because they prefer to take this measurement and not be required to follow a measurement taken by the prescriber. In addition, although many opticians stated a preference for a one-year expiration date, they did not object to a two-year expiration period unless a medical reason exists for requiring a shorter period of time.

III. Requirements for Eyeglass Sellers

Although the Eyeglass Rule imposes certain requirements and limitations on prescribers—namely that they automatically release eyeglass prescriptions and do not charge fees or demand liability waivers for doing so—the Rule does not otherwise regulate the sale of eyeglasses. In this respect, the Eyeglass Rule diverges from the Contact Lens Rule. For example, among other things, the CLR provides that a dispenser may only sell contact lenses in accordance with a valid prescription that is either presented to the seller or verified by the prescriber. The CLR is based on the language Congress set forth in the FCLCA, 15 U.S.C. 7603, whereas the Eyeglass Rule is more narrowly tailored and does not regulate the terms of sale for eyeglasses. The Commission’s September 3, 2015 ANPR did not specifically request comment on this issue. However, in response to the Commission’s request for feedback on general issues, including its request for modifications to the Rule that may increase benefits to consumers, some commenters offered their views on this topic, with many opining that the FTC should more closely regulate eyeglass sales.

In particular, the Opticians Association of America, a national organization of opticians with over 10,000 members, commented that to ensure patient safety, the Commission should mandate that all sellers only sell eyeglasses after obtaining a copy of the prescription, or after verifying the prescription information with a prescriber.

Some commenters also stated that eyeglasses sold online are inferior in quality, or may come with an incorrect prescription. The Opticians Association of America, Inc., for example, commented that much of the eyewear sold online “does not meet national tolerance standards,” and asserted that consumers often rely on brick and mortar dispensers to remedy problems stemming from poorly manufactured eyeglass products purchased online.

The Opticians Association of America and others commented that consumers’ eye health may be negatively affected by unrestricted sales practices, and called the lack of required verification for sellers a “loophole” in the Rule. Other commenters proposed that, regardless of whether a prescription is presented or verified, the online sale of eyeglasses should be limited or even banned altogether.

However, commenters submitted very little empirical evidence of consumer harm that would support restrictions on sales practices. The only data refers to or is submitted in support of additional Commission regulation of eyeglass sales was a 2010 study focusing solely on the online sale of eyeglasses. That study, conducted by Dr. Karl Citek and others, found that many eyeglasses sold by online retailers did not pass ANSI (American National Standards Institute) standards for prescription accuracy or safety. In the study, ten individuals (consisting of the researchers and their colleagues and associates) ordered two pairs of eyeglasses apiece from ten online sellers. The published report does not identify the sellers used, stating only that they were online eyeglass sellers with the ten highest page rankings (most visited) at the time. According to the report, the eyeglasses purchased, and subsequently received in the mail, were then tested by an individual—described in the study as a researcher—for prescription accuracy, and tested by an independent laboratory for impact resistance. The study found that of the eyeglasses purchased online, 28.6 percent contained at least one lens that failed at least one parameter of optical analysis, and 22.1 percent had at least one lens that failed impact testing at the lab.

The Commission has reviewed the Citek study and has significant reservations about the study’s conclusion that eyeglasses purchased online might not be “of equal performance, value, or safety” as those dispensed in person. Significant weaknesses in the study’s design and reporting limit its usefulness. For example, the study does not name the individual online retailers from whom lenses were purchased, nor provide results for each retailer in the study. Hence, even for the ten retailers in question, it is not possible to determine whether the 28.6 percent and 22.1 percent average failure rates reported are typical failure rates or are skewed due to significantly higher failures among a small number of relatively poorly performing actors. In addition, the study does not report how click-rates correspond to sales in the online market. Hence, it is unclear whether those online retailers were also the ten leading online retailers in terms of sales.
(either in dollars or pairs of eyeglasses), whether they accounted for any particular percentage of online eyeglass sales overall, or whether they were, by some measure, representative of online sellers generally.

It is also unclear whether the Citek study’s reported failure rate for online sellers is any different from that for eyeglasses purchased from traditional optical dispensaries. The study did not include eyeglasses purchased directly from prescribers or brick and mortar dispensaries.136 The study does note, however, that, according to a previous study published in 1978, approximately 25 percent of eyewear manufactured for traditional dispensaries fail at least one parameter of optical analysis, a rate comparable to the online failure rate cited in the Citek study.137

In addition, the Citek study is a decade old, and was conducted when the online sale of eyeglasses was in its relative infancy. The eyeglass market has changed considerably since 2010, and it is probable that online sales have changed in various ways: new sellers have entered the market, seller market shares have probably shifted (as well as relative page visits and click-through rates), and online vendors from 2010 who are still operating may have modified their business practices. Because of these and other concerns about the study, the Commission cannot accord it significant weight.

Even if the Citek study were more compelling, however, it is unlikely it would provide, by itself, sufficient justification for adding new regulatory requirements to the Rule. The evidentiary record as a whole does not contain sufficient empirical evidence establishing that current eyeglass sales practices, whether by online vendors or competing brick and mortar establishments, are harmful to consumers and, therefore, should be banned or otherwise restricted. If the Commission had evidence of significant harm associated with one distribution channel in particular, it would need to assess whether new regulatory restrictions would ameliorate those harms in a way that would provide a net benefit to consumers. Furthermore, the Commission notes that certain states expressly permit sellers to duplicate eyeglasses, or do not require written prescriptions to make eyeglasses,138 and a Commission regulation requiring presentation of a prescription or verification of a prescription would have to preempt these state laws. The Commission declines to take such action without more compelling empirical evidence of consumer harm or benefits.

IV. Section 456.2—Separation of Examination and Dispensing

A. Automatic Prescription Release

Section 456.2(a) of the Eyeglass Rule provides that it is an unfair act or practice for a prescriber to fail to provide to the patient one copy of the patient’s prescription immediately after the eye examination is completed. This provision provides, however, that a prescriber may refuse to give the patient a copy of the patient’s prescription until the patient has paid for the eye examination, but only if that prescriber would have required immediate payment from that patient had the eye examination revealed that ophthalmic goods were required.139 Sections 456.2(b) and 456.2(c) prohibit prescribers from imposing conditions for patients to receive eye examinations and prescriptions. Section 456.2(b) provides that it is an unfair act or practice for a prescriber to condition the availability of an eye examination on a requirement that the patient agree to purchase any ophthalmic goods from the prescriber. Section 456.2(c) provides that it is an unfair act or practice for a prescriber to charge any fee in addition to the examination fee as a condition for releasing the prescription to the patient. These provisions, typically referred to as the automatic prescription release requirement (also sometimes referred to historically as the required “separation of examination and dispensing”),140 were intended to ensure that consumers have “unconditional access” to their ophthalmic prescriptions so they are able to “price shop” for eyeglasses.141 As noted in the Eyeglass I Report, without the ability to unconditionally obtain their prescriptions, consumers lack available information to choose the mixture of quality and price that best satisfies their needs.142

5. Comments on Whether To Retain Automatic Prescription Release

In response to a request for comments on the continuing need for the automatic prescription release provision,143 many commenters—including opticians, optometrists, ophthalmologists, eyeglass sellers, and consumers—expressed strong support.

136 While none of the commenters submitted or referenced any additional studies evaluating eyeglass sales practices, the Commission is aware of a 2016 study from the United Kingdom analyzing the acceptability, quality, and accuracy of glasses purchased online and from optometry practices. Alison J. Alderson, A Comparison of Spectacles Purchased Online and in UK Optometry Practice, 93 Optometry and Vision Science 1196–1202. The study involved 33 eyeglass wearers who purchased 154 pairs of eyeglasses online and 155 pairs in person from optometry practices in the United Kingdom. Eyeglasses were evaluated based on participant-reported preference, acceptability, and satisfaction, as well as fit, frame and fit quality; and the accuracy of prescriptions to an international standard. Compared to the practice eyeglasses, participants rated more of the online eyeglasses unacceptable or unsafe due to poor fit, poor cosmetic appearance, or inaccurate optical centration distance. While participants preferred eyeglasses purchased from optometry practices to those purchased online, lens quality and prescription accuracy were similar between the two groups. Frame quality differed based on price, and the authors noted that the online frames were significantly cheaper and thus lower quality. The study authors noted areas for potential improvement in sales practices both for online sellers and optometry practices.

This study is informative of the types of problems eyeglass wearers can encounter in an online or in-person purchase and the preferences that may motivate consumers when choosing where to purchase eyeglasses, but the Commission does not believe it provides an adequate basis for imposing further regulatory requirements on eyeglass sellers. The study took place in the United Kingdom, rather than the United States, and online retailers were limited to those with a base in the United Kingdom, so the results are not necessarily applicable to the US market. The study had design limitations similar to the Citek study, such as not identifying the online retailers (or, in this case, the optometry practices), or providing the results for each retailer. Study authors selected online retailers based on search engine results, rather than sales volume, while study participants selected their own optometry practices within a limited set of restrictions. In addition, 97% of study participants had previously purchased their eyeglasses from optometry practices (and may have chosen to purchase from those same practices as part of the study), which might have led to confirmation bias in the study results. Moreover, the study findings did not support a meaningful difference in the quality or accuracy of glasses purchased online as compared to those purchased in person.
Several stated that the provision benefits consumers by fostering comparison-shopping and competition.\textsuperscript{144} As one consumer commented, “[o]btaining a prescription for my eyeglasses has been crucial, improving my ability to purchase glasses at fair prices.”\textsuperscript{145} Another declared that the Rule “has provided consumers the benefit of choosing where they’d prefer to buy their eyeglasses, saving them money on that expense.”\textsuperscript{146}

Other commenters stressed a continued need for this provision in the Rule, with some contending that the need is as great or greater now as when the Rule was first implemented. According to one comment (submitted on behalf of three individuals), the advent of online optical dispensaries can put more pressure on prescriber profits, making it even more vital to mandate automatic release in order to ensure that prescribers do not try to recoup lost profits by coercing patients to buy eyewear in-house.\textsuperscript{147} According to this comment, the automatic release provision compels prescribers to remain competitive, leading to lower prices and higher quality eyeglasses.\textsuperscript{148} Another commenter, the Professional Opticians of Florida, stated that since the Rule was first implemented, there has been a “dramatic increase” in prescribers’ offices with attached optical dispensaries, increasing the potential for such prescribers to steer patients into purchasing eyeglasses in-house.\textsuperscript{149}

Opticians, in particular, expressed strong support for the automatic prescription release requirement, with the National Association of Optometrists and Opticians (“NAOO”), a trade association representing co-located optical dispensaries, characterizing the Rule as a “triumph of narrowly tailored government action that directly addresses [a] specific consumer problem with minimal cost and remarkable benefits.”\textsuperscript{150} According to NAOO, any costs to prescribers from prescription release has been “trivial,” while benefits to consumers have been significant, allowing them to comparison-shop and choose the optical dispenser of their choice.\textsuperscript{151} This, in turn, according to the commenter, has helped foster exponential growth in the ophthalmic goods market.\textsuperscript{152} NAOO added that it was critical to maintain the automatic release requirement due to the continuing “imbalance of power between patient and prescriber,” and powerful financial incentives for prescribers—who sell the products that they prescribe—to keep sales in-house.\textsuperscript{153}

On the other hand, the AOA commented that, “[i]t is our understanding that doctors of optometry widely comply with the Rule,” and did not believe that compliance with the prescription release provision remains an issue.\textsuperscript{154} The AOA also stated that patients are well informed of their ability to obtain their eyeglass prescriptions and have a greater expectation to receive their health information from their doctors as a result of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).\textsuperscript{155} Accordingly, the AOA posited that “[g]iven that the requirements outlined in the Rule are now standard practice, it is questionable as to whether the Rule serves a continued benefit to patients.”\textsuperscript{156} Nonetheless, the AOA did not expressly expressing support for automatic prescription release;\textsuperscript{157} Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Hoffman (Comment #0026).

151 Comment #0748 submitted by Cutler. The NAOO noted that based on member experience and observation, thousands of optometrists affiliated in co-location with their members comply with the Rule with “little or no added costs or other burden on the eye care practice.” Id.

152 Id.

153 Id. NAOO noted that optometry and ophthalmology are among the very few health care professions in which prescribers also sell, and often derive a significant portion of their income from, the products they prescribe. Id.; see also note 66, supra (product sales typically account for 55 to 65 percent of optometrist revenue). In commenting on the AOA’s comment, the CLR, however, pointed out that health care professionals in other areas—such as ambulatory surgery centers, orthopedic centers, and dental service providers, among others, also sell what they prescribe or recommend for treatment. AOA (CLR SNPRM Comment FTC–2019–0041–0096). The Commission acknowledged this fact. CLR Final Rule, 85 FR 50668, 50679–80 (stating that the Commission’s interpretation of the automatic release provision is “solely on a belief that contact lens prescribers’ role and market is necessarily unique, but rather considered the structure of the market as a contributing factor to the increased prices and costs solely on a belief that contact lens prescribers’ role and market is necessarily unique, but rather considered the structure of the market as a contributing factor to the increased prices and costs”)

154 Comment #0849 Submitted by Peele.


156 Comment #0849 submitted by Peele.

...
should be noted, however, that prescribers may be aware in a general way of their obligation to release prescriptions and yet be ignorant of the precise requirements of the prescription release provision. For example, in some instances, prescribers may violate the Rule by waiting for a patient to ask for the prescription, or asking a patient, “Do you want a copy of your prescription?” In both circumstances, the prescriber has violated the Rule since the prescription is not automatically provided. Indeed, a number of prescribers admitted to doing exactly that when commenting on the CLR, with many misstating the prescription release requirements and asserting that they always “offer” prescriptions to their patients or provide them “when requested,” rather than automatically providing prescriptions “whether or not requested by the patient,” as required under both the Contact Lens Rule and Eyeglass Rule. Many prescribers may thus believe they are complying with the Rule even though they are not, and might also be incorrect in assessing, and reporting on, their own compliance and that of their colleagues.

A number of commenters, meanwhile, asserted that, even though the Rule has required, for more than four decades, that prescribers automatically release eyeglass prescriptions to their patients, prescribers still routinely fail to comply, either by failing to provide a prescription unless requested, requiring a waiver in exchange for a prescription, or failing to provide a prescription at all. According to eyeglass seller and manufacturer Warby Parker, “[i]t is well known in the industry that many [prescribers] refuse to give patients prescriptions unless they specifically request it, and some [prescribers] place intimidating and unnecessary warnings or waivers of responsibility on the prescriptions they do release.”

One commenter, an optician, opined that the practice of prescribers failing to automatically release prescriptions is “flagrant,” while another commented that “[i]t has been my observance that the Eyeglass Rule is not being complied with at all.” These two commenters asserted that prescribers often do not provide patients with prescriptions until after patients are led into the prescriber’s in-house optical dispensary, a practice that would violate the Rule because the examination has concluded, and the patient should have already been provided with the prescription. And the NAOO commented that while it did not possess empirical evidence, “experiential and anecdotal evidence and observation of industry leaders indicates that while many consumers are getting a copy of their eyeglass prescription upon completion of the eye exam, some are not, and some are faced with resistance when they attempt to obtain their prescriptions.”

The Commission did not receive many comments from consumers specifically addressing the issue of prescription release in response to the ANPR. However, a number of consumers who commented during the CLR review stated that their prescribers failed to provide them with their prescriptions for contact lenses and for eyeglasses. And separate from these rule review processes, the Commission continues to receive consumer complaints about noncompliance with the automatic release provisions of both the Eyeglass Rule and Contact Lens Rule. In December 2020, the Commission sent warning letters to 28 prescribers after receiving complaints alleging violations of the Eyeglass Rule. Press Release, Fed. Tr. Comm’n, FTC Issues Warning Letters Regarding Agency’s Eyeglass Rule (May 13, 2016), https://www.ftc.gov/news-events/press-releases/2016/05/ftc-issues-warning-letters-regarding-agency’s-eyeglasses-rule.

Two commenters also submitted consumer survey evidence about prescriber compliance. Warby Parker submitted results from an October 2015 consumer survey, conducted on the company’s behalf by the polling firm SurveyMonkey, which reported that, of consumers who had purchased eyeglasses within the last three years, 47 percent of those who saw optometrists and 31 percent of those who visited ophthalmologists were not automatically provided with a physical copy of their eyeglass prescription.

167 Santini (Comment #0047) (“In my area, it is common for eye care providers who exam [sic] AND Sell glasses to not be forthcoming with providing the spectacle Rx, particularly when consumers demand it.”).

168 Tesedo (Comment #0042).

169 Id.; Santini (Comment #0047); see also Opticians Association of Virginia (Comment #0647 submitted by Nelms).

170 Comment #0748 submitted by Culler.

171 See, e.g., Nichols (CLR WS Comment FTC–2017–0099–0209) (said she was charged for her eyeglass prescription); Tennison (CLR WS Comment FTC–2017–0099–0453) (does not receive written prescriptions for lenses or eye glasses after exams); Bogner (CLR NPRM Comment FTC–2016–0098–1368); Vaszacky (CLR NPRM Comment FTC–2016–0098–1415); Strobel (CLR NPRM Comment FTC–2016–0098–1446); Austin (CLR NPRM Comment FTC–2016–0098–1514); Martinez (CLR NPRM Comment FTC–2016–0098–2096). A few other CLR consumer commenters, however, stated that although they do not receive their prescriptions after a contact lens fitting, they typically do receive them after a refraction exam for eyeglasses. See, e.g., Hall (CLR WS Comment FTC–2017–0099–0227); Krainman (CLR WS Comment FTC–2016–0098–1373); Zeledon (CLR NPRM Comment FTC–2016–0098–1377).


174 Comment #0817 submitted by Kumar. The SurveyMonkey survey comprised 1,329 respondents recruited from a Census-balanced and representative of the national distribution of major demographic factors, including age, gender, geography, and income. Participants were not informed of the identity of the survey sponsor. Survey respondents who had purchased eyeglasses within the last three years (65% of the total respondents) answered questions about prescription information, purchase behavior, and prescriber experience. Within the set of consumers who had purchased within the last three years, 54% had purchased within the last 12 months. There were no significant differences in responses regarding automatic prescription release between those who had purchased within the last year and those who had purchased within the last year and those who had purchased within the last year.
Another commenter, contact lens seller 1–800 CONTACTS, cited a survey—conducted on its behalf by the firm Survey Sampling International (“SSI”) and submitted previously with a comment on the Commission’s Contact Lens Rule review—which found that only 34 percent of eyeglass wearers automatically received their prescriptions on the day of their office visit, with another 19 percent receiving it during their visit, but only after asking for it.177 According to the SSI survey, some consumers were able to obtain their prescriptions at a later point by returning to their prescriber’s office, but 39 percent of consumers never received their prescription at all.176

The Commission has also reviewed five consumer surveys—submitted and considered during the CLR review—which found that between 21 and 34 percent of contact lens users did not receive their prescriptions after their exam and fitting.178 These surveys and three years prior to the survey. The significant difference in automatic release compliance between ophthalmologists and optometrists may be due to the fact that fewer optometrists sell eyeglasses, and might thus have less incentive to withhold a consumer’s prescription, but the survey did not directly explore this issue.

176 Comment #0834 submitted by Williams. According to 1–800 CONTACTS, the data derive from a telephone survey of 300 prescription eyeglass wearers. See “FCLCA Study, Focus on Prescription (Rx),” attached as Exhibit B to 1–800 CONTACTS (CLR RFC Comment FTC–2015–0093–0555 submitted by Williams). Respondents were not informed of the identity of the survey sponsor. The Commission has some concerns about the methodology utilized for this survey, particularly about the lack of an “I don’t know” response option, but believes the information may still be suggestive, particularly when viewed in conjunction with information from other sources and the absence of contradictory data.

177 Id.

178 The results from the individual consumer surveys are as follows: (1) June 2019 survey by Dynata on behalf of 1–800 CONTACTS of 1,011 contact lens users found that 21% said they never received their prescriptions (1–800 CONTACTS (CLR SNPRM Comment FTC–2019–0041–0135)); (2) January 2017 survey by Caravan ORC International on behalf of Consumer Action of 2,018 adults found that 31% of contact lens users said that at their last eye exam, their doctor did not provide them with a paper copy of their prescription (Consumer Action (CLR NPRM Comment FTC–2016–0098–2954)); (3) December 2017 survey of 1,000 contact lens users by SSI on behalf of 1–800 CONTACTS found that 24% of consumer respondents said they did not receive their prescription (1–800 CONTACTS (CLR NPRM Comment FTC–2016–0098–2738)); (4) May 2015 SSI survey of 2,000 contact lens wearers found that 34% said they did not receive their prescription (1–800 CONTACTS (CLR NPRM Comment FTC–2015–0093–0555 submitted by Williams, Ex. C)); and (5) November 2014 SSI survey of 2,000 contact lens wearers found that 34% said they did not receive their prescription (1–800 CONTACTS (CLR RFC Comment FTC–2015–0093–0555 submitted by Williams, Ex. C)). As noted in the CLR SNPRM, the manner in which a few of the questions were phrased in the 2014 and 2015 surveys raised some issues with the survey data.

Commission concerns, since some questions were leading, lacked an “I don’t know” response option, and used a term—“hard copy”—which not all consumers may have recognized. These surveys represented an improvement because they included an option for respondents to acknowledge that they do not recall whether they received their prescriptions, and used the term “paper copy” rather than “hard copy.” CLR SNPRM, 84 FR 24664, 24672.

179 As noted, supra note 171, a small number of consumer commenters to the CLR stated that although their prescribers failed to give them their contact lens prescriptions, they typically do provide them with their eyeglass prescription after each eye exam. See, e.g., Individual Comment FTC–2017–0099–0227; Krainman (CLR NPRM Comment FTC–2016–0098–1373); Zeleon (CLR NPRM Comment FTC–2016–0098–1377). The Commission has not seen empirically based supports this (and, in fact, it appears to be contradicted by the consumer survey data).

180 See CLR Final Rule, 85 FR 50668, 50675; CLR SNPRM 84 FR 24664, 24673.

181 See CLR NPRM, 85 FR 50668, 50675, 50678.

182 See Warby Parker (Comment #0817 submitted by Kumar).

183 According to Warby Parker (Comment #0817 submitted by Kumar), before it processes an order it verifies every prescription by viewing a copy of the prescription or speaking with the consumer’s prescriber. In discussions with Warby Parker, the company has indicated that in 12 percent of all prescription eyewear orders (including both online and in-store orders), consumers commented that what is known as a “call doctor” request, whereby the customer requests that Warby Parker call the prescriber on behalf of the customer to obtain prescription information. However, the company noted that as of March 15, 2017, 15 percent of all “call doctor” requests Warby Parker made on behalf of its customers have been unanswered (i.e., the prescriber has not provided the requested prescription information to Warby Parker). As a result, Warby Parker believes it may be more efficient for a customer to request the prescription information from the prescriber himself/herself. See, e.g., Dehnamb (Comment #0039); White (Comment #0053); Kidwell (Comment #0064).

184 It is reasonable to expect that if consumers possessed copies of their prescriptions, many would provide them to third-party sellers instead of asking the sellers to obtain their prescriptions from their prescribers. It is also possible, however, that some consumers could have received copies of their prescriptions but misplaced them, or simply thought it easier for the third-party seller to obtain copies of the prescription than to locate and provide the copies themselves in the format requested by the seller.
of data does not allow the Commission to conclusively determine the level of prescriber compliance with automatic prescription release, or the number or percentage of consumers who might not have received a copy of their eyeglass prescription, it likely supports the finding that many patients are not automatically receiving a copy of their eyeglass prescriptions.

Lastly, it must be acknowledged that the same structural issue—an “inherent conflict of interest” in that prescribers sell the items they prescribe—that led the Commission to enact the Eyeglass Rule and CLR, and for Congress to enact the FCLCA,187 and that the Commission cited as an existing factor in its decision to amend and strengthen the CLR,188 still exists with respect to the eyeglass market and the Rule. According to some industry sources, eyeglass sales amount to approximately 37 to 44 percent of an optometric practice’s gross revenue, with gross profit on eyeglass sales in the area of 62 percent.189 While many prescribers with gross profit on eyeglass sales in the optometric practice’s gross revenue, according to industry sources, eyeglass sales amount to approximately 37 to 44 percent of an optometric practice’s gross revenue, with gross profit on eyeglass sales in the area of 62 percent.189 While many prescribers with gross profit on eyeglass sales in the optometric practice’s gross revenue. According to some industry sources, eyeglass sales amount to approximately 37 to 44 percent of an optometric practice’s gross revenue, with gross profit on eyeglass sales in the area of 62 percent.189 While many prescribers with gross profit on eyeglass sales in the optometric practice’s gross revenue, according to industry sources.

188 CLR Final Rule, 85 FR 50668, 50678–80 (“Motivation is a crucial factor in the decision to purchase in the U.S., which bars a consumer from obtaining contact lenses without a prescription while permitting prescribers to sell what they prescribe, creates regulatory incentives for some prescribers to not release prescriptions, or to not release them unless requested by the consumer.”).

189 ECP University, “Key Metrics: Assessing Optometric Practice Performance & Best Practices of Spectacle Lens Management Report,” 25, 40–41; see also note 66, supra.

190 AOA (Comment #0849 submitted by Peele).

191 This, of course, was the basis for the Eyeglass Rule in the first place. The Commission determined that there was a long documented history of prescribers taking action to prevent or discourage

7. Evidence Regarding Consumers’ Awareness of Their Right To Receive Their Prescription

As with the question of Rule compliance, there was little consensus among commenters as to whether consumers are fully aware of their right to their prescriptions.192 In its comment, the AOA asserted that patients are now well-informed of their ability to obtain their eyeglass prescriptions.193 Other commenters disagreed, with some eyeglass sellers asserting that many patients are still not aware of the Rule and their rights.194 In previous reviews of the Eyeglass Rule, the Commission received conflicting empirical evidence regarding the extent of consumer awareness, with some studies suggesting a relatively high degree of awareness,195 and others indicating that consumers, particularly older patients, were unaware of their right to automatically receive a copy of their prescription.196 For this review, none of the commenters submitted survey evidence specifically focused on consumer awareness of their right to their eyeglass prescription. One commenter, 1–800 CONTACTS, however, cited a survey submitted to the Commission during the Contact Lens Rule review which indicates that lack of awareness of a right to an eyeglass prescription is still an issue.197 According to the survey, 49 percent of prescription eyeglass wearers are not aware that they have a right to receive a copy of their prescription, and 51 percent are not aware that their eye exam provider cannot charge for a copy of their prescription.198 Furthermore, multiple other consumer surveys examined during the Contact Lens Rule review indicate that a high percentage of consumers (46 to 60 percent, according to submitted data) do not realize they are entitled to receive their contact lens prescription, and it is likely that many of these consumers are also

See “FCLCA Study, Focus on Prescription (Rx),” attached as Exhibit B to 1–800 CONTACTS (CLR RFC Comment FTC–2015–0093–0553 submitted by Williams).

198 Id. The manner in which the consumer awareness questions were phrased in the survey submitted by 1–800 CONTACTS did raise some concerns about the weight given to the submitted data. See Diamond, Reference Guide on Survey Research, in Reference Manual on Scientific Evidence, 2nd. ed., 248–264 (Federal Judicial Center 2000), available at https://www.law.northeastern.edu/faculty/fulltime/diamond/papers/referenc eaguidesurveyresearch.pdf; Fowler, How Unclear Terms Affect Survey Data, The Public Opinion Quarterly (Summer 1992) available at https://www.jstor.org/stable/2749171; see generally, Carl A. Latkin, et al., The relationship between social desirability bias and self-reports of health, substance use, and social network factors among urban substance users in Baltimore, Maryland, 73 Addictive Behaviors 133–136 (2017) (social desirability bias is the tendency of survey respondents to answer questions in a manner that will be viewed favorably by others, and can skew survey results by over-reporting negative behaviors that may be considered desirable attributes, while underreporting less desirable attributes). Social-desirability bias in this instance likely underestimates the number of patients unaware of their right to their prescription. In other words, the way the question was phrased could lead to results that make it appear that more patients are aware of their rights, than is, in fact, the case. See “FCLCA Study, Focus on Prescription (Rx),” attached as Exhibit B to 1–800 CONTACTS (CLR RFC Comment FTC–2015–0093–0553 submitted by Williams). The question was phrased, “Are you aware of the following? . . . Your eye exam provider cannot charge you for an actual hard copy of your prescription?”

See “FCLCA Study, Focus on Prescription (Rx),” attached as Exhibit B to 1–800 CONTACTS (CLR RFC Comment FTC–2015–0093–0553 submitted by Williams).
had found "significant non-compliance," and noting that in a 1989 rule review, the Commission found poor compliance in the past, compliance was widespread, and that this constituted an unfair act or practice under section 5. In subsequent Eyeglass Rule reviews, the Commission noted that despite the Rule, compliance remained a problem, and expressed concern that if the automatic release requirement were removed, more prescribers might return to the practice of refusing or failing to release prescriptions. And while some commentators assert that automatic prescription release is now such standard practice that it would be adhered to even absent a rule, the weight of the evidence in this Rulemaking clearly favors retaining the automatic release requirement. Furthermore, the Commission notes that when it relied on voluntary compliance in the past, compliance was poor.

The Commission remains concerned that a lack of compliance with the Rule is still prevalent, and that removing the automatic prescription release requirement might further reduce the number of consumers who receive their prescriptions, whether automatically or on request. The Commission has not seen evidence suggesting that the structure of the market or financial incentives for prescribers have changed in such a way as to make the automatic prescription release requirement no longer necessary. Arguably, the incentive that prescribers have to steer patients to in-house optical dispensaries rather than giving patients their prescription remains the same, if not stronger, than when the Rule was first implemented. Moreover, the evidentiary record indicates that a significant percentage of prescribers still do not automatically provide a prescription. The evidence also suggests that many consumers are still not fully aware of their right to receive or obtain their prescription. Furthermore, the population of eyeglass wearers is not static, and large numbers of consumers become first-time wearers each year. The Commission thus concludes that many consumers cannot reasonably avoid prescribers’ failure to automatically release prescriptions as required by the Rule. It is important that this be remedied, and that consumers are aware of, and receive the benefits of, their right to comparison-shop for eyeglasses.

The Commission also has not seen evidence that the automatic release provision imposes an unreasonable burden on prescribers, or that there is a substantial countervailing benefit that would result from eliminating the automatic release requirement. Indeed, while a few prescribers asserted it was wasteful or unnecessary, other commenters felt it was not a significant burden, and the AOA stated that the automatic release provision was not “harmful” to prescribers. The Commission previously concluded that the requirement enhances consumer choice among eyeglass sellers at a minimal compliance cost to eye care prescribers. Moreover, since the automatic prescription release provision has been in existence since 1978, maintaining it as part of the Rule would not impose new costs on prescribers. By contrast, eliminating it for eyeglass prescriptions would create the potential for confusion amongst patients and prescribers alike, since the automatic prescription release requirement still applies to contact lens prescriptions.

The Commission also concludes that the potential benefits of including the number of patients who receive their prescriptions automatically are substantial. These benefits include: increased patient flexibility and choice in comparison-shopping for eyeglasses; fewer disputes between consumers and prescribers; fewer requests from patients for a copy of their prescription, and arguably, fewer requests for a copy of, or a verification of, a prescription from third-party sellers of eyeglasses, which some prescribers find burdensome; and a reduction in costs and voided sales by third-party sellers. The cumulative effect of increased compliance and consumer awareness would likely increase competition, lower costs, and improve convenience and flexibility for patients, sellers, and prescribers.

9. Proposals for Improving Compliance and Consumer Awareness

Having reached a determination that the automatic release provision should be retained, and that it would be beneficial to increase compliance with, and awareness of, the provision, the Commission now evaluates proposals for how best to achieve this goal.

a. Proposal To Increase Enforcement

Of the commentators who discussed the automatic prescription release provision, very few offered suggestions for amending the Rule to increase compliance with, or consumer awareness of, this provision. A few, however, suggested that the Commission should improve compliance by bringing more enforcement actions against prescribers.
who fail to automatically release prescriptions. Warby Parker, in particular, noted that Commission enforcement actions have been “virtually non-existent,” and asserted that more aggressive enforcement would quickly increase both prescriber compliance and consumer awareness. To assist the Commission in its enforcement, Warby Parker also suggested creating a more “user-friendly” online complaint process for consumers. The Commission recognizes the need for increased enforcement of the automatic prescription release provision. Simply put, with the evidence in the Rulemaking showing significant noncompliance with this provision after 40 years, it is clear that more enforcement is necessary to improve industry adherence. In this regard, the absence of documentation often makes it difficult in an enforcement investigation to determine whether, in any particular case, a prescriber provided a patient with a prescription. The lack of documentation also makes it difficult to determine how many times, or how frequently, a particular noncompliant prescriber has violated the Rule. Instead, allegations and denials of non-compliance often become a matter of a patient’s word against that of the prescriber, making violations difficult to prove. Commission staff first identified this issue in its Eyeglass II Report, where it explained that the automatic release requirement had not helped to avoid “evidentiary squabbles” as the Commission had hoped it would—but instead had increased them, because whether or not a prescriber had released a prescription could not, in most cases, be ascertained by documentary evidence. Accordingly, the Commission has brought only one enforcement action against an eyeglass prescriber for failure to comply with the automatic release provision. The Commission believes that improvement in its ability to assess and verify compliance with the Rule’s automatic prescription release requirements will increase its ability to monitor and enforce compliance.

b. Proposal To Require an Eye Care Patients’ Bill of Rights

Commenter Warby Parker proposed that the Rule be amended to require that prescribers provide patients with written notices informing them of their right to their prescription. According to the proposal, such notices would take the form of a “bill of rights” for eyeglass patients, notifying them of their rights under the Eyeglass Rule, including their right to receive their prescription free of charge and to purchase glasses from a provider of their own choosing. Such a proposal, if implemented and complied with, might increase consumer awareness and, presumably, increase the percentage of patients who receive prescriptions from their providers. Providing the document would also remind prescribers and their staffs of their obligation to provide patients with their prescriptions, and would remind patients to ask for their prescriptions in the event that prescribers failed to provide them without request, as the Rule requires. A bill of rights would also impose a relatively small burden upon prescribers, since they would only need to provide a brief, standard, pre-drafted form for each patient, and would not have to perform additional recordkeeping. On the other hand, patients already receive forms and other paperwork when they visit a prescriber, increasing the possibility that patients might not read or attend to the information in a bill of rights. Moreover, the Rule already requires that prescribers provide patients with copies of their prescriptions, and yet evidence indicates that prescribers do not always do so. Without some mechanism to ensure prescriber compliance with the new obligation to provide a bill of rights, the requirement might not provide material benefits. For example, under Warby Parker’s proposal, patients would be given a copy of the bill of rights to take with them, but there would be no requirement that prescribers maintain records of their compliance. Therefore, the bill of rights proposal does not require the type of prescriber recordkeeping that would allow for better Rule monitoring and enforcement, and help resolve disputes between patients and prescribers over whether a prescription had been released. It is thus possible that adding a bill of rights requirement would impose an increased burden on prescribers without providing tangible, countervailing benefits to consumers or prescribers.

Many prescribers might also object to an eyeglass patient’s bill of rights out of concern that it might impart the impression to consumers that prescribers are untrustworthy. Prescribers voiced numerous objections of this type during the CLR review when the Commission proposed including a sentence on a consumer acknowledgment of prescription stating, “I understand I am free to purchase contact lenses from the seller of my choice.” According to prescribers, such a statement implies that they have done something wrong. It seems likely prescribers would oppose an eyeglass patient’s bill of rights for the same reason.

In fact, a similar bill of rights proposal was put forth by commenters to the Contact Lens Rule and considered,
and the Commission ultimately decided against adopting it for many of the reasons cited herein. In light of these considerations, the Commission does not propose amending the Rule to require that prescribers provide patients with a bill of rights.

c. Proposal To Require Signage

Some commenters proposed that one way to increase compliance with, and awareness of, the automatic release provision, would be to amend the Rule to require that prescribers post conspicuous signage in their offices informing patients of their right to their prescriptions. Such signage is currently required by state law in California.

If adopted, such a requirement could provide some of the same benefits as a bill of rights by educating consumers and, presumably, might also increase the percentage of patients who receive their prescription from their provider. A sign could also serve as a reminder to patients to look for their prescription in the event a prescriber fails to provide it. Furthermore, a sign would impose relatively little burden on prescribers, since it would only have to be posted once. Lastly, enforcing such a provision could be relatively straightforward, since the Commission could simply perform spot checks on prescribers’ offices.

On the other hand, the Commission lacks evidence about the effects of California’s signage requirement on automatic prescription release. It is unclear how many patients would notice a sign at prescribers’ offices, particularly since many prescribers’ offices already have numerous ads or other postings about various patient rights, requirements, and obligations. It is possible that in the context of prescribers’ offices, a signage requirement would not be as effective in increasing consumer awareness as a requirement that consumers be handed or shown a specific document. A sign would also not require a prescriber, or the prescriber’s staff, to interact with each patient about their prescription, so it would serve as less of a reminder for patients to ask for their prescription in the automatic prescription release provision. Moreover, since sign would increase prescription release only if more consumers see a sign and ask for their prescription, relying on signage essentially shifts the burden of prescription release compliance and enforcement to the consumer, an approach the Commission has repeatedly rejected in the past.

During its review of the CLR, the Commission gave extensive consideration to the possibility of using signage, particularly as an alternative to some form of written acknowledgment of prescription from the patient. The Commission ultimately decided against a signage provision, after determining that the benefits were limited and that requiring signage would be significantly less effective at ensuring contact lens prescription release than requiring a written patient confirmation. The Commission reaches the same conclusion with respect to proposed signage reminding consumers about their contact lens prescriptions.

d. Proposal To Require a Confirmation of Prescription Release

Having determined that some type of documentation is necessary to increase adherence and improve enforcement of the Rule, the Commission next turns to consider what type of documentation should be required.

In 2020, the Commission amended the Contact Lens Rule to add a requirement that prescribers retain documentation confirming that they released contact lens prescriptions to patients as required by the CLR. The CLR’s confirmation requirement was adopted subsequent to the publication of the ANPR, and while none of the commenters to the ANPR explicitly proposed a signed acknowledgment, commenters to the CLR review made such a suggestion, and the Commission ultimately determined there would be substantial benefits to such an approach. In promulgating the requirement, the Commission stated its belief that the confirmation requirement would increase compliance with prescription release requirements and awareness of the CLR’s requirements among consumers by mandating that prescribers present a document for patients to sign confirming that they received their prescription at the end of their contact lens fitting.

The Confirmation of Prescription Release provision added to the CLR in 2021 requires prescribers do one of the following:

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

In order to relieve prescribers of the burden of crafting their own confirmation language, the CLR provides sample language for options (A), (B), and (C), but also allows prescribers to create their own wording for the signed confirmation if they so desire. Prescribers are required to maintain records or evidence of consumer confirmation, or that a digital copy was provided to the patient, for at least three years. Lastly, in order to limit the burden as much as possible, the CLR confirmation requirement only applies to prescribers with a financial interest in the sale of contact lenses. The Commission believes a similar requirement for eyeglass prescriptions would have many benefits. A signed patient confirmation of release for eyeglass prescriptions would notify and

223 See CLR NPRM, 81 FR 88526, 88534; CLR SNPRM, 84 FR 24664, 24679; CLR Final Rule, 85 FR 50668, 50684–85.
224 CLR Final Rule, 85 FR 50668, 50685.
225 The Commission further notes that imposing a signage requirement for eyeglass prescriptions, where one does not exist for contact lens prescriptions, could result in confusion for both consumers and prescribers.
226 16 CFR 315.3(c).
230 CLR Final Rule, 85 FR 50668, 50687–88; 16 CFR 315.3(c).
remind consumers of their prescription portability rights and, in all likelihood, increase the percentage who receive their prescription from the prescriber. Providing the confirmation document, and obtaining the patient’s signature, would remind prescribers and their staffs to provide prescriptions, and remind patients who might have received a confirmation document (and are asked to sign) but did not receive their prescription to ask for it.

Since the document is given to the patient, and the patient asked to sign it, such a document is less likely to go unnoticed or unread by patients than a bill of rights or office signage reminding patients of their prescription rights. And requiring prescribers to retain a signed confirmation would improve the Commission’s ability to verify whether prescribers had complied with the Rule’s requirement to release prescriptions to their patients. It would reduce the number of instances where a filed complaint simply pits the patient’s word against that of the prescriber. Prescribers would also have valuable documentation to present in their defense should a patient lose or dispose of his or her prescription copy and mistakenly believe the prescriber had not provided it, a scenario cited by at least one commenter.234 In short, a confirmation of release would eliminate certain evidentiary problems related to Rule enforcement, one of the reasons the Commission adopted automatic prescription release when it promulgated the Eyeglass Rule in the first place.235 Ultimately, adding a confirmation of release requirement should result in more consumers having a copy of their prescriptions, and thus improve consumer flexibility and choice, reduce the number of eyeglass sellers and consumers who call prescribers to obtain patient prescriptions, improve competition in the market for eyeglasses and frames, and lower prices for consumers.240

The primary drawback to requiring a signed confirmation is the increased recordkeeping burden imposed on prescribers, since they would have to provide the piece of paper and retain the signed form for a certain period of time.241 This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and inputted automatically into the electronic record. Furthermore, prescribers could scan signed paper copies of the confirmation and store those forms electronically to lower their compliance costs. Moreover, the added paperwork requirement may apply only to prescribers who use a separate form to get the patient’s signed confirmation, since those who opt to add the confirmation to a copy of the patient’s prescription or sales receipt would, presumably, be maintaining those records anyway. Prescribers also will likely have an established means of collecting patient confirmations and maintaining records for the purpose of complying with the CLR. The marginal cost of adopting such forms and systems to include eyeglasses prescriptions is likely to be very low. Accordingly, the Commission believes that any recordkeeping burden would be relatively minimal and outweighed by the benefits described above.

One concern is the possibility that requiring consumers to sign a confirmation that they received their prescription will sow doubts about prescriber integrity, and sullying the doctor-patient relationship.242 The Commission believes this to be unlikely. Consumers are accustomed to signing acknowledgments or receipts.243 Many pharmacists require patients to acknowledge that they do not have questions upon receiving a prescription; physicians’ offices require visitors to sign in; and patients are accustomed to signing HIPAA acknowledgment forms signifying they received a provider’s Notice of Privacy Practices (“NPP”).244

234 Prescribers who choose to offer a digital copy of the prescription would avoid this aspect of recordkeeping for those patients who consent to receive a digital copy.

235 TheCommission considered this concern during its review of the Final Rule, 85 FR 50668, 50680–81 and came to the conclusion that this concern is not significant enough to change the result.

236 This fact was also considered in the CLR evaluation. Id.

237 The U.S. Department of Health & Human Services (“HHS”) proposed eliminating the requirement to obtain an individual’s written acknowledgment confirming a patient’s NPP, but patients have had experience signing such acknowledgments for many years. See Proposed Modifications to the HIPAA Privacy Rule To Support the Urban Core and Urban Underserved Populations, 86 FR 64480, 64484 (Jan. 1, 2021). As explained in the CLR, the impetus for the NPP signed acknowledgment and that for the CLR (and Eyeglass Rule) prescription release proposal were very different, and—in contrast to eyeprescriptions—there is little evidence that providers were not providing patients with their NPPs, and thus significant needs for patient acknowledgment of receipt. CLR Final Rule, 85 FR 50668, 50684–85 (noting that the primary intent of the HIPAA signed-acknowledgment was to provide patients an opportunity to review the provider’s Notice of Privacy Practices, discuss concerns related to their private health information, and request additional confidentiality, not to remedy a lack of compliance, and that the HHS record does not contain empirical evidence showing that doctors are not fulfilling their obligations to provide Notices of Privacy Practices to patients); see also Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, Office for Civil Rights, Department of Health and Human Services, 83 FR 64302, 64308 (Dec. 14, 2018) (discussing the limited evidence that justifies the HIPAA signed acknowledgment); see also generally Comments in Response to Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, Office for Civil Rights, Department of Health and Human Services, https://www.regulations.gov/document/HHS-OCR-2018- 0028-0001.

238 Should a prescriber wish to create a single document confirming receipt of both an eyeglass and a contact lens prescription (in cases where both prescriptions are finalized at the same time), the Commission believes such a provision will increase the number of patients who receive their prescriptions, inform patients of the Rule and their right to their prescriptions, reduce the number of seller requests to prescribers for eyeglass prescriptions, improve the Commission’s ability to monitor overall compliance and target enforcement actions, reduce evidentiary issues, complaints, and disputes between pharmacies and consumers, and bring the Eyeglass Rule into congruence with the Confirmation of Prescription Release requirement of the Contact Lens Rule.245 The addition of a patient confirmation requirement accomplishes the desired
objectives of the Rule with little increased burden on prescribers. The Commission therefore proposes to amend § 456.3 to add the requirement that upon completion of a refractive eye examination, and after providing a copy of the prescription, the prescriber shall do one of the following: (i) Request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription; (ii) Request that the patient sign a prescriber-retained copy of a prescription that contains a statement confirming receipt of the prescription; (iii) Request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming receipt of the prescription; or (iv) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable. If the prescriber elects to confirm prescription release via paragraphs (i), (ii), or (iii), 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. In the event the patient declines to sign a confirmation requested under paragraphs (i), (ii), or (iii), the prescriber shall note the patient’s refusal on the document and sign it. A prescriber shall maintain the records or evidence of confirmation for not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives. The prescription confirmation requirements shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of eye wear, including, but not limited to, through an association, affiliation, or co-location with an optical dispenser. The full text of the proposed Rule amendment is located at the end of this document.

B. Other Issues Surrounding Patients’ Access to Eyeglass Prescriptions

1. Prescriber Responsibilities To Provide Additional Copies of Prescriptions

The Eyeglass Rule requires an ophthalmologist or optometrist to provide “one copy” of the patient’s prescription immediately after the completion of the eye exam.246 In the ANPR, the Commission sought comment on whether it should amend the Rule to require prescribers to provide duplicate copies of prescriptions to patients who no longer have access to the original.247 Patients may need an additional copy because they lost or misplaced their prescriptions, or because the prescription was not returned after they ordered eyeglasses.248 The Commission believes that there is often a valid need for consumers to obtain additional copies of their prescriptions, and encourages prescribers to provide them when requested. However, in a previous Rule review, the Commission considered this issue and determined not to mandate a requirement to provide additional copies since it did not receive sufficient evidence indicating that the practice of refusing to release additional copies of eyeglass prescriptions is widespread.249 After reviewing the evidence in the instant rulemaking record, the Commission, for this same reason, declines to amend the Rule to require prescribers to provide patients with additional copies of eyeglass prescriptions upon request.

Optometrists, opticians, consumers, a consumer advocate, an online seller, and a telehealth prescriber commented in favor of amending the Rule to require that prescribers provide additional copies of prescriptions to patients that do not currently have access to their prescription.250 The NAOO stated its belief that, although optometrists affiliated with its member companies provide additional copies upon request at no charge, the Rule should clarify that consumers always have a right to their eyeglass prescriptions as part of their medical records.251 It pointed out that, although consumers already have a right to their prescriptions under HIPAA, the 30-day period allotted to prescribers (and other covered entities) for the production of medical records under HIPAA is overly long for consumers who may need replacement eyeglasses.252 Warby Parker commented that providing an additional copy furthers the original goal of the Rule to foster comparison-shopping in that it ensures that patients have the freedom to choose where to purchase their eyeglasses.253 Visibly, formerly known as Opternative, a telehealth prescriber, stated that such a requirement would be consistent with the Rule’s intent and furthers its purpose.254 Warby Parker also stated that some prescribers refuse to provide such copies and that others charge patients for them.255 One commenter stated that there is no real impact on a prescriber’s business to provide a duplicate copy, while it allows consumers access to their prescription without needing to undergo a new exam.256 Some commenters stated the prescriber should have to release additional copies, but suggested that prescribers should be able to impose a small administrative fee.257 One commenter who supported permitting the imposition of a small fee explained that such a fee is justified

251 Comment #0748 submitted by Cutler; see also Prevent Blindness (Comment #0385 submitted by Parry) (calling the right to one’s own prescription a “basic consumer right”); Professional Opticians of Florida (Comment #0803 submitted by Couch) (stating it is a consumer’s right to have access to his or her prescription).

252 Comment #0748 submitted by Cutler. In 2021, HHS proposed modifying the HIPAA Privacy Rule to "require that access [to protected health information] be provided 'as soon as practicable,' but in no case later than 15 calendar days after receipt of the request, with the possibility of one 15-calendar-day extension." Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6459. The Cures Act Final Rule, implementing the 21st Century Cures Act, also requires healthcare providers to make certain classes of data available to patients in their electronic health records. See Section IV.B.2.b. infra. This may result in consumers having greater access to their prescription records.

253 Comment #0817 submitted by Kumar.

254 Comment #0853 submitted by Dallek. Several consumers also wrote in support of adding this requirement to the Rule. DeMuth, Jr. (Comment #0055); Ellis (Comment #0189).

255 Comment #0817 submitted by Kumar.

256 Jozwik (Comment #0002).

257 Kiener (Comment #0593); Pulido (Comment #0019); see also Burchell (Comment #0866) (stating administrative charge should reflect the cost of the paper, other office supplies, and office staff time; suggesting that current market supports a fee of $2–$10; and clarifying the fee should not be a profit-making mechanism). One commenter recommended that the Rule mandate prescribers provide one replacement copy at no charge, but permit a charge for subsequent copies. Stuart (Comment #0841).

246 16 CFR 456.2(a).

247 Eyeglass Rule ANPR, 80 FR 53274, 53276.

248 The Commission distinguishes a request for an additional copy of a prescription from a request for an initial copy of a prescription in instances when a consumer did not receive the prescription immediately after the completed eye examination. In the latter event, the prescriber must provide a copy of the prescription without a fee unless the prescriber did not release the prescription immediately following the examination because the patient failed to pay for the examination and the prescriber requires immediate payment from all patients, whether or not the exam reveals a need for ophthalmic goods. See 16 CFR 456.2(a).

249 See Eyeglass II Rule, 54 FR 10825, 10303.

250 DeMuth Jr. (Comment #0055); Ellis (Comment #0189); Prevent Blindness (Comment #0385 submitted by Parry); Schwartz (Comment #0514); Burchell (Comment #0866); Kiener (Comment #0593); Opticians Association of Virginia (Comment #0647 submitted by Nelsa); NAOO (Comment #0748 submitted by Cutler); Pulido (Comment #0019); Professional Opticians of Florida (Comment #0803 submitted by Couch); Warby Parker (Comment #0817 submitted by Kumar); Stuart (Comment #0841); Opternative (now Visibly) (Comment #0853 submitted by Dallek).
because the prescriber faces a burden in providing the additional copy, and consumers should bear (or share) the responsibility for not having safeguarded the original copy they received following their examination.\(^{258}\)

The NAOO stated that additional copies should be provided without requiring that patients file formal HIPAA requests and at no charge because the cost to the prescriber is trivial.\(^{259}\)

Other commenters, including the AOA and the AAO, opposed amending the Rule to require that prescribers provide additional copies upon request.\(^{260}\) These commenters stated that most prescribers already provide additional copies at no charge and, therefore, there is no need to mandate it by rule.\(^{261}\) Some commenters stated that consumers should be responsible for copying and maintaining their prescription,\(^{262}\) and that prescribers should not have to shoulder the burden of consumers who are remiss at recordkeeping.\(^{263}\) The AOA expressed concern with the possible health effects to consumers that could result from requiring prescribers to provide prescriptions long after an initial refraction, and stated that prescribers must be allowed to use their clinical judgment to determine whether it is medically appropriate to provide subsequent copies of a prescription that may not be recent.\(^{264}\) The organization did not detail specific negative health effects, but stated that there are scenarios wherein an optometrist may not want to reissue an eyeglass prescription to a patient. For example, the optometrist may have performed a more recent comprehensive eye exam that renders the previous prescription no longer appropriate, or the prescriber may be aware of other health changes for the patient that could necessitate a change in the prescription.\(^{265}\)

The AO also pointed out, as a comparison, that medical doctors are not required to give patients multiple copies of pharmaceutical prescriptions upon request and that some medical doctors may require payment for such additional copies.\(^{266}\)

a. Analysis of Whether To Require Provision of Additional Copies of Prescriptions Upon Request

It is unnecessary to decide whether failure to provide an additional copy of a prescription upon request is an unfair act or practice because the Commission has not been presented with, and is unaware of, evidence that refusing to provide duplicate copies of prescriptions upon request is a prevalent problem. The NAOO, the AAO, and the AOA commented that prescribers do provide additional copies of prescriptions upon request.\(^{267}\) The only commenter who asserted that prescribers are not releasing duplicate copies of prescriptions upon request was Warby Parker.\(^{268}\) In support of its statement that some of its customers are being denied additional copies of prescriptions, Warby Parker cited to a survey that it said showed that 30 percent of consumers were not offered a copy of their prescription.\(^{269}\) This fact, however, may relate to the failure to initially release prescriptions to consumers, not the provision of additional copies, and thus does not establish that prescribers are refusing to provide additional copies to consumers upon request. Since the rulemaking record does not support a showing of prevalence, which is necessary for any Eyeglass Rule amendment,\(^{270}\) the Commission does not believe it has sufficient evidence to propose amending the Rule to require that prescribers provide additional copies of prescriptions upon request.\(^{271}\)

b. Analysis of Whether To Permit Prescribers To Charge Fees for Provision of Additional Copies of Prescriptions

In addition to not requiring that prescribers provide additional copies of prescriptions, the Eyeglass Rule does not set forth whether or not prescribers are permitted to charge for providing such copies. Some of the commenters requested the Commission amend the Rule to either permit a prescriber to charge a fee,\(^{272}\) or to prohibit a prescriber from charging a fee,\(^{273}\) for providing additional copies. Since the Commission determined not to propose amending the Rule to require prescribers provide additional copies, it is unnecessary to address the issue of fees for mandated duplicate copies.\(^{274}\)

In the current Rule review, as noted above, little evidence was placed on the record indicating that prescribers are not providing duplicate prescriptions upon request or that prescribers are charging more than nominal, administrative fees for providing additional copies of prescriptions. As a result, the Commission has not been presented with evidence that these practices are prevalent and does not believe an amendment prohibiting or limiting the imposition of fees for additional copies of prescriptions is necessary.

2. Electronic Delivery of Prescriptions as a Means for Automatic Prescription Release Under § 456.2(a)

As previously noted, § 456.2(a) of the Eyeglass Rule provides that it is an unfair act or practice for a prescriber to fail to provide to the patient one copy of the patient’s prescription

---

\(^{258}\) Burchell (Comment #0866).

\(^{259}\) Comment #0748 submitted by Cutler. The HHS’ proposed modifications to the HIPAA Privacy Rule would clarify that providers may not charge individuals a fee to inspect their protected health information (including when they photograph or record the information themselves) or to view and capture an electronic copy of their information via an internet-based method. Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6465–6466.

\(^{260}\) See, e.g., AAO (Comment #0864 submitted by Haber); AO (Comment #0849 submitted by Peele); Publi (Comment #0040); Haas (Comment #0359); Sharma (Comment #0069); Berry (Comment #0067).

\(^{261}\) Comment #0849 submitted by Haber.

\(^{262}\) AO (Comment #0864 submitted by Haber); AO (Comment #0849 submitted by Peele); Sharma (Comment #0069); Berry (Comment #0067). The AAO stated that if practices are inflexible with regard to providing duplicate copies, patients will go elsewhere for their eye care needs. Comment #0864 submitted by Haber. One commenter indicated that amending the Rule is not necessary because consumers should have access to their prescriptions through electronic health records or patient portals. Bolenbaker (Comment #0633).

\(^{263}\) Publi (Comment #0040); Haas (Comment #0359).

\(^{264}\) See, e.g., Haas (Comment #0359).

\(^{265}\) Comment #0849 submitted by Peele.

\(^{266}\) AAO (Comment #0864 submitted by Haber); AO (Comment #0849 submitted by Peele); Sharma (Comment #0069); Berry (Comment #0067).

\(^{267}\) NAOO (Comment #0748 submitted by Cutler); AAO (Comment #0864 submitted by Haber); AO (Comment #0849 submitted by Peele); see also Sharma (Comment #0069) (stating duplicates already being provided on voluntary basis); Berry (Comment #0067) (same).

\(^{268}\) Comment #0817 submitted by Kumar.

\(^{269}\) Id.

\(^{270}\) See 15 U.S.C. 57a(b)(3).

\(^{271}\) The Commission recognizes that this result differs from the FCLCA and the CLR, which require prescribers to respond to requests for additional copies of prescriptions. 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2). See also CLR NPRM, 41 FR 86526, 88536 (explaining Act and Rule’s requirements to provide a copy of an additional contact lens prescription upon request). However, as previously explained, the authority for the Eyeglass Rule is different than for the CLR, and requires a showing that the problem is prevalent.

\(^{272}\) Kiener (Comment #0593) (proposing a small administrative fee); Burchell (Comment #0866) (stating administrative charge should reflect the cost of the paper, other office supplies, and office staff time; suggesting that current market supports a fee of $2–$10; and clarifying the fee should not be a profit-making mechanism); Pulido (Comment #0019) (proposing a small fee).

\(^{273}\) NAOO (Comment #0748 submitted by Cutler); Warby Parker (Comment #0817 submitted by Kumar). One commenter recommended that the Rule mandate prescribers provide one replacement copy at no charge, but permit a charge for subsequent copies. Stuart (Comment #0841).

\(^{274}\) As noted above, if the prescriber has failed to provide a copy of the prescription following the completed examination in violation of the Rule, the prescriber must provide a copy of the prescription when a patient later asks for it. Because the prescriber could not charge a fee had he or she provided it immediately following the examination, the prescriber may not do so in response to that patient’s later request for an initial copy.
immediately after the eye examination is completed. The Rule does not expressly permit electronic delivery of prescriptions as a means for automatic prescription release. The Commission believes expressly permitting electronic delivery in certain circumstances could provide benefits to consumers.

In 2021, the CLR was amended to allow prescribers to satisfy the CLR’s automatic release requirement by providing the patient with a digital copy of his or her contact lens prescription, such as by text message, electronic mail, or an online patient portal, in lieu of a paper copy, provided the prescriber first identified the specific method of delivery to be used and obtained the patient’s verifiable affirmative consent to this method of delivery.275 In the CLR SNPRM, the Commission noted that providing patients with an electronic copy of their prescription could enable patients to share prescriptions more easily with sellers when purchasing eyewear, and this in turn could potentially reduce the number of patient and seller requests for verification or additional copies of the prescription. To enhance portability, the Commission noted that electronic delivery methods should allow patients to download, save, and print the prescription.276

As discussed above, the Commission is proposing to amend the Rule to add a Confirmation of Prescription Release requirement.277 The proposed text of the Rule would provide prescribers with four alternative means of complying with the Confirmation of Prescription Release requirement. The fourth option states, “If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.” In order to allow prescribers to meet the Confirmation of Prescription Release requirement in this way, the Rule must describe the conditions under which electronic delivery of the prescription will satisfy the automatic prescription release requirements. The Commission therefore proposes to define the phrase, “provide to the patient one copy,” which appears in § 456.2(a) and creates the requirement to automatically release the prescription immediately after the eye examination is completed.278 This new definition expressly permits electronic delivery in certain circumstances.

a. The Commission’s Proposal To Add a Definition to § 456.1 To Permit Electronic Delivery of the Patient’s Prescription

Accordingly, the Commission proposes to modify the Rule by adding a definition of the term “provide to the patient one copy.” The Commission proposes to require that prescribers provide patients with either a paper copy of their prescription or, with the patient’s verifiable affirmative consent, a digital copy of the patient’s prescription in lieu of a paper copy. Verifiable affirmative consent means that a patient must have provided his or her consent to the prescriber in a way that can be later confirmed, such as through a signed consent form or an audio recording. The consent must also identify the specific method or methods of electronic delivery to be used because it is possible that a patient may prefer one method of electronic communication, but not others, and the patient should be able to make an informed choice.

Prescribers would be required to keep a record or evidence of a patient’s affirmative consent for a period of not less than three years, which would facilitate Commission enforcement efforts to monitor compliance with the Rule. As the Commission concluded in the CLR Final Rule, the burden of retaining a record of patient consent should be minimal, “since prescribers who opt for electronic delivery of prescriptions will, in all likelihood, obtain and/or store such consent electronically.”279 At any rate, obtaining and storing a record of patient consent should not take longer than obtaining and storing a patient’s Confirmation of Prescription Release under option (i), (ii), or (iii), and prescribers choosing to use the fourth option to confirm prescription release would not need to collect additional information from the patient beyond the consent to electronic delivery. Finally, offering a prescription in a digital format would be an option for prescribers, but is not mandatory, so prescribers can choose not to offer electronic delivery of prescriptions if they find the recordkeeping provision overly burdensome.

The amended Rule would also require that if the prescription is provided electronically, it must be in a digital format that can be accessed, downloaded, and printed by the patient. The Commission believes this could enable patients to have easier access to and use of a prescription, reduce requests for additional copies and calls from sellers to verify a prescription, and potentially lower costs while providing flexibility for prescribers and patients.

Therefore, the Commission proposes to amend § 456.1 to define the phrase “provide to the patient one copy” to mean giving a patient a copy of his or her prescription:

1. On paper; or
2. In a digital format that can be accessed, downloaded, and printed by the patient. For a copy provided in a digital format, the prescriber shall identify to the patient the specific method or methods of electronic delivery to be used, such as text message, electronic mail, or an online patient portal, and obtain the patient’s verifiable affirmative consent to receive a digital copy through the identified method or methods; and maintain records or evidence of a patient’s affirmative consent for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

The full text of the proposed Rule amendment is located at the end of this document.

b. Technological Advances That May Improve Prescription Portability

Technological advances—including many spurred by federal and state health information technology initiatives280—have fostered the

275 CLR Final Rule, 85 FR 50668, 50717.
276 CLR SNPRM, 84 FR 24664, 24668.
277 See Sections II.A, IV.A.6, supra.
278 10 CFR 456.2(a).
279 CLR Final Rule, 85 FR 50668, 50683.
280 Numerous federal and state programs have been designed to foster the development of health information technology and the electronic processing, storage, and transmission of patients’ health information. For example, under the Health Information Technology for Economic and Clinical Health Act or HITECH Act of 2009—Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009—Congress directed the Medicare and Medicaid programs to make direct payments to eligible healthcare professionals, hospitals, and certain other healthcare providers specifically to incentivize the adoption and meaningful use of electronic health records systems (“EHRs”). American Recovery and Reinvestment Act of 2009, Public Law 111–5, Division B, Title IV, §§ 4101, 4102, and 4201 (2009) (Medicare incentives for eligible professionals, Medicare incentives for hospitals, and Medicaid provider payments, respectively). According to a 2016 report, more than $30 billion in such incentive payments were made between 2011 and 2015. U.S. Dep’t Health & Human Servs., Office of the National Coordinator for Health Information Technology, Update to Congress, “Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information” 17 (2016), https://www.healthit.gov/sites/default/files/Attachment_1_-_2-26-16_RTC_HIT_Progress.pdf. Regarding patient portals in particular, see, e.g., U.S. Dep’t Health & Human Servs., Office of the National Coordinator for Health
proliferation of patient portals, application programming interfaces, and other developing technologies, through which health care providers can securely share medical information, such as prescription information, directly with patients. The increasing number of prescribers who have adopted various health information technologies to support patient engagement, such as patient portals, has made it possible for prescribers to provide online access to prescriptions. This, along with the patient’s ability to email or otherwise upload prescription copies to sellers, increases prescription portability.

Available information suggests, however, that the number of patients accessing EHRs, such as patient portals, remains limited, and that certain patients, including older patients, are less likely to use these tools.

Through the 21st Century Cures Act, Congress authorized HHS to take action to promote the interoperability of health IT, support the use, exchange, and access of electronic health information, and limit information blocking. The Cures Act Final Rule, promulgated by the Office of the National Coordinator for Health Information Technology (“ONC”), requires healthcare providers to enable patient access to enumerated classes of data in their electronic health record systems. These data classes include providers’ clinical notes and information on medications, and may result in consumers having greater access to their prescription information from their refraction exam.

The use of patient portals for presentation of eyeglass prescriptions to sellers could provide many benefits to consumers—potentially at low marginal cost to those providers who already maintain EHRs and patient portals. When using a portal, the patient could have direct access to a current, exact copy of the eyeglass prescription, reducing the chance of errors caused by an inaccurate or expired prescription, and the need for follow-up corrections by prescribers. The use of health information technologies, such as patient portals, could also reduce costs for prescribers and sellers by making it easier and more efficient for patients to obtain and share eyeglass prescriptions and by reducing the number of requests placed on prescribers to verify prescription information, or provide duplicate copies, of prescriptions. In addition, patient portals may not raise the same privacy concerns expressed by some prescribers about sharing patient prescription information with third parties because patient portals can enable the secure sharing of such information directly with the patients themselves, who may then provide the prescription to the third-party seller.

Accordingly, the Commission believes that the use of health information technologies, such as patient portals, to provide patients with access to electronic copies of their eyeglass prescriptions can benefit prescribers, patients, and sellers. The Commission encourages prescribers to consider whether, in addition to providing patients with copies of their prescriptions immediately following the completion of the eye examination, they should make prescriptions available electronically and online via health information technologies, in accordance with federal and state law and HHS guidance. To facilitate the likelihood that patient portals will increase prescription portability, prescribers should consider whether to configure patient portals to allow the patient to download, save, and print the prescription. In addition, prescribers should explore whether designing the portal to allow the patient to securely transmit the prescription directly to a seller will further foster prescription portability.

The proposed Rule amendment permitting electronic delivery of prescriptions to satisfy the automatic prescription release requirement expressly contemplates the use of patient portals to deliver prescriptions. Significantly, the proposed change to allow for a digital copy in lieu of a paper copy does not alter the timing of when a prescriber must provide the prescription to the patient. In both instances, whether a digital or paper copy is given, prescribers must provide the prescription immediately after completion of the refraction eye examination. The Commission believes increased future use and adoption of health information technologies, such as patient portals, in response to the 21st Century Cures Act and other developments, has the potential to facilitate prescribers’ compliance with the automatic prescription release requirement of the Rule and believe it is appropriate to provide an option for prescribers to use electronic delivery of prescriptions, so long as patients have expressly consented in advance to the mode of delivery used.
c. HIPAA Concerns Regarding Eyeglass Prescriptions

In response to the ANPR, the Commission did not receive any comments that identified concerns with how the Eyeglass Rule interacts with HIPAA and the HIPAA Privacy and Security Rules (“HIPAA Rules”). However, in other contexts, the Commission has received questions and complaints related to prescribers’ HIPAA obligations under the Eyeglass Rule. For example, some prescribers have asked staff whether HIPAA precludes optometrists from emailing copies of a prescription to a patient without written authorization. Correspondingly, some consumers have complained that their eye care practitioners have cited HIPAA in refusing to email or fax eyeglass prescriptions to them.

As a preliminary matter, the HIPAA Rules do not require the prescriber to obtain a signed HIPAA authorization from a patient in order for the prescriber to release an eyeglass prescription to the patient. The HIPAA Rules also do not prohibit covered prescribers from emailing eyeglass prescriptions to patients. According to guidance provided by HHS, the HIPAA Rules allow health care providers to communicate electronically with patients, provided they apply reasonable safeguards. Although a covered provider must consider encryption to protect against unintentional disclosures, the provider may determine that it is not reasonable and appropriate, and may instead apply ordinary precautions when transmitting unsecured email, such as checking the email address for accuracy before sending, sending an email alert to the intended recipient for address confirmation prior to sending the message, and limiting the amount and type of protected health information ("PHI") transmitted through the email.

Moreover, where a patient requests that the covered entity transmit PHI (such as a copy of an eyeglass prescription) by unencrypted email—as is their right under the HIPAA Privacy Rule right of access—a covered entity must do so, even if the email is an unsecure mode of transmission. Before sending unencrypted email containing PHI to a patient, the entity must advise the patient of the risk that the unencrypted PHI could be intercepted and accessed by unauthorized third parties. If, after having been advised of the risks, the patient still opts to receive his or her PHI via unencrypted email, the patient has the right to receive the PHI in that manner, and the covered entity is not liable for unauthorized access to the PHI during electronic transmission, or for safeguarding the PHI once delivered to the patient. Conversely, a covered prescriber must honor a patient’s reasonable request that the prescriber not send communications via unencrypted email, by offering other means of delivery, such as encrypted email, secure patient portal, postal mail, or telephone.

While permitting electronic delivery with a patient’s verifiable consent, the proposed Rule amendment would not mandate that prescribers use electronic delivery, nor would it obligate patients to accept such delivery. As with the recent CLR amendment, patients who decline to consent to electronic delivery, for any reason, must be given a paper copy of their prescription. Likewise, because technology is still developing or may be costly to implement, prescribers who prefer to provide paper copies to their patients would not be required to offer an electronic option under the amended Rule.

3. Insurance Coverage as Payment Under § 456.2(a)

The Eyeglass Rule requires that prescribers provide consumers with a copy of their prescription, but also contains an exception to allow a prescriber to refuse to give the patient a copy of their prescription until the patient has paid for the eye examination, so long as the prescriber would have required immediate payment had the eye examination revealed that no ophthalmic goods were required. The CLR contains the same provision, but also provides that for purposes of this exception, a patient’s proof of insurance coverage shall be deemed to constitute a payment. The Eyeglass Rule does not contain this insurance clarification, and staff has received questions from the public about this issue. The Commission believes that such a proviso, which was initially formulated by Congress in drafting the FCLCA, should be added to the Eyeglass Rule, both because it is appropriate that a patient’s proof of

---

291 45 CFR parts 160, 164.
292 See 45 CFR 164.502(a)(1); U.S. Dep’t of Health & Human Servs., Office for Civil Rights, “Summary of the HIPAA Privacy Rule” 4–5 (2003), http://www.hhs.gov/sites/default/files/privacy/summary.pdf (“A covered entity is permitted . . . to use and disclose protected health information, without an individual’s authorization, for the following purposes or situations: (1) To the individual (unless required for access or accounting of disclosures) . . . Covered entities may rely on professional ethics and best judgments in deciding which of these permissible uses and disclosures to make.”) (footnote omitted).
293 U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Does the HIPAA Privacy Rule permit health care providers to use email to send health information and treatment with their patients?” http://www.hhs.gov/hipaa/for-professionals/faqs/570/does-hipaa-permit-healthcare-providers-to-use-email-to-discuss-health-issues-with-patients/; see also 45 CFR 164.530(c).
294 Encryption of PHI must be implemented where a covered entity has determined that it is a reasonable and appropriate safeguard as part of its risk management. See U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Is the use of encryption mandatory in the Security Rule?” http://www.hhs.gov/hipaa/for-professionals/it-security-law/2001/is-the-use-of-encryption-mandatory-in-the-security-rule/index.html. A covered health care provider also must protect PHI in those emails while they are stored on servers, workstations, mobile devices, and other computer systems, through encryption and other safeguards, as appropriate. See 45 CFR 164.306(c).
295 The HIPAA Privacy Rule right of access requires a covered provider to provide, upon request, a copy of a prescription to the patient or to another person or entity she designates. 45 CFR 164.524(c)(3); see also U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Individuals’ Right under HIPAA to Access their Health Information 45 CFR 164.524.” http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/. HHS has proposed modifying the Privacy Rule to clarify that an individual’s right of access to a provider to transmit PHI to a third party is limited to an electronic copy of PHI contained in an electronic health record. Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6462.
296 U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Do individuals have the right under HIPAA to have copies of their PHI transmitted or transferred to them in the manner they request, even if the requested mode of transfer or transmission is unsecure?,” https://www.hhs.gov/hipaa/for-professionals/faq/2006/do-individuals-have-the-right-under-hipaa-to-have/index.html (“individuals generally have a right to receive copies of their PHI by mail or email, if they request. It is expected that all covered entities have the capability to transmit PHI by mail or email and transmitting PHI in such a manner does not present unacceptable security risks to the systems of covered entities, even though there may be security risks to the PHI once it has left the systems. Thus, a covered entity may not require that an individual travel to the covered entity’s physical location to pick up a copy of her PHI if the individual requests the copy be mailed or emailed.”)
297 Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 76 FR 5565, 5634 (Jan. 25, 2013).
298 45 CFR 164.522(b).
299 The proposed amendment would also not alter or pre-empt existing state and federal requirements pertaining to the electronic delivery of records and consumer consent, such as the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. 7001 (“E-Sign”).
300 The proposed amendment would not mandate that prescribers use electronic delivery, nor would it obligate patients to accept such delivery. As with the recent CLR amendment, patients who decline to consent to electronic delivery, for any reason, must be given a paper copy of their prescription. Likewise, because technology is still developing or may be costly to implement, prescribers who prefer to provide paper copies to their patients would not be required to offer an electronic option under the amended Rule.
301 The Eyeglass Rule does not contain this insurance clarification, and staff has received questions from the public about this issue. The Commission believes that such a proviso, which was initially formulated by Congress in drafting the FCLCA, should be added to the Eyeglass Rule, both because it is appropriate that a patient’s proof of
insurance coverage equates to payment, and to bring the two rules into conformity, to eliminate unnecessary confusion. The Commission thereby proposes a technical amendment to the Rule to add a statement to the end of § 456.2(a) clarifying that the presentation of proof of insurance coverage shall be deemed to be a payment.

C. Requiring Prescribers To Respond to Authorized Third-Party Seller Requests for a Copy of Prescription or Verification of Prescription Information

In contrast to the CLR, the Eyeglass Rule does not require a prescriber to provide a copy to, or verify prescription information with, third-party sellers authorized by the patient.105 The Commission requested comment on whether it should amend the Rule to obligate prescribers to respond to either or both of these requests from sellers.106

1. Comments on Requiring Prescriber Response to Third-Party Seller Requests

Some commenters recommended that the Commission align the Eyeglass Rule with the CLR, which requires that prescribers provide authorized third parties with a copy of, and verification of, a prescription.107 Under the CLR, a seller may only sell contact lenses in accordance with a prescription that is presented to the seller by the patient or prescriber, or verified by the prescriber.108 A prescription is verified only if the prescriber confirms the prescription is accurate, the prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription, or the prescriber fails to respond to the seller within eight business hours after receiving a complete verification request (“passive verification”).109 A prescriber is also required to respond to an authorized seller’s request for a copy of a prescription.110

The verification requirements for contact lenses derive from the FCLCA, which created the framework for contact lens sales and directed the Commission to promulgate the CLR.111 The FCLCA requires that sales of contact lenses occur only with a copy of a prescription, or after verifying a prescription with a prescriber, and sets forth the requirements for passive verification.112 Commenters in favor of amending the Eyeglass Rule to require that prescribers provide copies of prescriptions to sellers, or verify prescriptions with sellers, include the NAOO, several state optician groups and individual opticians, some prescribers (including a telehealth prescriber), eyewear seller Warby Parker and some of its employees, a United States Senator, and numerous individual consumers.113 Warby Parker and a number of consumers stated that there is a need for such a requirement because, at present, when sellers request or verification of prescription information, prescribers do not always respond114 or respond in a timely fashion.115 Warby Parker commented that it expires substantial resources “persuading[ing] prescribers” to provide the information required to fill a consumer order, and that it informs between 50 and 100 consumers per day that it is unable to complete their eyeglass orders.116 As a result, some consumers complained that they waited a long time for their eyeglasses, or that they were ultimately unable to purchase glasses from a seller other than their prescriber.117 Some of these commenters felt that prescribers have unfairly kept their medical information from them.118

In addition to comments recommending that the Commission require sellers to obtain a copy of, or verify, a prescription before manufacturing eyeglasses,119 one commenter opined that a verification provision would promote fair business practices and better options and pricing for consumers;120 and others supported rule improvements that would increase access to affordable prescription eyewear.121 U.S. Senator Charles Schmer commented that not having a verification requirement limits consumer choice and leads to higher prices.122 In addition, state opticians

Warby Parker (Comment #0817 submitted by Kumar).

105 16 CFR 315.3(a).
108 See, e.g., Opticians Association of America (Comment #0638 submitted by Allen); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Duff (Comment #0653); NAOO (Comment #0748 submitted by Cutler); South Carolina Association of Opticians (Comment #0822 submitted by Harber); DeMuth Jr. (Comment #0805); Senate Majority Leader Charles Schumer (Comment #0865); Ramiah (Comment #0139); Capurso (Comment #0491); Mendelsohn (Comment #0429); Groenke (Comment #0697); Scheck (Comment #0765); Kuhl (Comment #0766); Gorsch (Comment #0774); Hopkins (Comment #0776); Feldman (Comment #0780); Anderson (Comment #0781); Lyden (Comment #0792); Jackson (Comment #0792); Meinkin (Comment #0780); Keas (Comment #0798); Burkhardt (Comment #0805); Allee (Comment #0806); Rivera (Comment #0809); Warby Parker (Comment #0817 submitted by Kumar); Warden (Comment #0820); Anderson (Comment #0714); Sansbury (Comment #0825); Williamson (Comment #0827); Ardis (Comment #0830); Polline Vision Centers (Comment #0837); Rump (Comment #0841); Murtha (Comment #0944); Heaton (Comment #0843); Gage-Halman (Comment #0846); Malonjao (Comment #0856). Some commenters used the term “verify” to mean that prescribers should be required to provide a copy of a prescription to an optical shop. See, e.g., Debnam (Comment #0039) (consumer did not have a copy of the prescription so asked optical shop to call the doctor to verify the prescription); Panaccio (Comment #0340) (same). In other instances, it was unclear whether commenters were discussing requiring the prescriber to provide a copy of, or verify, prescriptions.
109 See, e.g., Debnam (Comment #0039); White (Comment #0053); Kidwell (Comment #0054); Averett (Comment #0057); Silva-Sadder (Comment #0065); Tresham (Comment #0073); Zewdie (Comment #0150); Lass (Comment #0197); Moran (Comment #0202); Vieira (Comment #0237); Laviere (Comment #0242); Panaccio (Comment #0340); Schermerhorn-Cousens (Comment #0350); Stout (Comment #0527); and Dallek (Comment #0653).
110 16 CFR 315.5.
111 Id.
groups, individual opticians, and at least one optometrist, stated that enabling sellers to verify prescriptions with a patient’s optometrist or ophthalmologist would better ensure patient safety.323

The NAOO and Warby Parker specifically requested the Rule be amended to include “passive verification,” similar to that in the CLR, which would allow the sale of eyeglasses after a seller requests prescription verification and the prescriber fails to respond within a certain period.324 To support, the NAOO stated that there is only a very small health or safety risk, if any, in improper fitting or inaccurate prescriptions for corrective eyewear, and such risk is substantially less for eyeglasses than contact lenses (since eyeglasses are not placed on the eye itself).325

On the other hand, several commenters, mostly prescribers, objected to amending the Rule to require prescribers to respond to sellers’ requests for prescription information.326 The AOA did not comment on whether prescribers should be required to provide a copy of a prescription to third-party sellers,327 but “strongly oppose[d]” adding a verification process similar to that utilized under the CLR, stating that the CLR’s passive verification process had various “problems and weaknesses.”328 Another, as noted in Section IV.B.1 above, that a verification requirement would waste a prescriber’s time since the customer already receives a copy of the prescription.329 The AAO recognized in its comment that the expansion of online eyeglass vendors has led to a growing need for third-party verification, but stated that ophthalmic practitioners have worked diligently to meet that need without the Eyeglass Rule mandating it.330 The AAO also contended that, due to the larger volume of eyeglass prescriptions as compared to contact lens prescriptions, amending the Rule to require strict timeframes for

prescribers to respond to verification requests would pose undue financial burden on prescribers.331

2. Analysis of Whether To Amend the Rule To Require Prescriber Response

The Commission declines to propose to amend the Rule to require that prescribers respond to third-party requests for prescriptions or the verification of prescription information. The Commission bases this decision on a number of factors. Initially, the Commission notes that the evidence regarding this issue is primarily anecdotal and the Commission does not, at present, have adequate data as to the number of such third-party requests, nor the percentage of requests that prescribers decline to fulfill. Furthermore, according to comments from the AAO and the AOA, many prescribers are complying with patient requests for duplicate copies of their prescription, even without such conduct being mandated by the Eyeglass Rule.332 This may be because prescribers are required to respond to patient requests for their prescription under HIPAA’s right of access to medical records and many state laws.333

331 Comment #0864 submitted by Haber. There are approximately 165 million eyeglass wearers compared to about 45 million contact lens wearers. See VisionWatch Report, supra note 70, at 24 (165.4 million eyeglass wearers; 42.4 million contact lens wearers); Centers for Disease Control and Prevention, Contact Lenses: Fast Facts [July 26, 2018], https://www.cdc.gov/contactlenses/fast-facts.html (an estimated 45 million contact lens wearers in the U.S.). Although more individuals in the United States wear eyeglasses than contact lenses, many consumers do not wear a pair of eyeglasses every year. In fact, in 2019, consumers purchased approximately 79 million pairs of eyeglass frames and 88 million pairs of lenses, whereas nearly 103 million contact lens units were sold in the same period. See VisionWatch Report, supra note 70, at 12, 82. Further, many contact lens wearers make more than one order in a year. “The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study,” 45–46 n.18 (2005), https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf (finding that just 12–20 percent of consumers purchase a year’s supply at a time). As a result, the burden of responding to requests for a copy of, or verification of, eyeglass prescriptions is necessarily greater than that for contact lens prescriptions.

332 AAO (Comment #0864 submitted by Haber) (duplicate copies traditionally provided at no charge); AOA (Comment #0849 submitted by Peele) (calling provision of duplicate copies common practice among optometrists); Haas (Comment #0359); Sharma (Comment #0609); Berry (Comment #0863); Haas (Comment #0359); Sharma (Comment #0609); Berry (Comment #0863). 333 45 CFR 164.524(c). Although in order to exercise this right, consumers may have to file a formal HIPAA request and wait several days. See note 252, supra. Consumers in most states have a separate right of access to their medical records, including prescriptions, under state law. See Health Information and the Law, Individual Access to Medical Records: 50 State Comparison, http://www.healthinfoway.org/comparative-analysis/
Moreover, the Commission has proposed a requirement for prescribers to obtain a signed confirmation from patients that they received a copy of their prescription. It is the Commission’s belief that this proposal will remind prescribers to release prescriptions and increase compliance with the automatic release provision of the Rule, resulting in more patients in possession of their prescription, and, consequently, less need for third-party verification. The signed confirmation proposal, in conjunction with consumers’ ability to access an additional copy of their prescription through HIPAA, other laws, or voluntary release by prescribers, should ensure that the vast majority of consumers have a prescription in hand. With that prescription, consumers should experience greater convenience and flexibility, including increased choice of style and service, and lower costs.

The Commission’s goal in adopting the Confirmation of Prescription Release requirement is to further the purpose of the Rule: to enable consumers to comparison-shop for eyeglasses. The Commission is mindful that, at present, a significant percentage of prescribers do not automatically provide a prescription, and many consumers cannot reasonably avoid the resulting injury. The Commission is hopeful that compliance will improve without adding a requirement that prescribers provide prescriptions to, or verify prescriptions with, third parties. The Commission therefore believes it is unnecessary at this time to impose possible additional costs upon prescribers that might arise from mandating they respond directly to third-party sellers’ requests, but may revisit this issue in the future if we receive additional information.

V. Prescription Requirements

A. Requiring Prescribers To Include Pupillary Distance on Eyeglass Prescriptions

The Commission’s ANPR sought feedback on whether the Commission should amend the Rule’s definition of prescription to require that prescribers provide pupillary distance on a prescription. Pupillary distance is the measurement (in millimeters) of the distance between the pupils of one’s eyes and is a measurement needed to properly fit a pair of eyeglasses. Unlike a patient’s refraction dimensions (sphere, cylinder, etc.), pupillary distance remains relatively constant for adults over time, although it can change a small amount. According to prescriber and optician comments, providing a complete set of accurate pupillary distance is important to the health of the patient as wearing eyeglasses made based on an inaccurate measurement can lead to visual discomfort, headaches, or even vision loss for some children.

The burden presented from the CLR’s verification requirement. CLR RFC Comment FTC–2015–0093–0623 submitted by NAOO (Comment #0748 submitted by Cutler). Eyeglass Rule ANPR, 80 FR 53274, 53276. See AClens “Measuring Pupillary Distance (PD),” https://www.aclens.com/measuring-pupillary-distance. As discussed later in this section, some commenters explained that a pupillary distance measurement was required prescription information. See, e.g., Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Callen); South Carolina Association of Opticians (Comment #0822 submitted by Harbert); Robinson (Comment #0643); Duff (Comment #0651); Johnson (Comment #0654); Theford (Comment #0659); Crabtree (Comment #0666); Groenke (Comment #0697).

Several commenters also pointed out that an accurate pupillary distance is even more important for those consumers who have higher-powered prescriptions. See, e.g., Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Heuer (Comment #0670); LensCrafters (Comment #0819 submitted by Tavel).

The AOA did not address the burden of verification in its comment to the Eyeglass Rule, its comments during the CLR review raised concerns about the accuracy of pupillary distance measurements. After considering the various comments concerning whether to require that prescriptions contain pupillary distance and other measurements needed to make eyeglasses were part of the eye examination or the dispensing of eyeglasses, and whether prescribers or opticians were more qualified to take pupillary distance measurements, it left to the states the determination of whether a pupillary distance measurement was required prescription information.

The manner of purchasing eyeglasses when the Commission first promulgated the Rule differed greatly from the present, however. Then, if a prescriber did not provide pupillary distance on prescriptions, consumers could generally obtain that measurement at the brick and mortar business where they purchased their eyeglasses. Today, consumers also have the option to purchase their eyeglasses online and need that measurement to place their order. Several commenters to this Rule review suggested that the Rule should now be amended to require that prescriptions include a patient’s pupillary distance.

Understanding what currently occurs in the marketplace with respect to

individual-access-medical-records-50-state-comparison (compiling and explaining state laws that give consumers the right to access their medical records).

334 See Section IV.A.6, supra.

335 See Section IV.A.4, supra.

336 The Commission is not indicating that prescribers should ignore such requests, but rather is declining to propose to amend the Rule to require such a response.

337 Several commenters pointed out that there is a burden associated with requiring prescribers to respond to requests for a copy of, or to verify a third-party’s request for, a prescription, though they do not agree on how large the burden is. NAOO (Comment #0748 submitted by Cutler) (declaring that the overall burden would be trivial when compared to the benefit); Kiner (Comment #0593) (processing third-party requests poses a non-insignificant operating expense); Opternative (now Visibly) (Comment #0853 submitted by Dallek) (stating its willingness to take on the burden for the benefit of greater consumer choice). Although the AOA did not address the burden of verification in its comment to the Eyeglass Rule, its comments during the CLR review raised concerns about the burden. Under the Rule, a prescription is defined as “the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses. The Rule defines an eye examination as “the process of determining the refractive condition of a person’s eyes or the presence of any visual anomaly by the use of objective or subjective tests.”

338 Eyeglass Rule ANPR, 80 FR 53274, 53276.

339 See AClens “Measuring Pupillary Distance (PD),” https://www.aclens.com/measuring-pupillary-distance. As discussed later in this section, some commenters explained that a pupillary distance measurement was more complex than this definition suggests.

340 NAOO (Comment #0748 submitted by Cutler); see also Barry Santini, “The Power and Politics of the PD,” 20/20 Magazine (Mar. 2014), http://www.2020mag.com/l-and-i/46893/ [hereinafter Santini article] (explaining that the average change in pupillary distance is three percent between the ages of 18 and 50, and changes even more slowly after the age of 60).

341 See, e.g., Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Callen); South Carolina Association of Opticians (Comment #0822 submitted by Harbert); Robinson (Comment #0643); Duff (Comment #0651); Johnson (Comment #0654); Theford (Comment #0659); Crabtree (Comment #0666); Groenke (Comment #0697).

342 Several commenters also pointed out that an accurate pupillary distance is even more important for those consumers who have higher-powered prescriptions. See, e.g., Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Heuer (Comment #0670); LensCrafters (Comment #0819 submitted by Tavel).

343 Clark (Comment #0855).

344 See Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand) (incorrect pupillary distance for child with anhidropia (commonly known as “lazy eye”) could lead to further vision loss and impairment); Peaslee (Comment #0700) (an incorrect pupillary distance could permanently damage a child’s vision).
pupillary distance informs the Commission’s discussion and analysis. Some prescribers who measure pupillary distance provide it on prescriptions automatically; others provide it free upon request or for a nominal fee, while others refuse to provide it to consumers.\footnote{NAOO (Comment #0748 submitted by Cutler); see also Fainzilberg (Comment #0051) (prescriber did not initially provide pupillary distance and later refused to give the measurement out over the phone); Wintermute (Comment #0067) (prescribed refusal to provide pupillary distance measurement); Tidings (Comment #0100) (prescriber gave the consumer the “runaround” and provided the pupillary distance measurement a couple weeks after the request); Morris (Comment #0104) (prescriber did not provide the pupillary measurement on the prescription); Bray (Comment #0105) (same); Parazzite-Nascimbene (Comment #0106) (same); Fainzilberg (Comment #0110) (same). The FTC has received complaints from consumers stating that their prescription did not include, or that their prescriber refused to provide them with, their pupillary distance. Other consumer complaints received by the FTC indicate that consumers have been charged by prescribers between $15 and $40 for a pupillary distance measurement. See, e.g., Narula (Comment #0578); Hoffman (Comment #0587); Groenke (Comment #0697) (requirement would possibly mean prescribers would need to purchase expensive equipment); Hopkins (Comment #0776) (same); LensCrafters (Comment #0819 submitted by Tavel) (stating that the digital technology required to accurately obtain these measurements does not typically exist in the doctor’s space); Alvarez (Comment #0838).} Other prescribers do not ordinarily take pupillary distance, leaving that task to the optical dispensary that crafts a patient’s eyeglasses. Some prescribers, particularly some ophthalmologists, commented that they do not have equipment to measure pupillary distance.\footnote{352 See, e.g., Zenni Optical, “How to Measure Your Pupillary Distance (PD),” http://www.zennioptical.com/measuring-pd-infographic; Warby Parker, “Measure your pupillary distance,” https://www.warbyparker.com/pd/instructions.} Consumers who do not receive their pupillary distance on their prescription, and desire to purchase their eyeglasses online, are able to obtain that measurement in other ways, though it may cost them time, money, or, according to some commenters, accuracy. If the information is in a patient’s medical file, the individual may obtain it by filing a HIPAA request, a process that may require filling out a form, paying a fee, and waiting up to 30 days.\footnote{353 NAOO (Comment #0748 submitted by Cutler); see also Fainzilberg (Comment #0051) (prescriber did not initially provide pupillary distance and later refused to give the measurement out over the phone); Wintermute (Comment #0067) (prescriber refused to provide pupillary distance measurement); Tidings (Comment #0100) (prescriber gave the consumer the “runaround” and provided the pupillary distance measurement a couple weeks after the request); Morris (Comment #0104) (prescriber did not provide the pupillary measurement on the prescription); Bray (Comment #0105) (same); Parazzite-Nascimbene (Comment #0106) (same); Fainzilberg (Comment #0110) (same). The FTC has received complaints from consumers stating that their prescription did not include, or that their prescriber refused to provide them with, their pupillary distance. Other consumer complaints received by the FTC indicate that consumers have been charged by prescribers between $15 and $40 for a pupillary distance measurement. See, e.g., Narula (Comment #0578); Hoffman (Comment #0587); Groenke (Comment #0697) (requirement would possibly mean prescribers would need to purchase expensive equipment); Hopkins (Comment #0776) (same); LensCrafters (Comment #0819 submitted by Tavel) (stating that the digital technology required to accurately obtain these measurements does not typically exist in the doctor’s space); Alvarez (Comment #0838).} Consumers may also obtain their pupillary distance measurements by visiting a third-party brick and mortar store. Consumers may have to pay for this measurement, although at least one online seller has offered to reimburse consumers up to a certain dollar amount for the measurement. Online sellers also offer directions and online tools for consumers to measure their own pupillary distance, or to have someone they know measure their pupillary distance.\footnote{45 CFR parts 160, 164 (HHS has proposed reducing this time to require access be provided “as soon as practicable,” but in no case later than 15 days. See note 252, supra). One complication with filling a HIPAA request, however, is that a consumer may not know whether a pupillary distance measurement is in their doctor’s medical file, and might not be able to find out until receiving the records. Some consumers, though, may already possess a previous prescription containing their pupillary distance.} Some prescribers, though, may already might not be able to find out until receiving the new prescriptions for eyeglasses and contact lenses so that “measurements taken by opticians are not considered part of the patient’s prescription, and are not required to be released as part of a prescription.”\footnote{Warby Parker and consumers recounted numerous instances where they felt prescribers had engaged in anti-competitive behavior by refusing to provide, or by charging for, the measurement.} Warby Parker also commented that prescribers refuse to give this measurement as a tactic to keep business because they know that consumers who request this measurement are taking their eyeglass business online.\footnote{Some consumers stated that they had to obtain their pupillary distance from another brick and mortar store before buying online, making it far less convenient to obtain new eyeglasses. Some consumers said that they measured their pupillary distance themselves, but as a result experienced problems with their glasses. The NAOO commented that self-estimating pupillary distance can result in lower accuracy and a higher number of eyeglass remakes, but that many online sellers have developed accurate alternative ways to measure pupillary distance. Warby Parker also commented that the Commission has previously objected to state regulatory proposals designed to withhold certain information necessary to fill an eyeglass prescription. The eyeglass seller pointed to a 2011 FTC staff letter responding to the North Carolina State Board of Opticians’ proposed rule that would have, among other things, redefined the meaning of prescriptions for eyeglasses and contact lenses so that “measurements taken by opticians are not considered part of the patient’s prescription, and are not required to be released as part of a prescription.” The 2011 staff letter, which did not specifically mention pupillary distance, was not an opinion by staff that pupillary distance is a necessary part of a valid eyeglass prescription, or that failure to include pupillary distance is an unfair act or practice. Rather, Commission staff was concerned that adoption of the North Carolina proposal would decrease consumers’ existing access to information. By contrast, the current document considers whether to}
designate a failure to include pupillary distance as an unfair act or practice. In contrast to Warby Parker and consumer commenters, ophthalmologists and optometrists commenting on the Rule almost universally declared that the Rule should not require that a prescription contain pupillary distance. Some prescribers, especially ophthalmologists, stated that they do not take this measurement. The AOA and LensCrafters commented that prescribers do not routinely take this measurement as part of an "eye examination." Other prescribers indicated that while they take a “binocular” pupillary distance measurement during their examination, this is not always precise enough for an optician to use in making eyeglasses. Prescribers further indicated that their principal opposition to a requirement that they include a pupillary distance on a prescription is that the measurement is part of the dispensing of eyeglasses and not part of a refraction examination, and that the costs associated with taking these measurements are built into the eyewear product and not the examination. Some prescribers stated that if taking a pupillary distance were to become a required part of an eye examination, the price of an eye examination would increase. In fact, a number of prescribers commented that if required to include it, they would have to acquire new equipment and hire or train staff to take this measurement. The AAO suggested that the addition of such a requirement might cause ophthalmologists to stop providing vision-correction exams for eyeglasses and contacts altogether, and focus solely on eye health and medical issues. Opticians, in general, are also largely opposed to the Rule requiring that a prescription contain pupillary distance. Many opticians suggested prescribers used to hold about what ought to be included in a prescription. Prior to adoption of the Eyeglass Rule, many in the optometric industry strenuously advocated for "total vision care," in which it was the prescriber’s responsibility to determine all of the parameters required to fabricate a pair of eyeglasses, including pupillary distance. See Eyeglass I Report, supra note 6, at 255–57 (citing testimony from the Indiana Optometric Association, Ohio State University College of Optometry, and Ron Fair, former president of the AOA). See, e.g., Jones (Comment #0584); Goldberg (Comment #0824); AAO (Comment #0864 submitted by Haber). 372 Patterson (Comment #0469); Groecken (Comment #0697); Hopkins (Comment #0776); AAO (Comment #0864 submitted by Haber). 373 As a way to offset these costs, some commenters recommend that prescribers be able to charge consumers for this measurement. Kirkham (Comment #0511); Goodheiro (Comment #0731). See, e.g., Jones (Comment #0629) (cost of providing care to patients will increase if he must hire an optician or optometrist); Hopkins (Comment #0766) (new equipment); Goldberg (Comment #0824) (prescribers are not trained and do not have staff to take pupillary distance); AAO (Comment #0864 submitted by Haber) (would have to hire extra staff); Narula (Comment #0578) (would require acquisition of costly equipment). 374 AAO (Comment #0864 submitted by Haber); see also Kim (Comment #0508); Croyer (Comment #0519). 375 See, e.g., Opticians Association of America (Comment #0638 submitted by Allen); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Opticians Association of America (Comment #0646 submitted by Dalton); Opticians Association of Virginia (Comment #0647 submitted by Wexler); Poe (Comment #0648); Montavon (Comment #0649); Professional Opticians of Florida (Comment #0803 submitted by Couch); Opticians Association of America (Comment #0852 submitted by Brand); Shelton (Comment #0585); Evans (Comment #0661); Damisch (Comment #0675); Whaley (Comment #0678); Jackson (Comment #0679); Chamberlain (Comment #0713); Conner (Comment #0721); Tanzi (Comment #0723); Oxenford (Comment #0724); Reed (Comment #0738); Shroyer (Comment #0822); Hummel (Comment #0788). While the NAOO was unable to reach a consensus on this issue, it recognized that the absence of a pupillary distance on a prescription creates hurdles for consumers who wish to purchase their eyeglasses online. Comment #0748 submitted by Allen; Shelton (Comment #0585); Opticians Association of Iowa (Comment #0646 submitted by Dalton); Parent (Comment #0604); Evans (Comment #0611); Damisch (Comment #0675); Whaley (Comment #0678); Reynolds (Comment #0726). 376 Opticians Association of America (Comment #0819 submitted by Brand); Fitzgerald (Comment #0818); see also Cooper (Comment #0562) (ophthalmologist who indicates he would be unable to provide an accurate pupillary distance measurement in his patients); LensCrafters (Comment #0819 submitted by Tavel) (stating that the digital technology required to accurately obtain the pupillary distance does not typically exist in the retail space). 377 Edwards (Comment #0360); Cervantes (Comment #0671); Ahrens (Comment #0022); Stuart (Comment #0841); see also Shepherd (Comment #0477); Kim (Comment #0677). 378 Edwards (Comment #0360); Cervantes (Comment #0671); Ahrens (Comment #0022); see also Santini article, supra note 340 (as the sophistication of eyeglass lenses has advanced, prescribers have improved their understanding of how measurements beyond simple pupil location help optimize lens acuity, comfort, and utility). Commenters also stated that other measurements are needed for dispensing eyeglasses, such as base curve and segment height, and that the prescribers are not also required to take those measurements. Edwards (Comment #0360) (as important as the pupillary distance generally is, other measurements and considerations at least as important); Kohl (Comment #0048); Hais (Comment #0359); Yuhas (Comment #0505); Rosenblum (Comment #0629). 379 Edwards (Comment #0360); Cervantes (Comment #0671); Ahrens (Comment #0022); see also Santini article, supra note 340 (as the sophistication of eyeglass lenses has advanced, prescribers have improved their understanding of how measurements beyond simple pupil location help optimize lens acuity, comfort, and utility). Commenters also stated that other measurements are needed for dispensing eyeglasses, such as base curve and segment height, and that the prescribers are not also required to take those measurements. Edwards (Comment #0360) (as important as the pupillary distance generally is, other measurements and considerations at least as important); Kohl (Comment #0048); Hais (Comment #0359); Yuhas (Comment #0505); Rosenblum (Comment #0629).
Opticians indicated they are trained to take an accurate pupillary distance as part of the process of fitting eyeglasses, whereas prescribers are not specifically trained to take this measurement.\textsuperscript{382} According to these opticians, if prescribers are required to provide pupillary distance on a prescription, some opticians will by law be forced to adhere to the measurement on the prescription, rather than to their own measurement, which might be more accurate.\textsuperscript{383} For instance, in North Carolina, state law specifies that an optician may not contract measurements taken by a prescriber; in Oregon, opticians are required to grind eyeglasses in conformity with prescriptions.\textsuperscript{384} Should the Commission require prescribers to include pupillary distance on prescriptions, opticians in North Carolina, Oregon, and other states with similar laws might no longer have the right to make glasses from their own pupillary distance measurements. Opticians also expressed concern that this might make them liable for errors resulting from improper measurements written by a prescriber and that they would have to absorb the costs involved in remaking the glasses, or pass along those costs to consumers.\textsuperscript{385}

4. Analysis of Whether To Amend the Rule To Require Pupillary Distance

To determine that an act or practice is unfair, the Commission must find that the act or practice causes or is likely to cause substantial injury to consumers; the injury is not reasonably avoidable by consumers themselves; and, the injury is not outweighed by countervailing benefits to consumers or to competition.\textsuperscript{386} As previously discussed, purchasing eyeglasses online can be more convenient and less costly for consumers.\textsuperscript{387} Without a pupillary distance measurement included on their prescriptions, some consumers may be hampered in their ability to shop online for eyeglasses because they must obtain this information independently. However, such methods are available for consumers to obtain this measurement and use it to comparison shop, the Commission does not believe, at this time, that there is an adequate record to demonstrate that prescribers’ failure to provide pupillary distance measurements on prescriptions constitutes substantial injury. As discussed above, those consumers who wish to shop online and do not already have their pupillary distance can obtain that measurement through other methods, many of which are no cost or relatively low-cost, and can therefore provide sellers with this information. For example, a number of online sellers offer directions and online tools for consumers to measure their own pupillary distance, or to have someone they know measure their pupillary distance, using readily available objects like a credit card and a webcam.\textsuperscript{388}

In addition, according to many prescribers and optician commenters, imposing a requirement to include pupillary distance measurements in the prescription may be detrimental for prescribers and consumers in one or more of the following ways. Some prescribers would be required to take a measurement that they do not ordinarily take, or have never taken. According to commenters, due to a prescriber’s use of inadequate equipment, or a lack of training, and the fact that prescribers do not have the benefit of adjusting the pupillary distance to accommodate the fit of a particular pair of eyeglasses, consumers may obtain inaccurate measurements.\textsuperscript{389} Moreover, it is possible that optician reliance on a prescriber’s measurements, mandated by law in some jurisdictions, could result in improperly-made eyeglasses, which would increase the inconvenience and cost to opticians, consumers, and prescribers.\textsuperscript{390}

If an optician makes a pair of eyeglasses using a prescriber-provided pupillary distance measurement that a consumer finds uncomfortable, the consumer would need to obtain a new prescription containing a revised pupillary distance before an optician could remake the eyeglasses. If these prescribers and optician commenters are correct, a requirement to include pupillary distance in prescriptions could be detrimental to consumers and competition.

In addition, if the Commission required prescribers to include pupillary distance measurements on prescriptions, it is unlikely that prescribers would use less expensive pupillary distance rulers and the like, but instead—for professional and liability reasons—would likely select more technologically sophisticated methods, such as a digital centration device, to take the measurement. Such devices, and the training, staff, and exam time necessary to operate the devices, could be costly. Some prescribers could pass these costs on to their patients in the form of higher prices.\textsuperscript{391} Alternatively, some prescribers could choose not to provide refractive services.\textsuperscript{392}

As is evidenced by the title of the Rule, “Separation of examination and dispensing,” the Rule distinguishes between the examination that determines refraction and the sale of eyeglasses. Pupillary distance involves the fitting of a pair of eyeglasses to one’s face, and is thus typically considered part of the dispensing process. If the Commission required prescribers to include pupillary distance on prescriptions, in offices with dispensaries, the prescriber, instead of adding expensive pupillary-distance measurement equipment to the exam room, might lead the patient into the dispensary to measure the patient’s pupillary distance. Such a shift would place the patient in the dispensary prior to the patient receiving her prescription, undercutting both the Rule’s requirement to release eyeglass prescriptions to patients immediately upon completion of an eye examination, and the Rule’s long-standing emphasis on keeping the refractive examination distinct from, and unto the, sale of eyeglasses.

Based on its consideration of the relevant factors, the Commission is not convinced that there is adequate
evidence in the current rulemaking record to determine that the failure to provide a pupillary distance on a prescription is an unfair practice. The Commission therefore does not propose requiring prescribers to include the pupillary distance measurement on prescriptions. It does not appear to the Commission that the potential benefits to consumers or competition from a Rule change requiring the inclusion of pupillary distance on prescriptions outweigh the consequences detailed by prescribers and opticians, especially if consumers who wish to purchase their eyeglasses online can obtain their pupillary distance independently, at no cost or a relatively low cost. The Commission understands that requiring prescribers to provide pupillary distance might be more convenient for some consumers and online retailers, and may help foster a competitive market, but the Commission believes, as it did at the time of the Rule’s issuance, that absent a record demonstrating that the failure to include pupillary distance as part of the prescription constitutes an unfair practice, the states should continue to determine the contents of eyeglass prescriptions. The Commission recognizes that it last invited comment on the question of whether to require the inclusion of pupillary distance in a prescription in its 2015 ANPR, and the online market for optometry and eyeglasses may have evolved since that round of comments. Thus, it invites comments from any organizations or individuals who believe that, in analyzing this issue, the Commission should consider relevant changes to state regulations on the content of prescriptions, or to changes in the marketplace or to technology pertaining to pupillary distance, since it last sought comment.

B. Amending the Rule To Set an Expiration Date for Eyeglass Prescriptions

Although the 2015 ANPR for the Eyeglass Rule did not specifically request comment on the issue of expiration dates for eyeglass prescriptions, several commenters raised this topic. The Eyeglass Rule, as currently drafted, does not specifically address expiration dates for eyeglass prescriptions. Rather, the Rule defines an eyeglass prescription as the written specifications for lenses for eyeglasses, which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses. State laws determine whether a prescription must contain an expiration date, but these laws vary; some states require an expiration date on the prescription, others do not. Furthermore, to the extent state laws specify the length of time an eyeglass prescription is valid, these laws vary as well.

Some commenters have suggested a variety of Rule amendments that would address the length of an eyeglass prescription, while other commenters expressed the view that the Commission should not amend the Rule to set expiration dates for eyeglass prescriptions. In advocating for an amendment to the Rule, some commenters expressed concern that since the expiration period for eyeglass prescriptions is not standardized, it allows some states “to impose arbitrary and, in some cases, unnecessarily short, expiration periods for prescriptions.”

For example, Warby Parker commented that “many state laws allow ‘short-dated’ prescriptions, which force consumers to go back to their eye care professional each year if they want to obtain a valid prescription for new eyeglasses.” Warby Parker argued that these provisions are without justification because the “vast majority of [eyeglass] prescriptions do not change within one year, and there is no medical rationale for most patients to undergo annual eye exams.” U.S. Senator Charles Schumer requested that the Commission consider whether short-term prescriptions (for example, a year or less), are appropriate or fair for consumers given that vision does not necessarily change this rapidly. 1–800 CONTACTS concurred with this view, stating that allowing states to impose “arbitrary and, in some cases, unnecessarily short, expiration periods for prescriptions impairs the intent and effectiveness of the Eyeglass Rule and inhibits consumer’s ability to choose to obtain eyeglasses from third-party sellers.”

1–800 CONTACTS pointed out that, for this reason, the Contact Lens Rule includes a provision that addresses the expiration of contact lens prescriptions.

The Commission therefore proposed that the Commission amend the Eyeglass Rule to include a provision imposing a minimum expiration period for prescriptions, with an exception for documented medical necessity, as there is in the CLR. Similarly, Warby Parker proposed that the Commission amend the Rule to adopt a three-year minimum prescription expiration timeframe, absent a documented medical basis for any particular short-dated prescription.

Many consumers expressed frustration that eyeglass prescriptions expire too quickly and prevent them from purchasing new pairs of eyeglasses without undergoing another eye exam. For example, some
commenters stated that their prescription rarely or never changes, but if they want new glasses or a second pair of glasses more than a year or two after their initial examination, a prescription expiration date may nonetheless require them to return to the prescriber’s office for a new eye examination. Some commenters discussed the costs associated with having to obtain another eye examination to get a prescription even though they were satisfied with their current prescription, or believed that their vision had not changed. Other commenters argued that patients should be able to decide for themselves when they want to update their eyeglass prescriptions.

Some commenters proposed that the Commission amend the Rule to prohibit eyeglass prescriptions from including an expiration date at all. For example, the Opticians Association of Virginia stated that absent a medical reason with corroborating pathology, it saw no valid reason for an eyeglass prescription to contain an expiration date. This commenter argued that eyeglasses worn by the patient do not expire on a given date, and accordingly, there is no reason for the underlying prescription to expire. The association further explained that because opticians can use a customer’s existing pair of eyeglasses to ascertain the prescription parameters and make another pair using those parameters, from neutralizing or duplicating eyeglasses, expiration dates can be (and often are) circumvented. However, other commenters, citing the importance of annual eye exams to consumers’ eye health, stated that prescriptions should contain expiration dates, set at the discretion of the prescribing practitioner. The AAO, and several other commenters, stated that the Rule should not be amended to extend the expiration of prescriptions beyond one year. These commenters stressed the importance of yearly eye examinations, which function to monitor the health of the eye, and noted that patients’ prescriptions often change. Many opticians, also advocating for yearly eye examinations, stated a preference for one-year expiration dates, but said that they would not be opposed to accepting prescriptions within a two-year period.

However, other commenters argued that expiration dates on prescriptions prevent consumers from continuing to purchase eyeglasses for a sufficient long period before having to return to their eye doctors. The Commission lacks adequate evidence that eyeglass prescription expiration dates, whether imposed by state regulations or individual prescribers, impair comparison-shopping, and hence competition in the retail sale of eyeglasses, to an extent that would justify a new regulatory requirement. While requiring that consumers return to their prescriber periodically for exams may give the prescriber a competitive advantage in that they get a “first shot” at selling the consumers new eyeglasses, it does not necessarily limit the consumers’ choices or ability to comparison-shop, particularly if the prescribers abide by the Rule’s prescription release requirement.

Forrest (Comment #00270), Steele (Comment #00432), Martin (Comment #00437), Fernandez (Comment #00439), Washburn (Comment #00440), Birnbaum (Comment #00443), McLeod (Comment #00458), Kaminsky (Comment #00462), Munkittrick (Comment #00465), Kaprielian (Comment #00488), Rouse (Comment #00496), Pearsall (Comment #00499), Simmons (Comment #00513), Iginski (Comment #00516), Lauridsen (Comment #00526), Hamon (Comment #00537), Schutz (Comment #00549), Fair (Comment #00800), see also Garcia (Comment #0338) (Warby Parker optician reporting that expiration dates have not changed); Beaudoin (Comment #0339) (same); Geczy (Comment #0612) (Warby Parker optician reporting that expiration dates of less than two years make obtaining eyeglasses difficult and frustrating for some patients).

See, e.g., Nystrom (Comment #0254); Hollis (Comment #0307); Trout (Comment #0383); Bhattacharyya (Comment #0543); Morel (Comment #0712).

See, e.g., Sorenson (Comment #0800) (burden financially and time-wise to have to get re-examined every year); Kim (Comment #0192) (eye exams are expensive); Meszaros (Comment #0303) (one-year expiration dates increase annual costs without materially improving health care); Hollis (Comment #0526) (would like to see doctor less frequently); Gough (Comment #0422) (getting a new prescription not cheap); Holden (Comment #0428) (getting time off for an eye exam is difficult); Davis (Comment #0433) (have to pay for exam on top of new eyeglasses); Martin (Comment #0435); Washburn (Comment #0440); Birnbaum (Comment #0443); Kaprielian (Comment #0488); Rouse (Comment #0496); Pearsall (Comment #0499); Simmons (Comment #0513): Lauridsen (Comment #0526); Hamon (Comment #0537); Schutz (Comment #0549); Fair (Comment #0800); see also Garcia (Comment #0338) (Warby Parker optician reporting that expiration dates have not changed); Beaudoin (Comment #0339) (same); Geczy (Comment #0612) (Warby Parker optician reporting that expiration dates of less than two years make obtaining eyeglasses difficult and frustrating for some patients).

See, e.g., Hildenbrand (Comment #0049); Cordovari (Comment #0060); Sorenson (Comment #0080); Forrest (Comment #0270); Jump (Comment #0292); Loeb (Comment #0171); Richards (Comment #0401); Steele (Comment #0432); Davis (Comment #0433).

See, e.g., Forrest (Comment #0270) (prescriptions should not expire); Endelson (Comment #0407) (prescription should include date of examination but no expiration date); Professional Opticians of Florida (Comment #0803 submitted by Couch) (recommending the prohibition of expiration dates on prescriptions for adult patients with low risk factors).
Absent evidence that expiration dates are impeding consumer choice, the Commission sees no support for the proposal that expiration dates need to be standardized.

Although some patients will not be able to purchase eyeglasses using a prescription more than one or two years old, this does not mean that they were foreclosed from comparison-shopping or from purchasing from the retailer of their choice when they initially purchased eyeglasses. Furthermore, as long as patients are provided a copy of the eyeglass prescription after the eye examination is completed, there is nothing in the record to support the contention that merely returning to a prescriber’s office to obtain a new prescription will pressure the patient into purchasing from the prescriber. Accordingly, the Commission has determined not to propose to amend the Rule either to prohibit expiration dates or to set expiration dates for eyeglass prescriptions.425

C. Amending Other Rule Definitions

The Rule defines an “eye examination” as “the process of determining the refractive condition of a person’s eyes or the presence of any visual anomaly by the use of objective or subjective tests.”426 The AOA and several individual prescribers requested that the Commission modify the Rule to change the term “eye examination” to “refraction.”427 These commenters stated that an eye examination determines the health of the eye and includes many components that are not used to determine the refractive condition. According to some commenters, the Rule’s definition for, and use of, the phrase “eye examination” more accurately describes refractive services rather than the full scope of an eye examination.428

Two commenters, in particular, noted that eye examinations and refractions are separate services and that the Commission’s use of the terminology “eye examination,” instead of “refraction,” results in confusion for the consumer.429 Such confusion may stem from the fact that, in addition to assessing a fee for determining the health of the eye—a fee often covered by health insurance or Medicare—prescribers charge patients a fee for the refractive examination that results in a prescription, a fee that Medicare does not cover.430 The Rule currently allows eye care prescribers to refuse to provide the patient with their prescription when the patient has not paid for the “eye examination”—which refers back to the definition describing the refraction—as long as the prescriber does not have different policies for those whose examination revealed that no ophthalmic goods were required.431

The Commission proposes to replace the term “eye examination” with “refractive eye examination” throughout the Rule. The Eyeglass Rule’s purpose is to ensure that prescribers provide patients with a copy of their prescription at the completion of an eye examination determining the patient’s refraction, and that this prescription be provided free of any additional charge, without obligation, and without a waiver. The Commission believes clarifying that the eye examination referred to in the Rule is a refractive examination would likely increase consumer understanding of their rights and prescriber compliance with the Rule.

VI. Recommendations Regarding the Commission’s Complaint System

To assist the Commission in its enforcement of the Rule, Warby Parker suggested that the Commission create a more “user-friendly” online complaint process for consumers.432 The online complaint process has changed significantly since the receipt of this comment. The current website is user-friendly, and consumers can easily find eye care as a category for their complaints.433 On the home page, one of the 10 listed complaint categories is for “health (ex. weight loss, eye care, treatment).” When consumers select the health category, a new menu pops up which shows “eye care” as one of five choices, and after selecting that category, consumers are given ample room to describe their experience in a comment box under the request to “Describe what happened.” Accordingly, the Commission believes that the FTC complaint system is well-configured to capture and report eyeglass-related complaints it receives, whether they originate from consumers, prescribers, sellers, or others.

VII. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 6, 2023. Write “Eyeglass Rule, Project No. R511996” on the comment. Your comment—including your name and your state—will be placed on the https://www.regulations.gov website.

Because of public health measures and the agency’s heightened security screening, postal mailing addressed to the Commission will be subject to delay. We strongly encourage you to submit your comment online through the https://www.regulations.gov website. To ensure the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write “Eyeglass Rule, Project No. R511996” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex C), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website https://www.regulations.gov, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not...
include any sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule § 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule § 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule § 4.9(c). Your comment will be kept confidential only if the General Counsel grants that request in accordance with the law and the public interest. Once your comment has been posted publicly at www.regulations.gov—as legally required by FTC Rule § 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule § 4.9(c), and the General Counsel grants that request.

Visit the Commission website at http://www.ftc.gov to read this NPRM and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 6, 2023. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/site-information/privacy-policy.

The Commission invites members of the public to comment on any issues or concerns they believe are relevant or appropriate to the Commission’s consideration of proposed amendments to the Rule. The Commission requests that you provide factual data, and in particular, empirical data, upon which your comments are based. In addition to the issues raised above, the Commission solicits public comment on the specific questions identified below. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

Questions

A. General Questions on Proposed Amendments: To maximize the benefits and minimize the costs for prescribers and sellers (including small businesses), the Commission seeks views and data on the following general questions for each of the proposed changes described in this NPRM:

1. What benefits would a proposed change confer and on whom? The Commission in particular seeks information on any benefits a change would confer on consumers of eyeglasses.

2. What costs or burdens would a proposed change impose and on whom? The Commission in particular seeks information on any burdens a change would impose on small businesses.

3. What regulatory alternatives to the proposed changes are available that would reduce the burdens of the proposed changes while providing the same benefits?

4. What additional information, tools, or guidance might the Commission provide to assist industry in meeting extant or proposed requirements efficiently?

5. What evidence supports your answers?

B. Marketplace, Technological, and State Regulatory Changes:

1. Since the public last had an opportunity to comment, are there any technological changes, changes in the marketplace, or to state regulations pertaining to pupillary distance, that the Commission should consider?

C. Confirmation of Prescription Release:

1. Would the proposed Confirmation of Prescription Release provision increase, decrease, or have no effect on compliance with the Rule’s requirement that patients receive a copy of their prescription after the completion of a refractive eye examination? Why?

2. Would the proposed requirement that prescribers would have to maintain evidence of the Confirmation of Prescription Release for at least three years increase, decrease, or have no effect on the Commission’s ability to enforce, and monitor compliance with, the Rule’s automatic prescription release provision? Why?

3. Would the proposed Confirmation of Prescription Release requirement increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

4. Does the proposal to allow prescribers to satisfy the Confirmation of Prescription Release requirement by releasing a digital copy of the prescription to the patient (after obtaining the patient’s verifiable affirmative consent), such as via online portal, electronic mail, or text message increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

5. If prescribers choose to comply with the Confirmation of Prescription Release provision by providing a digital copy of the prescription (if the patient gives verifiable affirmative consent), what costs or burdens are associated with retaining evidence that the prescription was sent, received, or made accessible, downloadable, and printable?

6. Do the potential benefits of the Confirmation of Prescription Release requirement—having more patients in possession of their prescription—outweigh the burden on prescribers of having to provide patients with a Confirmation of Prescription Release and preserve a record for three years? Why or why not?

7. What other factors should the Commission consider to lower the cost and improve the reliability of executing, storing, and retrieving Confirmations of Prescription Release?

8. Are there alternate ways that the Commission has not yet considered to design a Confirmation of Prescription Release requirement that would reduce the burden on prescribers while providing the same, or greater, benefits for consumers? What are they and how do they compare to the current proposal?

9. Are there alternate ways that the Commission has not yet considered in this Rule review to increase compliance with the Rule’s requirement that patients receive a copy of their eyeglass prescription after the completion of a refractive eye examination? What are they and how do they compare to the current proposal?

10. Are there alternate ways that the Commission has not yet considered in its Rule review to increase the Commission’s ability to enforce and monitor compliance with, the Rule’s automatic prescription release
the use of objective or subjective tests,” a clear and accurate way of describing a refractive eye examination?
6. Would using the term “refractive eye examination” in place of “eye examination” have any other consequences for eye care, positive or negative?
7. What evidence supports your answers?

VIII. Communications by Outside Parties to the Commissioners or Their Advisors
Pursuant to FTC Rule § 1.18(c)(1)(i)-(ii), the Commission has determined that communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner advisor shall be subject to the following treatment. Written communications and summaries or transcripts of oral communications shall be placed on the rulemaking record if the communication is received before the end of the public comment period in response to this NPRM. They shall be placed on the public record if the communication is received later. Unless the outside party making an oral communication is a member of Congress, such communications are permitted only if advance notice is published in the Weekly Calendar and Notice of Sunshine Meetings.434

IX. Paperwork Reduction Act
The Paperwork Reduction Act (“PRA”), 44 U.S.C. 3501 et seq., requires federal agencies to obtain Office of Management and Budget (“OMB”) approval before undertaking a collection of information directed to ten or more persons. Pursuant to the regulations implementing the Paperwork Reduction Act,435 an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number.

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 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

---

434 See 5 U.S.C. 57a(i)(2)(A); 16 CFR 1.18(c).
435 5 CFR 1320.8(b)(2)(vi).
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. OMB staff estimates these PRA burdens based on its long-standing knowledge and experience with the eye care industry. The Commission is submitting these proposed amendments and a Supporting Statement to OMB for review.

A. Estimated Burden

The number of adult eyeglass wearers in the United States is currently estimated to be approximately 165 million. Assuming a biennial refractive eye exam for each eyeglass wearer, 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. We therefore estimate an annual disclosure burden for prescribers of approximately 1,375,000 hours (82.5 million annual exams x 1 min/60 mins).

Staff anticipates there will be an additional burden on individual prescribers’ offices to obtain 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 provider 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. 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, 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 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. Excluding that option from § 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.

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 CFR 456.1(h)(2). The burden to do so is included in the recordkeeping burden calculation of this PRA Section.

436 See Section I.B, supra.
438 The Commission relies on industry sources for its estimate that eyeglass wearers typically obtain one replacement every two years. See, e.g., AOA, Excel and Johnson Medical Information, The State of the Optometric Profession: 2013, at 4, https://www.review.com/wp-content/uploads/2016/11/0-21-13stateoptometrereport.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/seeomy (showing recommended examination frequency for adult patients 18-64 of ‘at least every two years’ for asymptomatic/low risk patients). In contrast to the CLR, which establishes a one-year minimum term for most contact lens prescriptions (16 CFR 315.6(a)(1) term-length mirrored by a majority of states, see CLR NPRM, 81 FR 88526, 88545, n.245), the Eyeglass Rule does not discuss or define prescription expiration terms, and many states do not set any limit for eyeglass prescriptions. See note 398, supra (summarizing a number of state laws that allow eyeglass prescriptions to be valid for periods longer than one year). 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.
439 It is quite possible that one minute is an overestimate of the amount of time required, and that in practice, this task takes less time and is often performed by the office staff. As of now, however, we have not seen conclusive evidence to justify making a change to the approach we have repeatedly taken in the past. See, e.g., CLR SNPRM, 84 FR 24664, 24693 n.347.
440 “The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within” the definition of “collection of information.” 5 CFR 1320.3(c)(2). It is also notable that for the options in proposed §§ 456.3(a)(1)(iii) and (ii), 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.
441 CLR Final Rule, 85 FR 50668, 50709. 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 CLR SNPRM, 84 FR 24664, 24693.
442 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 CFR 456.1(h)(2). The burden to do so is included in the recordkeeping burden calculation of this PRA Section.
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% × 82.5 million prescriptions yearly × 10 seconds each/60secs/60mins) to obtaining patient signatures as confirmations of prescription release.443

Maintaining those signed confirmations for a period of not less than three years would 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,444 and thus many prescribers who opt to include the confirmation of prescription release on the prescription itself would be preserving that document, regardless. Similarly, most prescribers already retain customer sales receipts for financial accounting and recordkeeping purposes, and thus prescribers who opt to include the confirmation of prescription release on the sales receipt also could be retaining that document, regardless. Moreover, storing a one-page document per patient per year should not require more than a few seconds, and an inconsequential, or de minimis, amount of record space. Some prescribers might also present the confirmation of prescription release in electronic form, enabling patients to sign a computer screen or tablet directly, and have their confirmation immediately stored as an electronic document.

For other prescribers, the 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 this PRA analysis, Commission staff will assume that all prescribers 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% × 82.5 million prescriptions yearly × 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 her 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,445 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 hours446 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 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).

B. Estimated Labor Cost

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 recordkeeping, but did not receive significant guidance on this.447 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.448 Using the aforementioned estimate of 229,167 total prescriber labor hours for obtaining patient signatures, 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,
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 burden 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. Furthermore, the actual burden is likely to be less, because many prescribers’ offices will require less than a minute to store the confirmation form.

C. Capital and Other Non-Labor Costs

The proposed recordkeeping requirements detailed above regarding prescribers impose negligible capital or other non-labor costs, as prescribers likely have already the necessary equipment and supplies (e.g., prescription pads, patients’ medical charts, scanning devices, recordkeeping storage) to perform those requirements.

The Commission invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the FTC’s burden estimates, including whether the methodology and assumptions used are valid; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collecting information.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this document to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The reginfo.gov web link is a United States Government website produced by OMB and the General Services Administration (“GSA”). Under PRA requirements, OMB’s Office of Information and Regulatory Affairs reviews federal information collections.

X. Preliminary Regulatory Analysis and Regulatory Flexibility Act Requirements

Under section 22 of the FTC Act, 15 U.S.C. 57b–3, the Commission must issue a preliminary regulatory analysis for a proceeding to amend a rule only when it: (1) estimates that the amendment will have an annual effect on the national economy of $100,000,000 or more; (2) estimates that the amendment will cause a substantial change in the cost or price of certain categories of goods or services; or (3) otherwise determines that the amendment will have a significant effect upon covered entities or upon consumers. For the reasons explained below, in the PRA section above, and in the main text of this document, the Commission has preliminarily determined that the proposed amendments will not have such effects on the national economy; on the cost of eye examinations or prescription eyeglasses; or on covered parties or consumers. The Commission, however, requests comment on the economic effects of the proposed amendments.

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601 et seq., requires the Commission to conduct an analysis of the anticipated economic impact of the proposed amendments on small entities. The purpose of a regulatory flexibility analysis is to ensure the agency considers the impacts on small entities and examines alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA provides that such an analysis is not required if the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.

The Commission does not anticipate that the proposed amendments will have a significant economic impact on small entities, although they may affect a substantial number of small businesses. The proposed amendments would require that prescribers obtain from patients, and maintain for a period of not less than three years, a signed confirmation of prescription release, acknowledging that patients received their eye exams for at least three years, noting that the majority of states already require that optometrists keep records of eye examinations for at least three years, and estimating a full minute for prescribers to meet their recordkeeping obligations. Prescribers who decide to collect or maintain signatures electronically may already have electronic health records systems in place, but the Commission requests information on costs prescribers are likely to incur to comply with the recordkeeping proposals in this document.

In addition, the proposal to permit prescribers to deliver prescriptions electronically would require prescribers to obtain, and maintain for three years, a patient’s consent to electronic prescription delivery. This requirement can be avoided altogether should a prescriber not wish to provide patients this option. Furthermore, whenever a prescriber enables a patient to receive a prescription electronically, this relieves the prescriber of the burden to obtain a signed prescription release confirmation.

449 1,375,000 hours × $60.31 (average hourly wage for optometrists) = $82,926,250.

450 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 VisionWatch Report, supra note 270, at 90, 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.
The proposed amendments to the Rule requiring that prescribers obtain from patients, and maintain for a period of not less than three years, a signed confirmation of patients’ receipt of their eyeglass prescriptions, permitting prescribers to comply with automatic prescription release via electronic delivery in certain circumstances, clarifying 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 under 16 CFR 456.2(a), and replacing the term “eye examination” with “refractive eye examination,” are reasonably related to remedying the unfair practices that led the Commission to promulgate the Rule.

D. Small Entities to Which the Proposed Amendments Will Apply

The proposed amendments apply to prescribers of eyeglasses. The Commission believes that many prescribers will fall into the category of small entities (e.g., offices of optometrists less than $8 million in size). Determining a precise estimate of the number of small entities covered by the Rule’s prescription release requirements is not readily feasible because most prescribers’ offices do not release the underlying revenue information necessary to make this determination. Based on its knowledge of the eye care industry, including meetings with industry members and a review of industry publications, staff believes that a substantial number of these entities likely qualify as small businesses. The Commission seeks comment with regard to the estimated number or nature of small business entities, if any, for which the proposed amendments would have a significant impact.

E. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed To Comply

As explained earlier in this document, the proposed amendments require that prescribers obtain from patients, and maintain for a period of not less than three years (in paper or electronic form), a signed confirmation of prescription release, acknowledging that patients received their eyeglass prescriptions at the completion of their refractive eye examination. The amendments also permit prescribers to comply with automatic prescription release via electronic delivery in certain circumstances, 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 under 16 CFR 456.2(a), and replace the term “eye examination” with “refractive eye examination” throughout the Rule.

The small entities potentially covered by these proposed amendments will include all such entities subject to the Rule. The professional skills necessary for compliance with the Rule as modified by the proposed amendments will include office and administrative support supervisors to create the confirmation form and clerical personnel to collect signatures from patients and maintain records. Compliance may include some minimal training time as well. The Commission believes the burden imposed on small businesses by these requirements is relatively small, for the reasons described previously in this section as well as the PRA section of this document. The Commission invites comment and information on these issues, including estimates or data on specific compliance costs that small entities might be expected to incur.

F. Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any other federal statutes, rules, or policies duplicating, overlapping, or conflicting with the proposed amendments. As noted previously, the majority of states already require that optometrists—of which many are most likely small businesses—maintain records of eye examinations for at least

---

451 Am. Fin. Servs. Ass’n v. FTC, 767 F.2d at 988 (quoting Jacob Siegel Co. v. FTC, 327 U.S. 608, 612–13 (1946)).
452 See 13 CFR 121.201 (Small Business Size Regulations).
454 According to one publication, 65 percent of optometrists work in a practice owned by an optometrist or ophthalmologist, practices that are likely small businesses. See AOA, “An Action-Oriented Analysis of the State of the Optometric Profession: 2013,” at 7, https://documents.aoa.org/Documents/news/state_of_optometry.pdf. This publication also reported that although it could not ascertain the precise number of independent optometric practices, it estimated that as of 2012, there were 14,000 to 16,000 optometric businesses with no corporate or institutional affiliation. Id.

455 The Commission does not believe it will require significant training to learn when and how to obtain a patient signature and preserve it, particularly since prescribers’ office staff will already know how to perform these tasks, due to similar signature requirements already in place for the Contact Lens Rule and the HIPAA NPP, among others.
three years. Further, as discussed elsewhere in this NPRM, HIPAA, the 21st Century Cures Act, and state laws provide consumers with a right of access to medical records, though the parameters and timing involved with access are different than the Eyeglass Rule.\footnote{Prescribers may have EHRs in place to comply with these laws, as well as having certified health information technology to receive direct payments per the HITECH Act. The fact that prescribers’ offices have EHRs and health information technology may make it less costly or burdensome for prescribers to comply with the proposed amendments to the Eyeglass Rule.} The Commission also notes that prescribers may reduce any burden associated with the proposed amendments by using 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. The Commission invites additional comment on the issue of duplicative, overlapping or conflicting federal rules.

G. Significant Alternatives to the Proposed Amendments

The Commission has not proposed any specific small entity exemption or other significant alternatives, as the proposed amendments clarify and update the Rule in light of marketplace practices to ensure that patients are receiving a copy of their eyeglass prescription at the completion of a refractive eye examination. Under these limited circumstances, the Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendments. As discussed above, the proposed recordkeeping requirement likely involves minimal burden and prescribers would be permitted to maintain records in either paper or electronic format. This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and inputted automatically into the electronic record. Furthermore, prescribers also could scan signed paper copies of the confirmation and store those confirmations electronically to lower the costs of this recordkeeping requirement. Similarly, when using a text message, electronic mail, or an online patient portal to satisfy the prescription release requirement (assuming the patient’s consent), prescribers may provide the required copy of the prescription electronically (i.e., digital format). Nonetheless, the Commission seeks comment on the need, if any, for alternative compliance methods to reduce the economic impact of the Rule on small entities. If the comments filed in response to this NPRM identify small entities affected by the proposed amendments, as well as alternative methods of compliance that would reduce the economic impact of the proposed amendments on such entities, the Commission will consider the feasibility of such alternatives and determine whether they should be incorporated into the final rule.

Proposed Rule Language

List of Subjects in 16 CFR Part 456

Advertising, Medical devices, Ophthalmic goods and services, Trade practices.

For the reasons set out in the preamble, the Federal Trade Commission proposes to amend 16 CFR part 456 to read as follows:

PART 456—OPHTHALMIC PRACTICE RULES (EYEGLASS RULE)

\footnote{\textsuperscript{456} Prescribers may have EHRs in place to comply with these laws, as well as having certified health information technology to receive direct payments per the HITECH Act. The fact that prescribers’ offices have EHRs and health information technology may make it less costly or burdensome for prescribers to comply with the proposed amendments to the Eyeglass Rule.} 1. Revise the authority citation for part 456 to read as follows:


2. Amend § 456.1 by revising paragraphs (a), (b), (d), (e) and (g), and by adding paragraph (h) to read as follows:

§ 456.1 Definitions.

(a) A patient is any person who has had a refractive eye examination.

(b) A refractive eye examination is the process of determining the refractive condition of a person’s eyes or the presence of any visual anomaly by the use of objective or subjective tests.

(d) Ophthalmic services are the measuring, fitting, and adjusting of ophthalmic goods subsequent to a refractive eye examination.

(e) An ophthalmologist is any Doctor of Medicine or Osteopathy who performs refractive eye examinations.

(g) A prescription is the written specifications for lenses for eyeglasses which are derived from a refractive eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.

(h) Provide to the patient one copy means giving a patient a copy of his or her prescription:

(1) On paper; or

(2) In a digital format that can be accessed, downloaded, and printed by the patient. For a copy provided in a digital format, the prescriber shall identify to the patient the specific method or methods of electronic delivery to be used, such as text message, electronic mail, or an online patient portal, and obtain the patient’s verifiable affirmative consent to receive a digital copy through the identified method or methods; and maintain records or evidence of a patient’s affirmative consent for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

3. Revise § 456.2 to read as follows:

§ 456.2 Separation of examination and dispensing.

It is an unfair act or practice for an ophthalmologist or optometrist to:

(a) Fail to provide to the patient one copy of the patient’s prescription immediately after the refractive eye examination is completed. Provided: An ophthalmologist or optometrist may refuse to give the patient a copy of the patient’s prescription until the patient has paid for the refractive eye examination, but only if that ophthalmologist or optometrist would have required immediate payment from that patient had the examination revealed that no ophthalmic goods were required. For purposes of the preceding sentence, the presentation of proof of insurance coverage for that service shall be deemed to be a payment;

(b) Condition the availability of a refractive eye examination to any person on a requirement that the patient agree to purchase any ophthalmic goods from the ophthalmologist or optometrist;

(c) Charge the patient any fee in addition to the ophthalmologist’s or optometrist’s refractive eye examination fee as a condition to releasing the prescription to the patient. Provided: An ophthalmologist or optometrist may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or

(d) Place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the ophthalmologist or optometrist for the accuracy of the refractive eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

4. Revise § 456.3 to read as follows:

§ 456.3 Eyeglass rule.

This rule establishes requirements for the dispensing of eyeglasses.

The rule applies to the dispensing of eyeglasses by practitioners performing refractive eye examinations. Under these circumstances, the practitioner is responsible for determining the refractive eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.

The rule requires practitioners to:

(a) Provide to the patient one copy of the prescription.

(b) Maintain records of the patient’s examination for a period of not less than three years.

(c) Provide to the patient, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the practitioner for the accuracy of the refractive eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

(d) Charge the patient any fee in addition to the practitioner’s refractive eye examination fee as a condition to releasing the prescription to the patient. Provided: A practitioner may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or

(e) Place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the practitioner for the accuracy of the refractive eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

(f) Obtain the patient’s verifiable affirmative consent to receive a digital copy through the identified method or methods; and maintain records or evidence of a patient’s affirmative consent for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.
§ 456.3 Confirmation of prescription release.

(a) (1) Upon completion of a refractive eye examination, and after providing a copy of the prescription to the patient, the prescriber shall do one of the following:

(i) Request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription;

(ii) Request that the patient sign a prescriber-retained copy of the prescription that contains a statement confirming receipt of the prescription;

(iii) Request that the patient sign a prescriber-retained copy of the sales receipt for the refractive eye examination that contains a statement confirming receipt of the prescription; or

(iv) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.

(2) If the prescriber elects to confirm prescription release via paragraphs (a)(1)(i), (ii), or (iii) of this section, the prescriber may, but is not required to, use the statement, “My eye care professional provided me with a copy of my prescription at the completion of my examination” to satisfy the requirement.

(3) In the event the patient declines to sign a confirmation requested under paragraphs (a)(1)(i), (ii), or (iii) of this section, the prescriber shall note the patient’s refusal on the document and sign it.

(b) A prescriber shall maintain the records or evidence required under paragraph (a) of this section for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(c) Paragraphs (a) and (b) of this section shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of eye wear, including, but not limited to, through an association, affiliation, or co-location with an optical dispenser.

§§ 456.3 through 456.5 [Redesignated]

5. Redesignate §§ 456.3 through 456.5 as §§ 456.4 through 456.6.

§ 456.3 [Reserved]

6. Add and reserve a new § 456.3.

By direction of the Commission.

April J. Tabor,
Secretary.

[FR Doc. 2022–27828 Filed 12–30–22; 8:45 am]

BILLING CODE 6750–01–P